NEW YORK STATE
OFFICE OF
CANNABIS MANAGEMENT

TWO YEAR MEDICAL CANNABIS REPORT

INNOVATION

ACCESS

OPPORTUNITY

SAFETY

EDUCATION

EQUITY & INCLUSION

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Letter from the Chair of the Cannabis Control Board

Dear Governor Hochul, Majority Leader Stewart-Cousins, Speaker Heastie, and all New Yorkers,

New York State's Medical Cannabis Program has come a long way since it was created in 2014. I'm excited to share the progress we've made expanding the program as we continue to implement the Marijuana Regulation and Taxation Act, which is encapsulated in the pages of this report.

Starting with our first meeting of the Cannabis Control Board in October 2021, we've worked hard to grow access to the program by expanding the types of health care providers who can certify patients, and by allowing the certification of a patient by a practitioner for any condition that the practitioner believes can be treated with medical cannabis. We also moved swiftly to allow for the sale of whole flower products, a lower cost option for patients.

At the same time, we've focused on maintaining the value the program provides to patients, with rules that ensure trained pharmacists are dispensing products to patients and helping them find the right ones for their treatment.

We want to assure New York's patients that this program, and the support it provides them, will remain in place even as the adult-use cannabis market continues to come online. To that end, we've also finalized regulations for the program, which, among other changes, allow patients to auto-register for the program, which will accelerate and simplify access to this medicine. We also now permit registered patients to grow up to six of their own medical cannabis plants.

New York's patients deserve a top-tier Medical Cannabis Program, and we will continue our efforts to not only maintain, but expand New York's Medical Program as we grow this industry across the state.

Sincerely,

Tremaine Wright

Tremaine Wright

NEW YORK STATE | Office of Cannabis Management

Letter from the Executive Director

Dear Governor Hochul, Majority Leader Stewart-Cousins, Speaker Heastie, and all New Yorkers,

Expanding and strengthening New York State's Medical Cannabis Program has been a central focus of our work since the creation of the Office. We have moved quickly to make necessary and long-awaited changes to improve patient access to medical cannabis. That work must continue but we are proud of the policy and programmatic updates made in the last 18 months including the recent implementation of auto-registration.

One of the key benefits of the State's Medical Cannabis Program is the patient-practitioner relationship that gives confidence to New Yorkers who are looking to medical cannabis to treat their conditions and symptoms. The access to pharmacists who can help guide those patients to the right products for their ailments is critical. This is also an important link as research continues around cannabis and our understanding of its medical benefits advances. Patients can't be expected to keep pace with all the scientific advancements, but the professionals at our medical dispensaries are and do.

The Office of Cannabis Management will continue to expand and strengthen the Medical Cannabis Program so it can provide this valuable service to New York's patients for years to come. We're proud of the program and look forward to continuing to work with you as we serve New York's patients.

Sincerely,

Chris Alexander

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Introduction

Legislative Mandate

The following report is issued pursuant to §37(3) of the Cannabis Law which provides, in relevant part, that the Cannabis Control Board (Board) "…report every two years, beginning two years after the effective date of this article, to the governor and the legislature on the medical use of cannabis under this article and make appropriate recommendations." (N.Y. CAN § 37(3)).

Purpose and Scope of the Report

This report describes progress and accomplishments by the Board and the Office of Cannabis Management (Office) regarding implementation, management, and expansion of the Medical Cannabis Program. This report will be submitted to the Governor and the Legislature on the 31st of March every two years beginning in 2023.

Summary of Medical Cannabis Legalization in New York State

The 2014 Compassionate Care Act became New York State's first cannabis legalization measure, creating the state's Medical Cannabis Program. Dispensaries opened in January 2016, affording eligible New York State residents with qualifying medical conditions the opportunity to purchase medical cannabis safely and under the supervision of trained practitioners. The Marihuana Regulation and Taxation Act (MRTA) that enacted New York State's Cannabis Law was signed into law on March 31, 2021, legalizing adult-use cannabis in New York State and consolidating all cannabis-related programs and functions under one newly created state entity, the Office of Cannabis Management (the Office). The Office was tasked with comprehensively regulating adult-use cannabis, medical cannabis, and cannabinoid hemp. This effort began in earnest in September 2021 when Governor Kathy Hochul appointed members to the Board and the Executive Director of the Office. The Board's inaugural meeting was held October 5, 2021, during which it appointed the Office's first cohort of staff, officially creating the Office of Cannabis Management.

Following the framework established within the MRTA, the Office has taken significant steps to expand the existing Medical Cannabis Program. These efforts include the implementation of the Medical Cannabis Data Management System (MCDMS), effectively streamlining the patient certification process for health care providers and the registration process for patients and their designated caregivers. To further increase accessibility to the program, the type of provider who can certify patients for the medical use of cannabis was broadened to include anyone who is licensed, registered, or certified by New York State to prescribe controlled substances (including dentists, midwives, and podiatrists who were previously prohibited from certifying patients).

