

# POLICY ADVOCACY REPORT



POLICY ADVOCACY PRACTICUM  
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Compassionate Care New York  
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## **EXECUTIVE SUMMARY**

On January 7th, 2016, New York became the 23<sup>rd</sup> state to roll out a medical marijuana program. The program's inauspicious start has been underscored by a growing recognition in the media about the lack of patient access and the state's lukewarm response to addressing the numerous barriers severely ill patients face in trying to access life-saving medicine. This report is the first real assessment of the program that provides a systematic overview of its problems and an evaluation of possible solutions. The report also details the lack of statistical data on various aspects of the program, which poses a significant challenge to the assessment and recommendation of policy solutions. Our two main recommendations are the passage of four bills that would improve patient access significantly and a listing of data that would assist policymakers and advocates in generating feasible solutions to address various problems associated with the program.

## INTRODUCTION

On July 7th, 2014, Governor Cuomo signed New York's medical marijuana bill into law. Under this law, a patient who has been certified by a healthcare provider to use medical marijuana can register with the New York State Department of Health (DOH) and receive a patient identification card. Many of the details regarding the implementation of New York's medical marijuana program have been left to the discretion of the New York State Commissioner of Health. On March 31st, 2015, the Department of Health, the program's implementing agency, issued the state's medical marijuana program's final regulations. On January 7th, 2016, New York's medical marijuana program was officially launched after an eighteen-month implementation process. Since the launch, the program's various restrictions – a combination of the legal provisions in the 2014 Compassionate Care Act and the restrictive regulations issued by DOH– have significantly hampered patient access to medicine.

Restrictive access has resulted in a substantially low number of patients who have registered with the program and accessed medical relief. Of nearly 500,000<sup>1</sup> patients who currently qualify or are eligible for medical marijuana treatment, slightly more than 2000 have registered to become a patient, and only 1000 have been able to access medicine. Because of low patient demand, medical marijuana products currently sold in dispensaries are too expensive, which deters patients from accessing medical relief.

As one of the nation's most populous states and the country's cultural capital, New York's implementation of its medical cannabis program has and will continue to receive intense scrutiny. Pundits and policymakers are looking to New York to see whether the state can create a workable system. New York has the potential and opportunity to develop a medical marijuana program that is both well-regulated and maximizes patient safety and access. In the absence of all but the most limited publicly available information from the state, we are issuing this report assessing the first four months of the program.

## PURPOSE OF THIS REPORT

### Who is Compassionate Care New York?

Coordinated by Drug Policy Alliance, CCNY is a coalition of individual patients, providers, family members, and several dozen organizations. At the height of the campaign- when it was most involved in passing legislation to legalize marijuana for medical use in New York State, CCNY's reach extended to over 35,000 people around the state, with a core membership of 800. CCNY is committed to advocating for swift and effective implementation of New York's medical marijuana program and ensuring that patients across NY with severe, debilitating illnesses have legal access to medical marijuana to relieve their suffering.

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<sup>1</sup> Estimates on the potential number of medical marijuana patients in New York State varies greatly and problems obtaining a precise figure will be discussed later in the report

## Why the Need for an Implementation Report?

Given that the constituents for whom we campaigned so long and hard for are struggling to gain real access to the program and are facing numerous barriers to obtaining the medicine they need, we hope that this report draws attention to the problems of the program's restrictiveness. Moreover, it gives a voice to the invisible population- the poor and sick around NYS- who are too dispersed and incapable of effectively advocating vocally for better access. Especially since the DOH has remained silent, unsympathetic, and the Governor believes that the program is working well. Program implementation is generally not considered a well-funded part of advocacy efforts, but patients will continue to be left out unless the law is expanded. Moreover, these are patients who are suffering from the severe illnesses they have and the side effects of those illnesses and their treatment. Young children with epilepsy have died while waiting in the 18 months since the bill was signed into law and the program implemented.

Given the imperative to loosen the program's restrictive nature, this report first describes the scope and extent of the problem, discusses policy alternatives, and expands upon the legislative solutions to expand patient access to compassionate medical care. Moreover, there is a need to monitor the program to ensure that it is working and making changes as needed. Having access to data on various aspects of the program is vital for stakeholders to know how NY's medical marijuana program is working and if/how their right to access medicine is not being impinged by restrictive regulations. Information about the program, however, has been minimal and piecemeal. Critical problems with data about the program: availability; transparency (or lack of, on the part of DOH), and centrality (no centralized source of info on product availability and cost that patients/caregivers can access)

Finally, implementation is essential to broader marijuana reform in New York State, a long-term project of the Drug Policy Alliance. Establishing a successful medical marijuana program is an integral part of that effort.

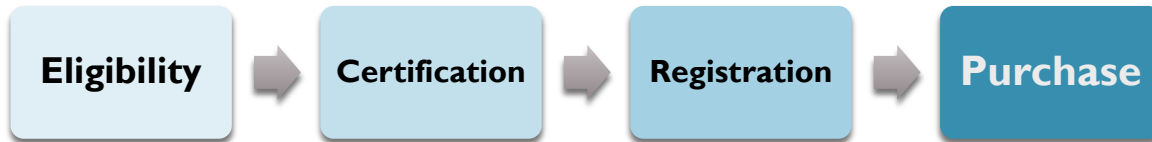
## TIMELINE OF EVENTS

- *June 20th, 2014.* New York passes a medical marijuana bill
- *July 7th, 2014:* Governor Cuomo signs the bill into law
- *December 18th, 2014:* Draft regulations released
- *March 31st, 2015:* Final regulations released
- *July 31st, 2015.* New York State Department of Health (NYSDOH) announces five medical marijuana producers
- *October 21st, 2015.* NYSDOH launches mandatory doctor training
- *November 11th, 2015.* Gov. Cuomo signs medical marijuana emergency access bill
- *December 23rd, 2015.* NYSDOH announces launch of medical marijuana patient certification and registration system
- *January 7th, 2016.* New York launches medical marijuana program (8 of 20 planned dispensaries open)



## PROCESS OF ACCESSING MEDICAL MARIJUANA

### What Is Patient Access?



- **Eligibility** – Qualifying for medical marijuana use. In order to obtain medical marijuana, a patient must first be diagnosed with one of ten severe medical conditions and an associated condition.
- **Certification** – Finding a trained and registered doctor. A patient must then obtain a certification from a physician who has undergone a Health Department-approved training course and has registered with the state as a recommending physician. Suppose a patient's treating physician is not registered and does not intend to participate in the program. In that case, the patient can request a referral whereby their doctor can access an online list of registered physicians, as there is no publicly accessible list.
- **Registration** – Being able to complete the online registration Upon obtaining a physician's certification, a patient may register online. They then wait to receive a patient registry card in the mail to purchase medicine at a state-licensed dispensary.
- **Purchase** – Having geographic access to a dispensary and being able to access and afford necessary medicine. After first locating the closest dispensary, a patient then makes an appointment. When visiting, they purchase the type and form of medicine, as recommended on the patient certification.

## POLITICAL CONTEXT

### New York's Marijuana Policy

The strictness of New York's medical marijuana program is a testament to the state's notoriously excessive criminalization of marijuana use since the 1930s, which earned it the reputation for being the "marijuana-arrest capital of the country." Public support for marijuana in NYS<sup>2</sup> strongly diverges from political sentiment towards marijuana policy<sup>3</sup>.