Patient access to the Medical Cannabis Program was expanded further by allowing additional qualifying conditions, authorizing the sale of whole flower, increasing the allowable dispensing limit from a 30-day supply to a 60-day supply, increasing the number of caregivers a certified patient may designate to assist them in obtaining, possessing, cultivating, and administering medical cannabis from two to five, and allowing certified patients or designated caregivers 21 years of age or older living in New York State to cultivate medical cannabis in their home.

Activities described herein cover the period of March 31, 2021, to March 30, 2023. Data included in the report are the most recent available as of December 31, 2022.

Summary of Key Updates

- **Data System.** On January 24, 2022, a major system upgrade was implemented replacing the former Medical Marijuana Data Management System with the Medical Cannabis Data Management System (MCDMS). The implementation of MCDMS streamlined the patient certification process for health care providers and the registration process for patients and their designated caregivers. The Office provides support to practitioners who are certifying patients, as well as to patients and caregivers who are registering with the Medical Cannabis Program.

- **Auto-Registration.** On February 22, 2023, Medical Cannabis Regulations were adopted, and included requirements for the auto-registration of patients at the point of certification. The MCDMS was enhanced to support this regulatory framework and auto-registration was released on March 20, 2023. This change makes it easier for patients to visit a medical cannabis dispensary after being certified by their health care provider.

- **Medical Home Cultivation.** Certified medical patients and designated caregivers who are 21 years of age or older are now allowed to cultivate medical cannabis at home. Part 115 Personal Home Cultivation of Medical Cannabis regulations were adopted on October 5, 2022. The regulations allow certified patients or designated caregivers 21 years of age or older living in New York State to cultivate medical cannabis in their home thereby making medical cannabis more accessible. The regulations include provisions that allow for designated caregivers to cultivate medical cannabis for patients under 21 years of age or for patients who have physical or cognitive impairments that keep them from being able to grow cannabis on their own. Additional information about home cultivation of medical cannabis including a Fact Sheet, A Home Cultivation Guide, and Frequently Asked Questions, is available on the Office's website.

- **Cannabis Research.** The Office filed Part 132 Proposed Cannabis Research Regulations on March 21, 2023, to support the establishment of the cannabis research license and the public comment period will close June 5, 2023. A Request for Information (RFI) was released by the Office on February 21, 2023, to obtain information about cannabis research currently being conducted or seriously contemplated and to provide the Office with a better understanding of the interests, challenges, and resource needs associated with cannabis research.

- **JAMA Publication.** A study was completed by the New York State Department of Health (DOH) to assess changes in opioid dosages among patients receiving medical cannabis. The study, titled "Changes in prescribed opioid dosages among patients receiving medical cannabis for chronic pain, New York State, 2017-2019," showed that receiving medical cannabis for a longer duration was associated with prescription opioid

dosage reduction among patients with chronic pain.[1] Higher opioid dosages were associated with a larger reduction. These findings contribute robust evidence toward potential clinical benefits of medical cannabis in reducing prescription opioid intake, which may decrease patients' risk of opioid overdose. Research of this nature better promotes medical cannabis as another tool that practitioners may be able to use to help their patients reduce their opioid doses.

- **New Product Forms.** The Office has expanded the allowable product forms, including flower products (whole, and pre-rolled) and other concentrates (waxes, shatter, and budder). Additionally, the limitation of 10 mg THC per dose was removed from Part 113 Medical Cannabis Program Regulations, removing limitations for patients who required a higher dose of medical cannabis. Prior to these changes, registered organizations were only permitted to manufacture medical cannabis products in liquid or oil preparations for metered oromucosal or sublingual administration or administration per tube; metered liquid or oil preparations for vaporization; topicals; patches; solid and semisolid preparations (e.g., suppositories, chews, capsules, chewable tablets, lozenges, oral powder); and ground flower and had a limitation of 10 mg THC per dose.

Regulations

The Cannabis Law empowers the Board to issue regulations governing the State's cannabis industry. Regulations proposed or finalized this year have instituted and, or, revised key aspects of the Medical Cannabis Program to increase access to medical cannabis through home cultivation, ensure proficient medical cannabis testing, and conduct cannabis research under licensure approvals.

Collecting input from the public is a foundation of the regulatory process and a cornerstone of the Office's work. Pursuant to the New York State Administrative Procedures Act (SAPA), before proposed regulations can be finalized, there must be an opportunity for the public to submit comments on the proposed regulations. Upon the filing of proposed regulations, the public has a 60-day window to comment on the proposed regulations. If the proposed regulations are reissued for a second public comment period, the public has an additional 45-day window to provide comment. Comments received during these periods are included in an assessment of public comment filed in the New York State Register. The Board revised many of the regulations proposed this year, and these revisions were rooted in the comments received from stakeholders across New York.

Table 1 below contains information regarding regulations critical to the Medical Cannabis Program that have been proposed or are in effect.

[1] Nguyen T, Li Y, Greene D, Stancliff S, Quackenbush N. Changes in Prescribed Opioid Dosages Among Patients Receiving Medical Cannabis for Chronic Pain, New York State, 2017-2019. *JAMA Netw Open.* 2023;6(1):e2254573. doi:10.1001/jamanetworkopen.2022.54573

Table 1: Regulatory Packages Released at the Time of Publication

Regulatory Packages	Effective Date
Part 113, Medical Cannabis	February 22, 2023
Part 115 – Personal Home Cultivation of Medical Cannabis Regulations, **Final**	October 5, 2022
Part 130 – Cannabis Laboratory Regulations, **Final**	March 8, 2023,
Part 130 – Emergency Laboratory Regulations	August 16, 2022 (emergency – effective for 120 days)
Part 130 – Emergency Laboratory Regulations Re-adoption	December 14, 2022 (emergency – effective for 120 days)
Part 132 – Cannabis Research License, Proposed	TBD – Out for Public Comment

Practitioner Registration

The categories of practitioners who can certify patients for the medical use of cannabis has been expanded to include anyone who is licensed, registered, or certified by New York State to prescribe controlled substances to humans. This allowed for the inclusion of dentists, midwives, and podiatrists, who were previously prohibited from certifying patients. Table 2 below depicts the categories of practitioners certifying patients for the use of medical cannabis in New York State as of March 1, 2023. Appendix 5 depicts the number of registered practitioners by county as of December 31, 2022.

Table 2: Number of Registered Practitioners by Profession as of March 1, 2023.

Practitioner Type	Count	Percent
Dentist	16	0.40%
Medicine	2,468	61.24%
Midwife	10	0.25%
Nurse Practitioner	1,331	33.02%
Podiatrist	10	0.25%
Registered Physician Assistant	195	4.84%
Total	**4,030**	**100%**

Patient Registration

Revised medical cannabis regulations were adopted February 22, 2023, which created an auto-registration process to further simplify the registration of medical cannabis patients. Certified patients are no longer required to manually register with the Office via the MCDMS before visiting a medical cannabis dispensary. Rather, patients will be automatically registered at the time of certification and be able to immediately go with their certification and their government photo identification to the medical dispensary without any additional steps. This new auto-registration process eliminates the requirement that patients wait to obtain their plastic registry identification card before accessing a medical dispensary. Removing the requirement of physical registry identification cards not only expedites patient access but also promotes environmentally friendly practices by reducing plastic waste. Removing this requirement also creates an opportunity for cost-savings within the Medical Cannabis Program.

Table 3 below depicts the cumulative number of patient registrations by age. As of December 31, 2022, there were 123,052 patients with active registrations. Prior to January 2022, the number of patient certifications was reported which did not accurately reflect the total number of active participants in the program since Cannabis law requires that the patient is registered in order to purchase medical cannabis products from a dispensary. Appendix 6 depicts the number of registered patients by county as of December 31, 2022.

Table 3: Number of Cumulative Patient Registrations by Age as of December 31, 2022

Age Bracket	Patient Registrations By Age	Percent by Age
0-5	17	0.01%
6-12	119	0.10%
13-17	188	0.15%
18-30	16,398	13.33%
31-40	23,950	19.46%
41-50	23,084	18.76%
51-60	22,624	18.39%
61-70	21,608	17.56%
71+	15,064	12.24%
Total	**123,052**	**100%**

A key step toward increasing patient access to the Medical Cannabis Program was to allow additional qualifying conditions. Practitioners can now utilize their clinical discretion to certify patients for any condition for which they feel their patients may experience relief. Among active patient registrations, the most common primary condition is “Other” (55.18%), followed by “Opioid Alternative For Pain” (13.23%) and “Post-Traumatic Stress Disorder” (PTSD) (11.11%) (see Appendix 3). Of active patient registrations within the “Other” category approximately 93.9% of patients had chronic pain alongside another condition documented by the practitioner on their certification.

Caregiver Registration

The number of caregivers a certified patient may designate to assist them in obtaining, possessing, cultivating, and administering medical cannabis increased from two to five. This increase was critical to provide flexibility for patients who require the support of multiple caregivers. As of December 31, 2022, there are 14,465 caregivers registered with the Medical Cannabis Program.

Registered Organizations

Registered Organizations (ROs) are responsible for manufacturing and dispensing medical cannabis in New York State, and each RO is registered to operate in a particular region. When the MRTA was signed into law on March 31, 2021, it included provisions that increased the number of dispensaries an RO may operate from four to eight, provided the first two additional sites beyond the original four must be in underserved or unserved geographic locations as determined by the Board. Section 68-a of Article 4 of the Cannabis Law also allows for up to three of an RO's eight total dispensaries to provide sales for adult-use cannabis at the same site, pending regulations which will define additional requirements for approval of those co-located dispensaries. Oversight of the existing ROs was transferred from DOH to the Office in October 2021.

The registrations of the ten operating ROs will expire in July 2023; to continue operations, ROs must submit a renewal application by March 31, 2023. Table 4 shows a summary of ROs that are currently operating, and Appendix 1 provides a list of the ten ROs' 40 approved dispensary locations.