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<sup>2</sup> Quinnipiac polls in 2014 found New Yorkers' support for medical marijuana hovering around 80 percent, and their support for legalizing recreational marijuana between 35 and 57 percent, numbers that track closely to national opinion

<sup>3</sup> In 1973, Gov. Rockefeller, passed a series of anti-drug laws that established steep mandatory-minimum sentences, even for many first-time nonviolent offenders. In the 1990s, during Mayor Giuliani's term,

For instance, Democratic State Sen. Daniel Squadron notes that the Republican-controlled Senate is why there still exist excessively punitive attitudes towards marijuana use and policy in a progressive state like New York. Moreover, in the context of legalizing marijuana for medical use in New York State, Cuomo's office tried its best to block legislation from being passed. Upon realizing that there was overwhelming support among the public and legislature, his Office "demanded dramatic changes to the bill,"<sup>4</sup> a compromise to which CCNY agreed, simply to avoid a possible veto of the bill by Cuomo; a restrictive medical marijuana law was better than none at all. After Gov. Cuomo signed bill S7923/A6357-E into law on July 7th, 2014, the Department of Health used its discretionary power to draft a set of regulations for the program, which turned out to be "even more restrictive than the statute."<sup>5</sup>

### Cuomo's Pot Problem

During the medical-marijuana debate, Cuomo described pot as a "gateway drug," citing the state's heroin and prescription opiate drug abuse problems, so it appears he is not evolving very quickly on the issue<sup>6</sup>. At a June 2014 press conference, "Cuomo stressed caution and control" on marijuana use and included a provision in the final bill that passed, which allowed him to suspend the program at any time. According to a New York political operative who spoke on the condition of anonymity, Cuomo's presidential ambitions are "not likely to push him toward marijuana reform" since his core political strategy is "cultivating rich people and running center-right," of which marijuana reform is not a big piece. Commentators have called New York's medical marijuana law a "half-measure hatched by Gov. Cuomo for political reasons," which is "just enough [for Cuomo] to say he has a legal program for when he runs [for higher office]"<sup>7</sup>

Cuomo's office and the Department of Health maintain that regulations were deliberately restrictive to ensure that a black market is not created and to prevent the program from becoming so broad that it becomes "subject not only to legal challenge but

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average number of annual arrests escalated from below 1,000 to more than 24,000, a trend that continued apace under Mayor Bloomberg, when marijuana-possession arrests rose to an average of more than 40,000 per year.

<sup>4</sup> [The original] legislation had included a list of about a dozen conditions eligible for treatment with marijuana, but had included a clause allowing doctors to recommend it for other conditions if they felt they met the standards of seriousness set forth in the bill. At Cuomo's insistence, that clause was eliminated. Cuomo also insisted that initially there be no more than five licensed marijuana suppliers. Equally problematic, Cuomo insisted that each of the five licensees would be allowed only four dispensing sites, meaning that a state of 20 million people would be served by all of 20 locations.

<sup>5</sup> Pinto, N. (2015, June 9). Andrew Cuomo's Pot Problem. *Rolling Stone*. Retrieved from: <http://www.rollingstone.com/politics/news/andrew-cuomos-pot-problem-20150609>

<sup>6</sup> Hartmann, M. (2016, Jan 7). New York's First Medical Marijuana Dispensary Opens Today: Answers to All Your Burning Questions. *Intelligencer*. Retrieved from <https://nymag.com/intelligencer/2014/06/new-york-medical-marijuana-explained.html>

<sup>7</sup> <http://www.suncommunitynews.com/articles/the-sun/puff-puff-pass/>

potential shutdown from the feds."<sup>8</sup> Moreover, Cuomo recently acknowledged that the program was moving slowly, but that he would "rather err on the side of caution than move it along too quickly" and create the "the reverse situation [whereby] people who are getting marijuana shouldn't be getting marijuana."<sup>9</sup>

## DATA SOURCES

### General data problems

To assess the program's rollout thus far, CCNY reached out to the Governor's Office and the Department of Health via email four weeks ago but has not received any response to data requests for information on how the program is performing. CCNY has also contacted the five producers, but they have declined to approve any data requests.

### Survey

To fill this information gap, we designed and distributed an anonymous survey<sup>10</sup> that patients and caregivers could complete. The survey was designed to capture the experiences of patients and caregivers who were either trying to enroll or had already enrolled in New York's medical marijuana program. Respondents were recruited via CCNY's Facebook page, where a link was posted twice over two months and one mass email to its 800-member mailing list. The survey yielded an anonymous, limited sample. As of May 17th, 255 people have taken the survey (207 patients; 17 caregivers for patients below 18; 31 caregivers for patients above 18).

### News articles

Another source of information CCNY drew upon was news articles from publications reporting on the development of NY's medical marijuana program.

### Estimating patient market in NY

It is difficult to estimate the number of potential medical marijuana patients in New York State and patients who qualify for medical marijuana based on their medical conditions. News reports have estimated a range of numbers from 200,000<sup>11</sup> to 500,000<sup>12,13</sup>

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<sup>8</sup> Pinto, N. (2015, June 9). Andrew Cuomo's Pot Problem. *Rolling Stone*. Retrieved from: <http://www.rollingstone.com/politics/news/andrew-cuomos-pot-problem-20150609>

<sup>9</sup> Velasquez, J. (2016, Feb 11). Cuomo defends state's medical marijuana program. *Politico*. Retrieved from <https://www.politico.com/states/new-york/albany/story/2016/02/cuomo-defends-states-medical-marijuana-program-031209>

<sup>10</sup> Refer to Appendix A1 for a list of survey questions

<sup>11</sup> Robinson, D. (2016, April 13). Medical marijuana patient's 'life-changing' results. *Lohud*. Retrieved from <https://www.lohud.com/story/news/investigations/2016/04/13/medical-marijuana-patient/82110856/>

<sup>12</sup> Warner, J. (2016, Feb 12). Medical Marijuana In New York State: Patient-Advocates Who Built The Program Are Fighting To Access It. *International Business Times*. Retrieved from: <http://www.ibtimes.com/medical-marijuana-new-york-state-patient-advocates-who-built-program-are-fighting-2302390>



Estimating the number of potential patients who might obtain recommendations to use medical marijuana in New York is difficult the lack of state registries and varying lists of qualifying conditions in each state has made it extremely difficult to know precisely how many patients are in each program. A more accurate way to determine how many people might use the program is to commission a needs assessment asking a representative sample of New Yorkers with likely qualifying conditions if they would use the program upon recommendation by their healthcare provider. Another way might be to build a model for New York based on another similar state's usage pattern data.

## ISSUES/CHALLENGES WITH THE PROGRAM: ELIGIBILITY

### Qualifying for the program

The current regulations cover only ten conditions, and to qualify for medical marijuana use, a patient in New York must not only have one of the ten qualifying conditions but an associated condition<sup>14</sup> as well. Unfortunately, this restriction fails to acknowledge that medical cannabis may have a therapeutic or palliative benefit for patients suffering from medical conditions not presently included in the law. The Commissioner was mandated to consider adding five additional conditions – Alzheimer's, muscular dystrophy, dystonia, post-traumatic stress disorder, and rheumatoid arthritis – by January 2016, 18 months after the Compassionate Care Act was signed into law. On January 11th, the Governor announced his decision not to include any of the five conditions<sup>15</sup> without providing a clear evidentiary justification. Cuomo claims to have consulted with medical professionals, examined scientific studies, and concluded that there was "not enough scientific evidence at this time to support the determination that medical marijuana will provide relief to patients suffering from any additional conditions."<sup>16</sup> This conclusion surprised many because there is rigorous research indicating the efficacy of medical marijuana in managing and treating the conditions associated with these severe illnesses<sup>17</sup>.

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<sup>13</sup> Margolin, M. (2016, Jan 20). New York's Medical Marijuana Program Off to a Slow Start; Critics Say Patients Are the Ones Suffering. *Village Voice*. Retrieved from: <http://www.villagevoice.com/news/new-yorks-medical-marijuana-program-off-to-a-slow-start-critics-say-patients-are-the-ones-suffering-8167747>

<sup>14</sup> The currently covered conditions are: cancer, HIV/AIDS, ALS, Parkinson's disease, multiple sclerosis, damage to the nervous tissue of the spinal cord with objective neurological indication or intractable spasticity, epilepsy, inflammatory bowel disease, neuropathies, and Huntington's disease. Current associated conditions are: cachexia or wasting syndrome; severe or chronic pain; severe nausea; seizures; severe or persistent muscle spasms

<sup>15</sup> (2016, Jan 11). PTSD, other diseases not added to medical marijuana list. *Politico*. Retrieved from: <http://www.capitalnewyork.com/article/albany/2016/01/8587598/ptsd-other-diseases-not-added-medical-marijuana-list>

<sup>16</sup> New York State Medical Marijuana Program Frequently Asked Questions. New York State Department of Health Website. Retrieved from [https://www.health.ny.gov/regulations/medical\\_marijuana/faq.htm](https://www.health.ny.gov/regulations/medical_marijuana/faq.htm)

<sup>17</sup> Compassionate Care New York. (2015, October 21). Fact Sheet: Medical Cannabis for PTSD. Retrieved from: [http://www.compassionatecareny.org/wp-content/uploads/mmj\\_ptsd\\_Fact-Sheet.pdf](http://www.compassionatecareny.org/wp-content/uploads/mmj_ptsd_Fact-Sheet.pdf)

According to our survey, many patients, who are not currently served by the program, would like access to medical marijuana to relieve their suffering. 19% (n=48) of respondents do not have one of the ten qualifying conditions, and among those who do not have a qualifying condition, 65% have severe, chronic pain and 35% PTSD.

## **ISSUES/CHALLENGES WITH THE PROGRAM: CERTIFICATION**

### **Obtaining a doctor's certification: the problem of physician access**

#### *Physician Requirements*

According to the regulations, only physicians licensed to practice in New York State can recommend medical marijuana to their patients. To do so, physicians have to complete a 4.5 hours, \$249 training course approved by the Department of Health. Since the start of the program, less than 1% of 80,000 doctors<sup>18</sup> in New York State have taken the training course and registered. As of May 24th, 583 doctors were registered with the Department of Health, which essentially means that there are only 583 in the entire State of New York patients can visit. (Refer to Appendix A2 for physician enrollment trends). This may create access problems, particularly in rural parts of the state where physicians are limited.

The lack of recommending physicians is a concern because, at the very least, physicians should expect inquiries about medical marijuana from patients, and to provide the best medical advice, they need to be knowledgeable about all potential forms of medical treatment. Moreover, in creating such restrictions like mandating that doctors undergo a training course to recommend medicine, the state overly restricts physician participation in the program and limits the pool of knowledge among doctors regarding a safe and effective form of medical treatment that patients respond well to.

#### *Absence of a publicly accessible list of registered physicians*

A growing number of patients and caregivers are unable to register for the program because they cannot locate a registered physician. Withholding a list of trained and registered physicians creates another barrier for patients since they do not have a way to find out which physicians are enrolled in the program. As a result, some patients have been waiting for weeks to consult with a registered doctor and, in the meanwhile, have been forced to cold-call doctors or resort to potentially unreliable sources of information online. In the absence of a list, NY could well end up with "pot doctors," unscrupulous providers who advertise their services and charge patients a hefty fee to certify them, and possibly the emergence of third-party vendors who also match patients and physicians

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<sup>18</sup> Kaiser Family Foundation (2016, April). State Health Facts: Total Professionally Active Physicians. Retrieved from: <http://kff.org/other/state-indicator/total-active-physicians/>

for a fee<sup>19</sup>. Such as situation will only exacerbate the inability of low-income patients to access the system.

New York State's rationale for withholding this information is unclear and, as our data show, is impeding patients' access to the program. According to a recent article by *Democrat and Chronicle*, at least 11 FOIL requests were sent to the Department of Health from January 1st to March 17th, and the DOH has declined every one of them<sup>20</sup>.

Problems faced in getting certified<sup>21</sup>:

Among survey respondents with a qualifying condition (n=201), more than half have not found a doctor. Of the 119 who have not yet been certified by a doctor, more than half (61%) have been trying for three to four months and one in five (19%) for one to two months. A third (29%) said their doctor does not believe in the therapeutic value of medical marijuana in general, and another third stated their doctors cited legal concerns about certifying patients for medical marijuana use. One in four (26%) are waiting for their doctor's institution to set a policy on medical marijuana, while 10% reported that their doctors were in the process of registering while 8% said their doctor did not believe medical marijuana would benefit them. Of the 38 who provided open-ended responses, 42% said they could not find a registered doctor in their area, and 18% noted that the institution or physician group their doctors belonged to had set a policy against certifying patients for medical marijuana use.

## **ISSUES/CHALLENGES WITH THE PROGRAM: REGISTRATION**

### Registering online as a patient/caregiver

As of May 24th, 4081 patients have been certified by their doctors for medical marijuana use<sup>22</sup>. This number, however, denotes only the number of patients who have registered online as a patient with the program and does not represent the actual number of people who have obtained medicine<sup>23</sup>. According to our survey, of the 72 patients/caregivers

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<sup>19</sup> Haglage, A. (2016 Jan 13). Brooklyn's Only Weed Dr. 'Got Rich' Off the Homeless and Mentally Ill. The Daily Beast. Retrieved from <https://www.thedailybeast.com/brooklyns-only-weed-dr-got-rich-off-the-homeless-and-mentally-ill>

<sup>20</sup> Singer, P. (2016, May 23). At least 11 FOIL requests for marijuana docs denied. Democrat and Chronicle. Retrieved from <http://www.democratandchronicle.com/story/news/health/blogs/all-about-health/2016/05/23/new-york-health-department-foil-requests-marijuana-docs/84786172/>

<sup>21</sup> Respondents were allowed to indicate more than one response

<sup>22</sup> New York State Department of Health. 2016, May. New York State Medical Marijuana Program. Retrieved from: [https://www.health.ny.gov/regulations/medical\\_marijuana/](https://www.health.ny.gov/regulations/medical_marijuana/)

<sup>23</sup> Velasquez, J. (2016, March 29). State estimates half of eligible patients received medical marijuana. Politico. Retrieved from

who were able to complete the online registration, 50% completed registration in less than an hour, while 50% took 1- 6 hours; 71% did not apply for a fee waiver, and of the 21 who did, 81% were granted the waiver. 70% received their patient registry cards within 1 to 7 days, while 30% within 1-3 weeks.