In the renewal process ROs will be subject to several new requirements related to energy use and environmental impact in accordance with the new medical cannabis regulations. These changes include, but are not limited to, information regarding the ROs' environmental sustainability plans and proposed actions to address environmental impacts. Sustainability plans include outlining strategies to shift to sustainable packaging such as non-plastic, compostable or recyclable materials and how the organization will collect reusable packaging. The ROs will be required to detail the actions the organization will take to minimize or eliminate adverse environmental impacts from energy and water consumption, carbon emissions, and other types of pollution, including single-use plastics. ROs will be asked to commit to participating in annual energy and water use benchmarking programs and to commit to adhering to updated standards for lighting and dehumidification equipment and updated requirements regarding waste generation and disposal.

In addition to new requirements related to energy and environmental impact, ROs must also show how they are providing services to unserved and/or underserved areas, as defined by the Office. These identified unserved and underserved areas are census tracts that are not adequately served by available health care resources and include an increased presence of medically vulnerable populations. The variables used to identify these areas included drivetime to healthcare, households with disability, low birth weight, lack of health insurance, age over 65, premature deaths, and the ratio of providers to population. The Office identified 600 census tracts that fell into the category of unserved and/or underserved.

Table 4: Summary of Operational Registered Organizations, by Year Registered or Renewed

	Year Registered/ Renewed			
Registered Organizations	**2015**	**2017**	**2019**	**2021**
Columbia Care	X	X	X	X
Etain	X	X	X	X
MedMen	X	X	X	X
PharmaCann	X	X	X	X
Vireo	X	X	X	X
Citiva		X	X	X
Curaleaf		X	X	X
Fiorello		X	X	X
NYCANNA		X	X	X
Valley Agriceuticals		X	X	X

Additional consumer protections were put in place with the release of the Medical Cannabis Dispensary Verification Tool (Figure 1). All registered medical dispensaries will be issued a Medical Dispensary Verification Tool to post in their windows, enabling consumers to verify that they are purchasing product from a state-registered dispensary. With the proliferation of unregulated cannabis retail storefronts, patients can be confident that they are entering a medical cannabis dispensary when they see this decal. The decals were distributed to ROs in the first quarter of 2023.

Figure 1: New York State Medical Cannabis Verification Tool

Product Forms

The Office has reviewed and approved new or reformulation of medical cannabis products. Notable changes included the introduction of whole flower and pre-rolls as new product types. The Office currently disallows the use of excipients or artificial flavoring agents in vaporization products. Registered organizations are still required to provide CBD dominant and CBD-THC balanced products for patients that do not need or want a THC dominant product.

Please refer to Appendix 2 for details about Available Product Forms with Route of Administration, Onset and Duration of Action as of December 31, 2022.

Adding whole cannabis flower as an available product form has provided a more cost effective and natural unprocessed cannabis product and has further expanded the available options for patients. As depicted in Figure 2, cannabis flower products have been dispensed to patients more frequently than any other type of medical cannabis product.

Table 5 and Figure 2 depict the percentage and number of medical cannabis products dispensed by product form between January 1, 2022, and December 31, 2022.

Table 5: Percentage and Number of Medical Cannabis Products Dispensed by Product Form between January 1, 2022 and December 31, 2022.

Product Form	Total Number of Products Dispensed	Percent Dispensed
Flower	992,279	39.18%
Oral	650,734	25.69%
Topical	17,262	0.68%
Vape	872,362	34.45%
Total	**2,532,637**	**100%**