## **ISSUES/CHALLENGES WITH THE PROGRAM: PURCHASE**

### **Purchasing medicine at the dispensary**

As of May 24th, 4081 patients have been certified by their doctors for medical marijuana use<sup>24</sup>. This number, however, denotes only the number of patients who have registered online as a patient with the program and does not represent the actual number of people who have obtained medicine. For instance, a March 29<sup>th</sup> *Politico* news report<sup>25</sup> stated that DOH estimates less than half of the 2039 patients registered at that time had purchased medicine from a dispensary. According to our survey, of the 72 patients/caregivers who were able to complete the online registration, around three in five (64%) could visit a dispensary and purchase medicine.

### **Geographic Access to Dispensaries**

The number of dispensaries statewide is limited to twenty. Of these, 18 have opened so far. Given that New York has 19.7 million people over more than 54,000 square miles, it is hard to imagine how twenty dispensaries will meet patients' needs across the entire state. The map below depicts where dispensaries are located and identifies significantly large areas of New York State that will be underserved by the lack of dispensaries. For instance, there are no dispensaries in Brooklyn, Staten Island, none in Western New York, and the Southern Tier, with only two on Long Island.

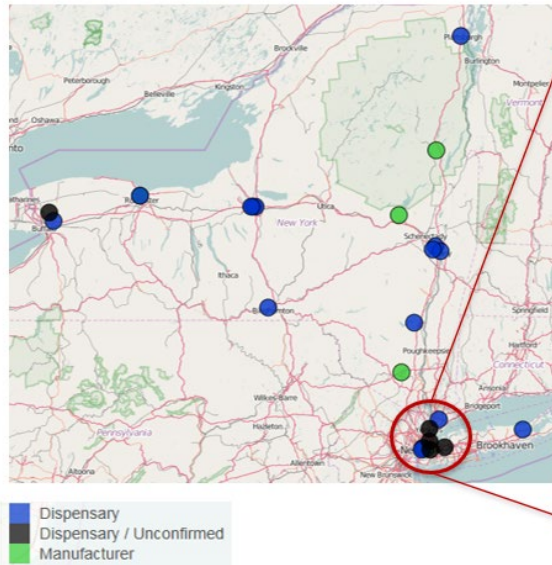
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<http://www.capitalnewyork.com/article/albany/2016/03/8594953/state-estimates-half-eligible-patients-received-medical-marijuana>

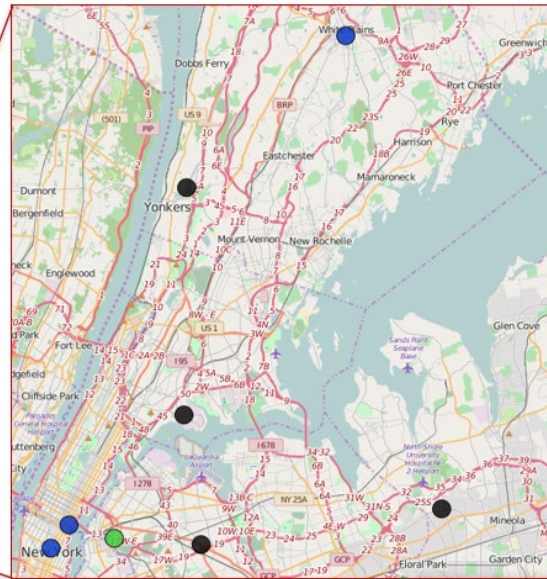
<sup>24</sup> New York State Department of Health. 2016, May. New York State Medical Marijuana Program. Retrieved from: [https://www.health.ny.gov/regulations/medical\\_marijuana/](https://www.health.ny.gov/regulations/medical_marijuana/)

<sup>25</sup> Velasquez, J. (2016, March 29). State estimates half of eligible patients received medical marijuana

## New York State



## New York City



Map of New York State Medical Marijuana Facilities

This problem is exacerbated by the fact that regulations prohibit the use of delivery services without the Health Commissioner's prior written approval. This limited access could create real issues for sick, disabled, or housebound patients.

There was talk of a delivery system<sup>26</sup> – reportedly "New York State [has been] working with medical marijuana manufacturers to help set up regulations to allow home delivery of medical marijuana," – but to date, a delivery system never materialized. The problem of geographic access is worsened by the limited availability of medicine (described further below).

According to our survey, of the 44 patients/caregivers who purchased medicine at the dispensary, a majority (73%) traveled for 30 mins to an hour, while 27% traveled for 1-5 hours.

## Purchasing Medicine at the Dispensary

### Product Availability

- **Forms.** The only allowable forms of medical marijuana, according to the regulations, are liquid and oil extracts to be consumed in vapor, tincture, or pill form. The laws prohibit access to the whole marijuana plant, edibles, suppositories, and topicals. Smoking of dried flowers ("bud") is not permitted by statute.
- **Brands.** The regulations have also restricted producers to manufacturing five

<sup>26</sup> The Citizen (2016, Jan 16). New York state editorial roundup: Grow marijuana market. The Auburn Pub. Retrieved from:[http://auburnpub.com/news/opinion/new-york-state-editorial-roundup-grow-marijuana-market-u-s/article\\_88f87643-67cc-5a88-96b6-6b6124628a6c.html](http://auburnpub.com/news/opinion/new-york-state-editorial-roundup-grow-marijuana-market-u-s/article_88f87643-67cc-5a88-96b6-6b6124628a6c.html)



"brands" of medical marijuana products when there are dozens of therapeutic strains, each having specific benefits for particular conditions.

Therefore, products have not always been available at dispensaries because the entire manufacturing process of such forms is complicated and lengthy due to various testing and inspection requirements to ensure quality and adherence to mandated ratios. According to our survey, of the 44 patients/caregivers who purchased medicine at the dispensary,

- Nearly 2 out of 5 (39%) reported that the dispensary they visited did not carry the specific form and ratio that was recommended to them by their physician
- Close to 2 in 5 (39%) or (n=17) respondents were not pleased with the quality of medicine received

### Affordability and Financial Assistance

News articles have reported a substantially large range of prices for a 30-day supply of medicine, which depends on the patient's specific needs. One article states that average prices range between \$100-\$400 for a month's supply,<sup>27</sup> whereas most patients find they must spend \$300-\$800 a month for the drug.<sup>28</sup> One of the producer's dispensaries we contacted said that a catalog/listing of product prices is not available because prices are constantly changing, subject to the production and manufacturing process. According to this producer, the fee a patient pays depends on the following factors: immediacy and duration of the relief sought, delivery mechanism chosen (i.e., vaporized liquids, tincture, pills), patient's prior THC/CBD tolerance (which affects the frequency of dose), and severity of symptoms (which affects amount and frequency of quantity needed). The lack of centralized or consistent information on the price of medical marijuana products sold greatly disadvantages patients by keeping them in the dark about how much money they can expect to spend every month on medicine (which will no doubt be a significant expense to most patients, since insurance does not cover the cost).

According to our survey, of the 79 patients/caregivers who have obtained a doctor's certification, nearly a third (33%) paid \$100-\$300 for the initial consultation visit, one in five (20%) spent more than \$300. Only one in three (33%) had their visitation/consultation fee covered by insurance.

Of the 44 patients/caregivers who purchased medicine at the dispensary,

- Only 7% reported an estimated monthly cost of less than \$100, and 23% said they expected to be paying \$100-\$300 for a month's supply of medicine.

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<sup>27</sup> Hughes, C. (2016, Feb 22). Lawmakers seek to expand New York's fledgling medical marijuana program. *Albany Times Union*. Retrieved from: <http://www.timesunion.com/tuplus-local/article/Lawmakers-seek-to-expand-New-York-s-fledgling-6845948.php>

<sup>28</sup> Hughes, C. (2016, March 9). Medical marijuana remains a hard sell for Albany doctors. *Albany Times Union*. Retrieved from: <http://www.timesunion.com/tuplus-local/article/Medical-marijuana-remains-a-hard-sell-for-Albany-6881036.php>

- Almost 2 out of 5 (39%) stated that their estimated monthly cost would be \$300-\$500, while 14% report an estimated monthly cost of \$301-\$500, and nearly a fifth (18%) expect to be paying more than \$1000.
- More than 3 in 4 (77%) stated they would not afford the medicine they need.
- 3 in 4 (75%) were not offered financial assistance to purchase medicine. Among the 11 patients/caregivers who were offered financial assistance, a 10% and 15% discount rate was most commonly provided.

## OVERALL ASSESSMENT OF THE PROGRAM

According to our survey of 229 patient/caregivers, 1 in 3 (or 34%) reported that they would *not* continue using or trying to use NY's medical marijuana program. Among the 68 patients/caregivers who responded as to why they will not continue using or trying to use NY's program, the most popular reasons cited are:

- Not eligible due to lack of qualifying medical conditions (19%)
- Unable to find or afford a doctor for certification (22%)
- Too unaffordable (29%)
- Too many hurdles/hoops to jump through (19%)
- Insufficient forms of medicine available (7%)

Of the 214 responses received regarding ways to improve New York's medical marijuana:

- 17% wanted more qualifying medical conditions added
- 24% suggested making it less difficult to locate a registered physician and obtain a doctor's certification
- 23% recommended increasing the forms of medical marijuana available (mainly permitting smokable options)
- 18% would like to see an increase in the affordability of medical marijuana

## COMPARING NEW YORK TO OTHER STATES

Comparing New York's medical marijuana program to other states allows us to realize that it is similar to roughly ten other states that are much more 'medical' in orientation than some of the early medical marijuana programs in states like Colorado, Oregon, and Montana, for example. Based on two studies that used two different metrics and rationale to characterize restrictiveness<sup>29</sup>, New York State emerged as the most restrictive on both analyses, underscoring just how restrictive its program. (Refer to the Appendix A4 for a table of how states scored).

Some comparisons that stand out are:

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<sup>29</sup> Williams, A. R., Olsson, M., Kim, J. H., Martins, S. S., & Kleber, H. D. (2016). Older, Less Regulated Medical Marijuana Programs Have Much Greater Enrollment Rates Than Newer 'Medicalized' Programs. *Health Affairs*, 35(3), 480-488; Chapman, S. A., Spetz, J., Lin, J., Chan, K., & Schmidt, L. A. (2016). Capturing heterogeneity in medical marijuana policies: a taxonomy of regulatory regimes across the United States. *Substance use & misuse*, 1-11.

- *On conditions.* Other states permit medical marijuana prescription any of the associated conditions caused by a disease or severe illness. These laws recognize that some diseases are rare but have severe side effects that are effectively and safely treated or managed by medical marijuana. Essentially, the medicine is intended to address not the primary illness but its associated conditions.
- *On certification:* New York is only one of 3 states to mandate doctors to take a training course to certify patients.
- *On geographic access.* Only New Jersey is worse off.
- *On forms.* Besides Minnesota, New York is the only state to prohibit access to whole plant matter.

## WHAT IS AT STAKE?

### Possible scenarios

With access to the program being so restrictive and medicine being so costly and unaffordable, the state risks creating a two-tier system, where only the rich who could afford to purchase it out-of-pocket will be able to access medicine. Moreover, marijuana sold on the underground market is generally cheaper<sup>30</sup> and is available in forms that might be considered more desirable among patients. Hence, New York's restrictive program might very well divert patients to the black market, which not only exposes them to a product that might be unsafe and of questionable quality, but also creates the risk of criminalization. By so tightly restricting access, some children with severe seizure disorders and old people with the most severe illnesses might die waiting for medicine or be forced to leave the state ("medical marijuana refugee")

## RECOMMENDATIONS

### Ways improve the access and affordability

Policy solutions are often evaluated by examining outcomes of similar policies in other states<sup>31</sup>. However, with respect to medical marijuana policies, the high degree of heterogeneity between states' medical marijuana programs renders fair comparison virtually impossible<sup>32</sup>.

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<sup>30</sup> Collins, S. (2015, Sept 21). The High Price Of Medical Marijuana Is Forcing People Back To The Black Market. Think Progress. Retrieved from <https://archive.thinkprogress.org/the-high-price-of-medical-marijuana-is-forcing-people-back-to-the-black-market-955b1481e234/>

<sup>31</sup> According to a recent report by the DEA, 80% of states have legalized some form of medical marijuana and [24] have broadly legalized marijuana use for medical purposes. Four of those states, along with the District of Columbia, have also legalized marijuana for recreational use.

<sup>32</sup> Chapman et al (2016). Capturing heterogeneity in medical marijuana policies: a taxonomy of regulatory regimes across the United States.

## Key criteria

- *Quality of medical relief*
- *Affordability of medicine*
- *Patient access.* The true extent of patient access cannot be as meaningfully captured by the sheer number of patients registered as it can by the number of active users of the program, a statistic we currently lack since. According to our survey, a significant percentage of respondents are not inclined to continue using or trying to access medicine after registration

Patient access is the key criterion to prioritize because expanding patient access would increase the affordability of medicine over time and also likely improve the quality of medical marijuana products offered for sale.

## Advocacy strategy

There are essentially two ways to expand patient access to NY's medical marijuana program: either through the Health Commissioner's regulatory powers<sup>33</sup> or through the legislative process. CCNY initially strategized to engage with the Department of Health and Commissioner Zucker around implementation issues, offering guidance and expertise, and assuming the role of a watchdog entity that can publicly press the DOH to do the right thing and correct mistakes, as well as put political pressure on the Commissioner.

However, since it is unlikely that we will be moving the Commissioner or the Governor on expanding access to the program<sup>34</sup>, CCNY has been working with the medical marijuana law's legislative champions to draft, introduce and advocate for several bills this legislative session that would ease the restrictiveness of the program. Moreover, even though many of the shortcomings of the bill that was passed could potentially be addressed by the Commissioner, making some changes legislatively will ultimately make the program more stable and robust and less reliant on any particular whims of the Commissioner or Governor. To date, Assemblyman Richard Gottfried and Senator Diane Savino introduced a total of nine bills that would fix some of the most pressing problems with the program and directly expand safe and legal access to compassionate medical care for patients in New York.

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<sup>33</sup> Under the statute, the Commissioner of Health not only oversees the promulgation of regulations governing everything from security to advertising, but has sole discretion to add covered conditions, determine whether or not nurse practitioners will be allowed to recommend medical cannabis, dictate the forms in which medicine may be sold, determine the number of producers and dispensaries, shape the requirements for healthcare providers who want to recommend medical cannabis, and establish guidelines by which industry players will be allowed to enter the marketplace. The nature of these regulations will have an enormous impact on patient access, the shape of the industry, the infrastructure the state develops to regulate marijuana, and the overall success of the program.