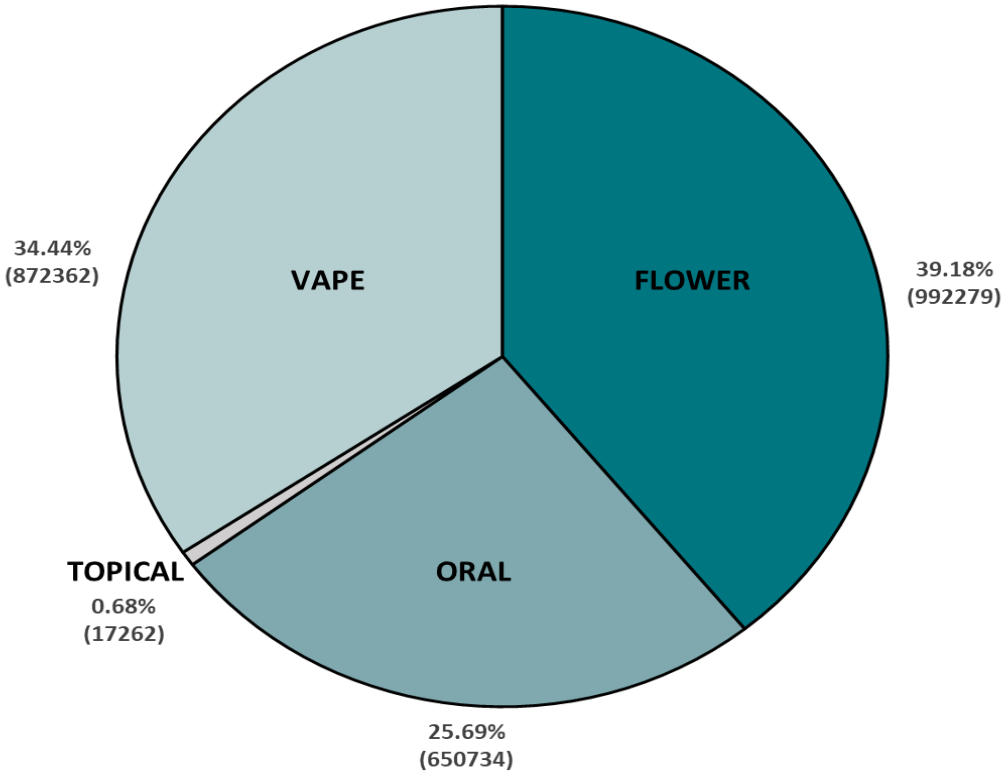


Figure 2: Percentage and Number of Medical Cannabis Products Dispensed by Product Form between January 1, 2022, and December 31, 2022.

Outreach and Education

Practitioner outreach and education is a major component of the Office's work on the Medical Cannabis Program. These efforts will help dismantle the stigma associated with cannabis, empower practitioners with the information needed to understand the therapeutic benefits of cannabis, attract new certifying practitioners to the program and improve the practitioner experience in the program overall. The Office's Health and Safety Unit conducted an anonymous medical practitioner survey to help better understand practitioner beliefs and attitudes toward the Medical Cannabis Program and certifying patients for the use of medical cannabis. Both certifying and non-certifying practitioners have an opportunity to complete the survey. Survey results will be compiled and analyzed to inform decision making with regard to practitioner education and outreach programs created and presented by the Office.

In March 2023, the Health and Safety Unit staff collaborated with the External Affairs Unit to provide a one-hour live stream outreach event about the New York Medical Cannabis Program. The program was intended to provide a broad overview of cannabis pharmacology and the Medical Cannabis program, featuring topics such as cannabinoids, cannabis product forms, home cultivation of medical cannabis, information about the patient certification and registration processes and incident/adverse event reporting. The Office intends to develop additional

programming for the public, taking into consideration the constructive feedback provided during this program, as well as feedback gathered from surveys. Future programs will reflect the public's increasingly sophisticated understanding and use of medical cannabis.

Research

Research is essential to advancing knowledge about medical cannabis and medical cannabis products for patients, practitioners, and other stakeholders. As a Schedule I controlled substance under federal law, cannabis research opportunities are limited and often require burdensome steps to be completed by researchers. Proposed regulations were recently approved by the Board for public comment. The proposed research regulations allow researchers in New York State to produce, process, purchase, and/or possess cannabis for research purposes as outlined in the Cannabis Law. Researchers will be able to perform plant-touching studies without going through the federal pathway, allowing for researchers to obtain cannabis for research purposes through regulated dispensaries, processors, and cultivators. Additionally, these regulations provide a framework for conducting studies with human and animal subjects.

Additionally, the Office has issued a Request for Information (RFI) as a way to assess the current landscape of cannabis research in New York State and identify key research priorities. The RFI provides researchers with an opportunity to provide feedback about their interests, challenges, and anticipated needs in performing cannabis research studies, as well as an overview of studies that are currently being conducted or contemplated. These efforts will help the Office develop policies, programs, and resources to support researchers working with cannabis and assist with fostering multi-disciplinary collaborations around New York State.

Laboratory Testing

Laboratory Oversight

Laboratory testing of medical cannabis products ensures certified patients have access to safer cannabis products that are absent of or below regulatory limits for contaminants of concern such as microorganisms, metals, mycotoxins, and growth regulators. The Cannabis Law mandated the transfer of cannabis laboratory testing oversight functions from DOH to the Office. Before that time, DOH had authority to certify laboratories under Title 10 of New York Codes, Rules, and Regulations, but that authority was limited to testing medical cannabis only. Upon assuming responsibility for cannabis laboratory testing oversight, the Office drafted 9 NYCRR Part 130 Cannabis Laboratories Regulations to address all requirements for permitting cannabis laboratories, as well as testing requirements for both medical and adult-use cannabis. The regulations were released for public comment on June 15, 2022. The public comment period closed on August 15, 2022.

In addition to the regulations that were released for public comment, the Board approved the laboratory regulations as an emergency rule on August 15, 2022. This was necessary to allow the Office to immediately create an application process to permit additional laboratories and

provide regulations for the testing of medical and adult-use cannabis. These emergency regulations were a crucial step toward building testing capacity that accommodates New York State's growing cannabis industry, both protecting the integrity of medical and adult-use cannabis products and protecting the health and safety of patients and consumers. The emergency regulations also include requirements for a state reference laboratory to test cannabis when needed for quality assurance matters, third-party laboratory compliance and to assist with laboratory method development.