<sup>34</sup> Because Commissioner rejected the addition of new conditions in January 2016; the DOH has refused to release a list of registered physicians who can recommend, set up a delivery system or create a charity pool to offer financial assistance. Moreover, Gov. Cuomo is of the belief that the program is rolling out smoothly as expected and that it was preferable to proceed apace

## Legislative Solutions

### [Eligibility]

- **Bill A9562/S6999**<sup>35</sup> adds the following conditions: Alzheimer's disease, traumatic brain injury, dystonia, muscular dystrophy, wasting syndrome, post-traumatic stress disorder, rheumatoid arthritis, and lupus.

*Rationale.* There is a growing base of promising research evidence attesting to medical marijuana's efficacy in treating these conditions. Some of them, such as PTSD and muscular dystrophy, are currently treated with medical marijuana in other states.

- **Bill A9514-A/ S7249-A**<sup>36</sup> adds severe, chronic pain as a qualifying condition.

*Rationale:* Cannabis, effective in treating certain kinds of pain, would afford new options. A recent study published in the Journal of the American Medical Association found that states with medical marijuana laws are associated with a significant reduction in mortality from opioid abuse<sup>37</sup>. Given medical marijuana's pain-relieving benefits, it presents a promising solution to reducing the morbidity and mortality related to prescription opioid use in New York State, creating broader access to medical marijuana for patients in need. Chronic pain should be included as a qualifying condition in its medical marijuana program.

### [Certification]

- **Bill A10123**<sup>38</sup> requires the Department of Health to publicly disclose the information of doctors trained and registered to certify patients for medical marijuana use.

*Rationale:* Bill A10123 would require the Health Department to make publicly available the information of trained and registered doctors who have consented to be listed, and also provides an option for doctors to opt-out of being listed. Moreover, there are precedents for government entities making lists of physicians

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<sup>35</sup> Bill A09562 Summary

[http://nyassembly.gov/leg/?default\\_fld=&leg\\_video=&bn=A09562&term=2015&Summary=Y&Actions=Y](http://nyassembly.gov/leg/?default_fld=&leg_video=&bn=A09562&term=2015&Summary=Y&Actions=Y)

<sup>36</sup> Bill A09514 Summary

[http://nyassembly.gov/leg/?default\\_fld=%0D%0A&leg\\_video=&bn=A09514&term=2015&Summary=Y&Actions=Y](http://nyassembly.gov/leg/?default_fld=%0D%0A&leg_video=&bn=A09514&term=2015&Summary=Y&Actions=Y)

<sup>37</sup> Bachhuber, M. A., Saloner, B., Cunningham, C. O., & Barry, C. L. (2014). Medical cannabis laws and opioid analgesic overdose mortality in the United States, 1999-2010. *JAMA internal medicine*, 174(10), 1668-1673

<sup>38</sup> Bill A10123 Summary

[http://nyassembly.gov/leg/?default\\_fld=%0D%0A&leg\\_video=&bn=A10123&term=2015&Summary=Y&Actions=Y](http://nyassembly.gov/leg/?default_fld=%0D%0A&leg_video=&bn=A10123&term=2015&Summary=Y&Actions=Y)



available to patients. For example, New Jersey has a public registry of its medical marijuana doctors, and the Substance Abuse and Mental Health Services Administration has a national registry of doctors who are certified to prescribe buprenorphine, a medication that treats addiction to heroin and other opioids.

- **Bill A9510/S6998**<sup>39</sup> allows nurse practitioners and physician assistants to recommend medical marijuana for patients, just like with most other drugs.

*Rationale:* The current set of regulations restricts the kinds of healthcare providers who can recommend medical marijuana to physicians only. In other words, nurse practitioners and physician assistants cannot recommend medical marijuana to their patients even though they can prescribe many other medications. With a low number of physicians enrolling in the program, the physician-only restriction has created patient access problems. Nurse practitioners and physician assistants would have to take the same training course that physicians take to recommend medical marijuana. Patients should not be denied access to compassionate medical care if they are under the care of a nurse practitioner or a physician assistant who has the appropriate training and is working within the legally defined scope of practice.

#### [Geographic Access to Dispensaries]

- **Bill A9747-A/ S7467**<sup>40</sup> allows five more registered organizations to be approved and allowing all registered organizations to operate eight dispensaries in a geographically-dispersed manner throughout the state.

*Rationale:* A total of 20 dispensaries are insufficient for a state of nearly 20 million people spanning more than 54,000 square miles. Bill A9747-A/S7467 authorizes the Commissioner to add five more producers and prioritize underserved areas when determining dispensary locations.

### Passing Legislation

*Legislative Process:* Bills can be introduced in either the Assembly or the Senate, but before becoming the law, the same bill (denoted by the "/") must pass both houses and then be signed by the Governor. A bill with both an Assembly and a Senate number is a bill introduced in both houses.

*Legislative Prospects:* As of May 26<sup>th</sup>, 2 Assembly bills – Bills A10123 and A9510 – were passed<sup>41</sup>. To become law, the identical Senate version of those bills must be passed.

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<sup>39</sup> Bill A09510 Summary

[http://nyassembly.gov/leg/?default\\_fld=%0D%0A&leg\\_video=&bn=A09510&term=2015&Summary=Y&Actions=Y](http://nyassembly.gov/leg/?default_fld=%0D%0A&leg_video=&bn=A09510&term=2015&Summary=Y&Actions=Y)

<sup>40</sup> Bill A09747 Summary

[http://nyassembly.gov/leg/?default\\_fld=%0D%0A&leg\\_video=&bn=A09747&term=2015&Summary=Y&Actions=Y](http://nyassembly.gov/leg/?default_fld=%0D%0A&leg_video=&bn=A09747&term=2015&Summary=Y&Actions=Y)

A10123 does not have an identical Senate bill, so until one is introduced, it is stalled. For A9510, if its identical Senate bill, S6998, is passed, Gov. Cuomo may sign it into law for it to become effective. Therefore, CCNY will target critical members of the Senate in our push for the passage of the above-mentioned bills. Having both the Assembly and Senate pass bills with overwhelming support applies political pressure on Governor Cuomo to sign the bills into law.

### Data collection and program monitoring

A rigorous reporting and tracking system is necessary to carefully monitor the program's progress since its rollout in January this year and hold the Administration accountable for its commitment to providing access to all patients who may benefit from the medical use of cannabis. There is a genuine, voracious demand for information from patients who wish to know how the program functions and what it offers patients in New York. According to Section 3367, Clause 3 of New York's medical marijuana law, "The Department shall report every two years, beginning two years after the effective date of this title, to the governor, and the legislature on the medical use of marijuana under this title and make appropriate recommendations."<sup>42</sup> This provision means that the Health Department is mandated to report on the program on July 7th, 2016. However, this section on reporting requirements does not mandate that DOH make available other data on the program, for instance, making program data publicly available on their website or producing reports regularly<sup>43</sup>. (Refer to Appendix A3 for a detailed listing of information necessary to inform policymaking)

## Overall Recommendations

We urge the New York State legislature to pass these four bills. The first three aim at directly expanding patient access to the program by increasing the number of eligible conditions for which a patient qualifies for medical marijuana use, increasing the number of healthcare providers who can certify patients. Increasing supply by adding 60 dispensaries statewide without easing patient entry into the program makes poor economic sense. Increasing supply of medicine without correspondingly increasing demand (number of registered patients) would hurt both consumers who would not be able to afford expensive medicine and producers who will have to keep their products expensive due to the unchanged patient market. Therefore, we recommend passing these four bills for comprehensive, meaningful expansion of New York's restrictive medical marijuana program.