The Board proposed revised regulations on December 14, 2022, and the emergency regulations were readopted on December 15, 2022, and would expire with the adoption of the revised regulations. The revised regulations were open for public comment until January 30, 2023. They were approved for adoption by the Board on March 2, 2023 and became effective as of March 22, 2023.

The Office released an application for cannabis laboratories and laboratory sampling firms on August 18, 2022. The application window was scheduled to close on March 31, 2023. The Office has recently announced that it is extending the Cannabis Laboratory application window from 3/31/2023 to June 1, 2023. Applications for Cannabis Sampling Firms will remain open on a rolling basis and available on the Office's website.

The Office created multiple guidance documents, providing information about cannabis testing, cannabis laboratories and cannabis sampling firms, application forms, evidence-based product testing requirements to support ROs, adult-use licensees, interested commercial laboratories and sampling firms. These documents can be found in the Resources section of the report.

Quality Assurance

To promote product quality and safety, quality assurance is one of the Health and Safety Unit's oversight roles of the Office, including providing quality assurance subject matter expertise and establishing and amending regulatory testing limits and standards based on current evidence and best practices. The Office has multiple resources related to quality assurance to support laboratories and sampling firms and has included this information on its website. These efforts include:

- Quality System Standards for cannabis testing to provide consistency across all cannabis testing laboratories, to define requirements, specifications, guidelines, and characteristics for services provided by cannabis testing laboratories, and to ensure compliance with Cannabis Law and 9 NYCRR Part 130; and

- Sampling Guidance to ensure all cannabis sampling firms use consistent sampling procedures and that samples are a statically significant representation of each cannabis product batch or lot when sampling from any licensee pursuant to the Cannabis Law or anyone authorized to cultivate medical cannabis or adult-use cannabis pursuant to the Cannabis Law.

Other quality assurance activities include review of testing results for each lot of final cannabis product produced to ensure product consistency and that contaminate results are within approved limits. See Table 6 for the number of lots tested since the Board voted to transfer laboratory oversight from DOH to the Office on October 5, 2021.

Table 6: Number of Lots Tested, by Medical Cannabis Product Form, 2-Year Period between March 31, 2021 and March 31, 2023

Medical Cannabis Product Form	Number of Lots Tested
Capsule	239
Chewable Gel	383
Lotion	14
Lozenge	31
Ground Plant	278
Vaporization	52
Ointment	31
Powder, Metered	19
Solution	55
Spray, Metered	19
Suppository	0
Tablet	173
Tincture	144
Vape Cartridge (Pre-filled)	607
Vape Oil, Bulk	104
Vape Pen, Disposable	191
Whole Flower	1117
Total	**3,457**

Incident Reporting

The Office monitors adverse events related to medical cannabis products using an Adverse Event Reporting Tool. This tool is a survey administered through the Person-Based Electronic Response Data System (PERDS), accessible through the Department of Health (DOH) Health Commerce System (HCS). PERDS is used to track and report adverse events related to medical cannabis products or devices and to help the program identify potential public health risks. Overall, the reported adverse event rate is less than one percent (<1%).

Because PERDS is housed within HCS, a platform not available to the general public, the Office developed a process that would make incident reporting available for the public to report adverse events related to cannabis products (medical, adult use and cannabinoid hemp (CBD)), as well as to licensees and law enforcement to accommodate reporting of cannabis-product related concerns, and cannabis business concerns. Web-based Incident Reporting was implemented on the Office's website on the opening of the first adult-use retail dispensary in December 2022.

Individuals also have the option to upload photos of the product, which can be helpful in determining whether the product originated from a licensed dispensary or the unregulated market.

The Office monitors for reported incidents every business day and adverse events are evaluated by staff to determine whether further action may be required. Similarities in product reports that may signal unexpected quality concerns with cannabis, cannabis products, CBD or associated administration devices may trigger further investigation.

Recommendations

Article 3 of the Cannabis Law creates a comprehensive regulatory structure to oversee the Medical Cannabis Program in New York State. It encourages social and economic equity, protects public health and safety, and fosters economic development as key priorities. The Office puts forward the following recommendations to support and strengthen the efforts already underway to achieve the purposes and intent of the Medical Cannabis Program.

#1 Expand Patient Access to the Medical Cannabis Program

Article 3 of the Cannabis Law provides a pathway for access to medical cannabis for patients who have any condition that may be helped by medical cannabis while comprehensively regulating the manufacture, sale, and use of medical cannabis to protect public health and safety. We recommend further expanding the Medical Cannabis Program to reach patients who may be self-medicating with cannabis from sources that are not regulated or held to the same high-quality standards as the medical cannabis products manufactured by ROs in New York State.

#2 Promote and Encourage Social and Economic Equity Throughout All Cannabis Markets

Upon release of the SEE report, we recommend the Board move quickly to approve the proposed expansion of the Medical Cannabis Program to expedite access in unserved areas. Establishing new dispensaries in historically unserved or underserved communities will be critical to expanding access for the State's most vulnerable populations.