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<sup>41</sup> Wooten, M. (2016, May 26). Assembly passes two medical marijuana bills. WGRZ. Retrieved from <https://www.wgrz.com/article/news/assembly-passes-two-medical-marijuana-bills/71-216485829>

<sup>42</sup> Full text of New York's Medical Marijuana Law (S7923/A6357-E). Retrieved from: <http://www.compassionatecareny.org/wp-content/uploads/A6357E-2013.pdf>

<sup>43</sup> This is done by virtually all other medical marijuana states, with varying regularity i.e. weekly, monthly, quarterly, biannually, and yearly

Finally, to aid policymaking, we recommend increasing access to data and publicizing information on the program's implementation, thereby increasing the transparency and accountability of the DOH's role in overseeing the program's development.

## APPENDIX A1: Patient/Caregiver Feedback Survey

Dear patient/caregiver,

We are trying to document the successes and problems with NY's recently launched medical marijuana program and would like your perspective. If you are trying to access the program and have not yet obtained medical marijuana, you can still answer this short survey.

We hope to use the feedback gathered in this survey to bring attention to the limitations of the program and identify potential areas for improvement. Please rest assured that this is an ANONYMOUS survey, and we will not be soliciting any identifying information from you. The survey should take about 5-10 minutes to complete. Please feel free to share this survey with others who may be interested.

**1. Are you a:**

- Patient
- Caregiver of a patient
  - Parent of a child under 18
  - Appointed caregiver of a patient above 18

**2. Do you have one of the 10 medical conditions that would currently qualify you for medical marijuana in New York?**

Yes/No

**[If yes] 2a. Please choose the qualifying medical illness (es) and associated condition(s) do you have/have been diagnosed with:**

*Severe medical conditions:*

- Cancer
- HIV infection or AIDS
- Amyotrophic lateral sclerosis (ALS)
- Parkinson's disease
- Multiple sclerosis
- Spinal cord injury with spasticity
- Epilepsy
- Inflammatory bowel disease
- Neuropathy
- Huntington's disease

*Associated conditions:*

- Cachexia or wasting syndrome
- Severe or chronic pain
- Severe nausea
- Seizures
- Severe or persistent muscle spasms

**[If no, proceed to Qn 3]**

**3. Do you have any other medical illness or associated condition (besides the 10 listed above) for which you know/believe MMJ to have a therapeutic or palliative effect? Please select from the following:**

- Alzheimer's
- Anxiety
- Dystonia
- Glaucoma
- Muscular dystrophy
- PTSD
- Rheumatoid Arthritis
- Severe, chronic pain
- Other:

**[Next Qns for these participants will be: 22; 24; 25]**

**4. Have you tried to find a doctor to certify you as a medical marijuana patient?**

Yes/No

**[If yes] 5. How long did it take you to find a doctor to certify you?**

1-2 weeks

2-4 weeks

More than a month

**6. How did you find a doctor to certify you?**

My primary care doctor has certified me for MMJ

My specialist certified me

My doctor referred me to a registered physician listed on DOH's Health Commerce Site

A dispensary referred me to a doctor

I used a third party referral services (e.g., [www.marijuanadoctors.com](http://www.marijuanadoctors.com))

I located one independently (searches online/word of mouth etc.)

Other:

**7. Did you have any of the following problems in getting certified by a doctor? (Check all that apply):**

Treating doctor denied certification because s/he is in the process of training & registering

Treating doctor denied certification because s/he does not believe I qualify for medical marijuana or that it would benefit me

Treating doctor does not believe in the therapeutic value of medical marijuana.

Treating doctor cited legal concerns about recommending medical marijuana.

Treating doctor is waiting for his/her institution to set a policy about medical marijuana.

Other:

**8. What did you pay out of pocket to get certified by a doctor for medical marijuana?**

Nothing (no charge or covered by insurance)

\$1-30

\$31-\$100

\$101-\$200

\$201-\$300

More than \$300

**9. How long did it take for you to complete online patient registration?**

1-3 hours

3-6 hours

More than 6 hours

**10. Did you apply for fee waiver during patient registration process? Yes/No**

**[If yes] 11. Were you granted the fee waiver? Yes/No**

**12. How long since submitting your patient registration online did you have to wait to receive your registry card?**

1-3 days

3-7 days

More than 1 week

**13. How long did you travel to get your medicine?**

1 hour

1-3 hours

More than 3 hours

**14. Did the dispensary nearest you carry the ratio and/or form that was recommended to you? Yes/No**



**15. Were you offered financial assistance or allowed to purchase reduced price products at the dispensary you visited? Yes/No**

**[If yes] 16. What kind of assistance was offered? (e.g., 10% discount)**

**17. How much did you spend on medical marijuana?**

- \$100-\$300
- \$301-\$500
- \$501-\$1000
- More than \$1000

**18. What is the estimated monthly cost of your medical marijuana?**

- \$100-\$300
- \$301-\$500
- \$501-\$1000
- More than \$1000

**19. Are you able to afford this? Yes/No**

**20. Were you pleased with the quality of the medicine you received? Yes/No**

**[If no] 21. Why not?**

**22. Has the Department of Health Medical Marijuana Program been helpful in addressing your questions or concerns with the problem?**