#3 Education on Medical Cannabis

Limited understanding of the benefits of medical cannabis among health practitioners, coupled with a lack awareness of the Medical Cannabis Program among patients continue to slow the program's growth. We recommend funding dedicated to the development and dissemination of health care provider and public education and outreach about the potential therapeutic benefits of medical cannabis. Now more than ever, the education around potential therapeutic utility of medical cannabis is critical, recognizing the risk of overdose associated with using opioids in patients with chronic pain and emerging evidence that there is an association with medical cannabis use and a reduction in morphine milligram equivalents. For the practitioners, the education would focus on lowering barriers recommending cannabis, including detailing the affirmative science on the therapeutic benefits of cannabis, how cannabis is dosed and dispensed, and the rights and protections afforded to practitioners who recommend cannabis to their patients. Similarly, consumer education would prioritize how cannabis can improve health

outcomes, appropriate dosing, the quality differences between regulated medical cannabis and products from the illicit market, and the new patient registration process.

We also recommend conducting practitioner education and outreach events directed toward various medical societies throughout the State, particularly to dentists, podiatrists, and midwives, three practitioner groups newer to certifying patients in New York. Increasing practitioner awareness about medical cannabis and how to incorporate patient certification into their practice may provide inroads to patients seeking relief. Outreach and education efforts are currently in process and under development by the Office.

#4 Expand Research to Address Gaps in Knowledge and the Evidence Base Related to Medical Cannabis

U.S. based research into medical cannabis has lagged behind other global centers of excellence, including in Israel, Spain, and the Netherlands. As New York builds a comprehensively regulated cannabis market, there is an opportunity to lead the nation in medical cannabis research. We recommend funding for academic researchers to advance our knowledge of the medicinal and therapeutic benefits of cannabis. A major obstacle inhibiting the growth of the cannabis industry is the availability of sound research and science, in large part due to the federal designation of cannabis as a Schedule I controlled substance which has impacted funding for research. Furthermore, the research that has been conducted has primarily focused on identifying the potential harms, misuse, and negative effects of cannabis. Researchers, particularly academic researchers, are limited in the work they can do by the availability of funding to perform scientific studies. However, within the current constraints of federal policy, significant opportunity exists for New York to build a market-leading cannabis research ecosystem anchored in the state's academic, medical, and research institutions.

#5 Facilitate Efforts in Environmental Sustainability and Foster Innovative Strategies

Part 113, the regulations for the Medical Cannabis Program, requires renewing ROs to submit metrics related to packaging with specific requirements intended to reduce the use of single-use plastics. We recommend analyzing data submitted by ROs to shed light on the volume of cannabis packaging going into waste and recycling streams, characteristics of the packaging material supply chain, and the impact of packaging on costs to licensees and consumers, thereby informing efforts to address environmental sustainability in cannabis product packaging.

#6 Recommended Legislative Changes

Article 3 of the Cannabis Law will require changes over time to meet the evolving needs of patients and practitioners in the program. The Office recommends the following legislative changes:

The removal of the requirement that practitioners check the Prescription Monitoring Program (PMP) database. Cannabis is no longer a controlled substance in New York, and the PMP is only utilized for prescribing and dispensing controlled substances. Additionally, practitioners are not prescribing cannabis, they are recommending it. It should be further noted that adult-use

dispensaries are not required to consult the PMP when dispensing adult-use cannabis to consumers.

Eliminate patient registration from Article 3 of the Cannabis Law to mirror similar changes made in Part 113 of the regulations to allow the patient or designated caregiver to receive a certification from a practitioner directly in the form of a unique code identifier rather than having to register with the Office separately also. This process would help to ease and streamline the patient certification process for practitioners, patients, and designated caregivers.

Bolster patient protections to ensure that maintenance and access of records would comply with HIPAA, as well as with all privacy and confidentiality protections afforded to individuals under the law. Patient and designated caregiver information would remain exempt from FOIL. This would add another layer of protection for certified patients' and designated caregivers' health and safety, as well as confidentiality and privacy.

Repeal the Controlled Substances Therapeutic Research Act and the Antonio G. Olivieri Controlled Substances Therapeutic Research Program and direct DOH, the Board, and SED to work expeditiously to transfer any and all records, documents, and papers to the Office and the State Archives. The Controlled Substances Therapeutic Research Act and the Antonio G. Olivieri Controlled Substances Therapeutic Research Program was first enacted in 1980, and although they provided the state with invaluable information, the Act and Program are no longer operational following the enactment of the MRTA. However, the legacy of the Program should continue within the Office and the State Archives so that its research can provide resources into the future.

Provide for the Division of Minority and Women's Business Development in the Department of Economic Development to establish a procedure to grant temporary certification to minority and women-owned business enterprise applicants which attest that the business enterprise is intending to participate in the medical cannabis industries, which would assist certain applicants applying to register as an RO.