Yes/No/I did not contact them

**23. Will you continue to use NY's medical marijuana program?**

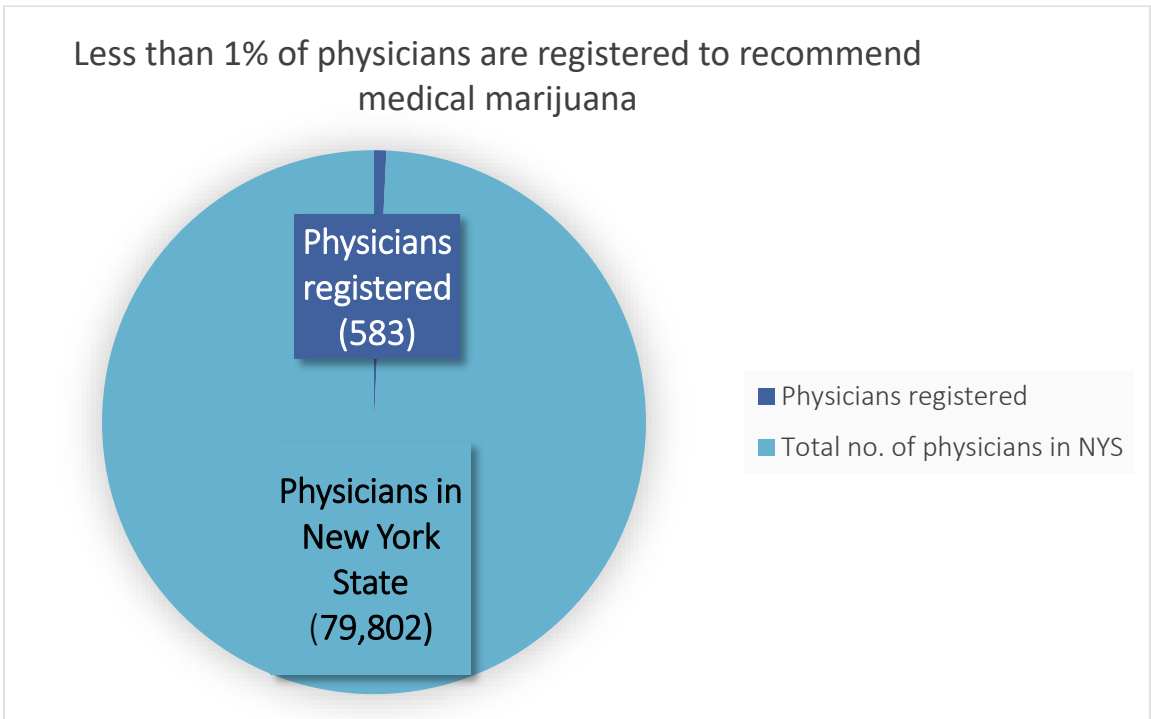
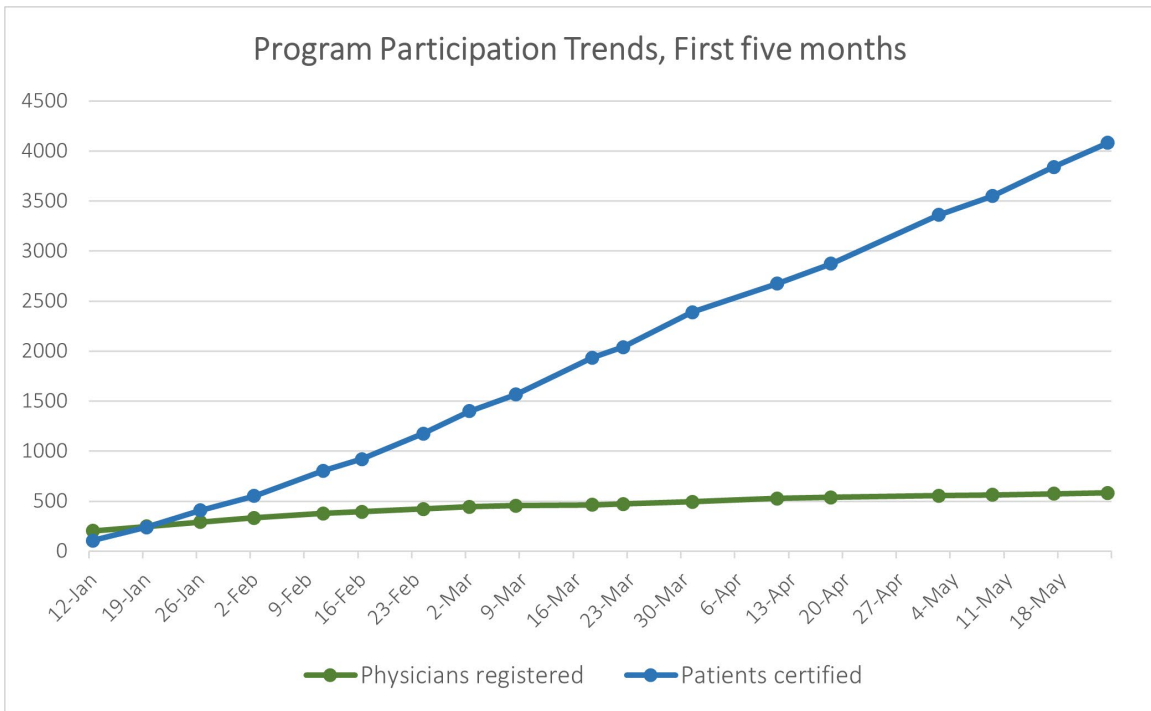
Yes/No

**24. If you could change one thing about NY's medical marijuana program, what would it be?**

**25. Can we share your comments with the NY Department of Health and/or on Compassionate Care NY's social media pages? All comment and answers are completely ANONYMOUS.**

Yes/No

## APPENDIX A2: Program Participation Trends trends



## APPENDIX A3: Data necessary to assess the implementation of the program from a patient access standpoint

### *[Eligibility]*

In order to better gauge the number of patients in New York who could benefit from the medical use of cannabis, we would like to know:

- Number of calls/emails to DOH from patients/caregivers who want to participate in the program but do not have a qualifying condition

### *[Certification]*

Given how challenging it has been for patients to find a registered doctor and obtain a certification for medicine, we would like the following data to better assess the availability/accessibility of physicians around the state:

- Physician enrollment based on county and specialty
- Median (and range) number of patients doctors are certifying
- Number of calls/emails to DOH from patients/caregivers who cannot locate a physician

### *[Registration]*

In order to assess how many patients are actually completing the registration process, data we would like:

- Patient/caregiver enrollment by medical condition, county, race/ethnicity, gender, age
- Median (and range) time from starting application to being registered
- Number of patients/caregivers who start the application and do not finish
- Number of patients/caregivers who applied for and qualify for the registration fee waiver

### *[Geographic access to dispensary + Purchase of medical marijuana products]*

Data we do not have on patient access to a dispensary and medicine:

- Number of patients/caregivers who successfully enroll (complete the online registration) but never purchase medicine
- Percent of patients who have registered who have purchased medicine
- Median (and range) time from successful registration to purchasing medicine
- Number of patients/caregivers making purchases at each dispensary
- Median (and range) distance between patient/caregiver's home address and dispensary where purchase is made
- Data we do not have on product availability:
- Products and forms of medicine available

Data we do not have on product affordability:

- No centralized source of information on cost of various MMJ products offered by each RO at their dispensaries
- Status and terms of financial assistance programs (if any)
- Number of patients being served by those financial assistance programs

## APPENDIX A4: Comparison of the ten most restrictive medical marijuana programs from a patient access/enrollment standpoint

### Seven elements of a medical marijuana program <sup>44</sup>

	DC	DE	IL	NH	MA	NJ	CT	MD	MN	NY
Doctor-Patient Relationship	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Manufacturing & Dispensing	✓	✓	✓	✓		✓	✓	✓	✓	✓
Testing & Labeling	✓	✓	✓	✓		✓	✓	✓	✓	✓
Use of non-smokable medical marijuana*									✓	✓
30-day supply limits						✓	✓	✓	✓	✓
Prescription Drug Monitoring					✓		✓			✓
Physician Training*					✓			✓		✓
<b>Restrictiveness Score</b>	<b>3</b>	<b>3</b>	<b>3</b>	<b>3</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>5</b>	<b>5</b>	<b>7</b>

### Three general medical marijuana policy domains <sup>45</sup>

	DC	DE	IL	NH	MA	NJ	CT	MD	MN	NY
Initiation	3	3	4	3	4	2	3	3	2	2
Quantity	1	2	2	2	4	1	1	2	1	1
Distribution	1	1	2	2	4	1	1	1	1	1
<b>Restrictiveness Score</b>	<b>5</b>	<b>6</b>	<b>8</b>	<b>7</b>	<b>12</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>4</b>	<b>4</b>

<sup>44</sup> Williams et al (2016). Older, Less Regulated Medical Marijuana Programs Have Much Greater Enrollment Rates Than Newer ‘Medicalized’ Programs

<sup>45</sup> Chapman et al (2016). Capturing heterogeneity in medical marijuana policies: a taxonomy of regulatory regimes across the United States