Revise the requirement that the Board submit a biennial report to the Governor and Legislature on the Medical Cannabis Program to instead include such information in the Annual Report which is required to be issued annually by January 1st. By requiring an annual update on the Medical Cannabis Program, it will provide a clearer picture to the Governor, Legislature and public of the goings on in the Medical Cannabis Program. For reference, here is a link to the Annual Report: https://cannabis.ny.gov/ocm-annual-report-2022.

Enact patient reciprocity. Over 265 million visitors came to New York state in 2019, many of whom visit from states with Medical Cannabis Programs. If just two percent of state visitors are medical cannabis patients, the non-resident patient population would exceed 5 million people. We recommend authorizing qualified patients from other markets to participate in New York's medical program, to disincentivize those patients from transporting their cannabis into the state or purchasing from the state's unregulated market.

Extend the validity of medical cannabis registrations from one year to two years. Reducing the renewal frequency will help reduce the barriers to patients staying in the program by lowering their administrative burden to remain registered.

Resources

Cannabis 101 Fact Sheet
- Provides a readily accessible resource to better educate stakeholders about the Medical Cannabis Program as well as the basic components of cannabis, different cannabis products and their effects, possible side effects, important considerations before one consumes, and other helpful details.

Therapeutic Use of Medical Cannabis in New York State
- Clinical guidelines authored by physicians and developed by the DOH AIDS Institute with support by the Office. These guidelines provide clinicians with information about the therapeutic use of medical cannabis in outpatient settings in New York State, adding to the knowledge base for practitioners.

Medical Home Grow Fact Sheet
- A fact sheet for certified patients and designated caregivers about growing medical cannabis at home.

Medical Cannabis Home Cultivation Guide
- A guide for certified patients and designated caregivers on the cultivation of medical cannabis at home.

Laboratory Testing Limits
- Office of Cannabis Management required testing limits for each lot of adult-use cannabis and medical cannabis product.

Laboratory Testing Guidance for AUCC and AUCP Licensees
- Laboratory Testing and Sampling Guidance for Adult-Use Conditional Cultivator (AUCC) and Adult-Use Conditional Processor (AUCP) Licensees.

Incident Reporting Tool
- Complete the Incident Reporting Form to report an adverse health event which includes any troublesome or undesired medical occurrence or symptom associated with the use of a cannabis product, a concern about a cannabis business which includes businesses that sell cannabis products including unlicensed business locations, sales to a minor or consumption in unauthorized areas or a concern regarding a cannabis product, such as product safety, product mislabeling, product formulation or product expiration date.

JAMA Article
- Recent study released that assesses changes in opioid dosages among patients receiving Medical Cannabis for longer duration compared with shorter duration.

Research Request for Information (RFI)
- Solicited information from researchers about cannabis research currently being conducted or seriously contemplated in New York State.

Appendices

Appendix 1: Medical Cannabis Registered Organizations and County of Approved Dispensary Locations

Registered Organization	County of Dispensary Location
Citiva Medical LLC	Chemung
	Dutchess
	Kings
	Richmond
Columbia Care NY LLC	Kings
	Monroe
	New York
	Suffolk
Curaleaf NY, LLC	Clinton
	Nassau
	Orange
	Queens
Etain, LLC	New York
	Onondaga
	Ulster
	Westchester
Fiorello Pharmaceuticals, Inc.	Monroe
	Nassau
	New York
	Saratoga
MedMen, Inc.	Erie
	Nassau
	New York
	Onondaga
NYCANNA, LLC	Erie
	Orange
	Queens
	Suffolk
PharmaCann of New York, LLC	Albany
	Bronx
	Erie
	Onondaga
Valley Agriceuticals, LLC	Kings
	Oneida
	Rockland
	Suffolk
Vireo Health of New York LLC	Albany
	Broome
	Queens
	Westchester

Appendix 2: Available Product Forms with Route of Administration, Onset and Duration of Action as of December 31, 2022

Product Form *As of December 31, 2022*	**Route of Administration**	**Onset of Action**	**Duration of Action**
Flower types – whole, ground, pre-rolled	Inhalation	Fastest	Shorter
Cannabis concentrates oil, distillates, and live resin in the form of vaporization cartridges, vape pens, and bulk oil for vaporization.	Inhalation	Fastest	Shorter
Solid/Semi-Solid oral dosage types – Tablets, capsules, soft gel capsules	Oral consumption	Slower	Longer
Chewable Solid/Semi-Solid oral dosage types- Chewable gel, chewable nano emulsion gels and chewable tablets	Oral consumption	Intermediate	Intermediate
Liquid oral dosage types – tinctures, oral spray, and oral solutions.	Oral consumption	Intermediate	Intermediate
Miscellaneous oral dosage types – effervescent tablets, oral powder for ingestion, lozenges, and mints.	Oral consumption	Intermediate	Intermediate
Liquid sublingual dosage types – drops, tinctures and nano emulsion solutions	Sublingual (under the tongue)	Faster	Shorter
Topicals- lotions, creams, topical spray, and balms	Topical/external use	Faster (locally)	Shorter
Suppositories	Rectal/Vaginal	Intermediate	Intermediate

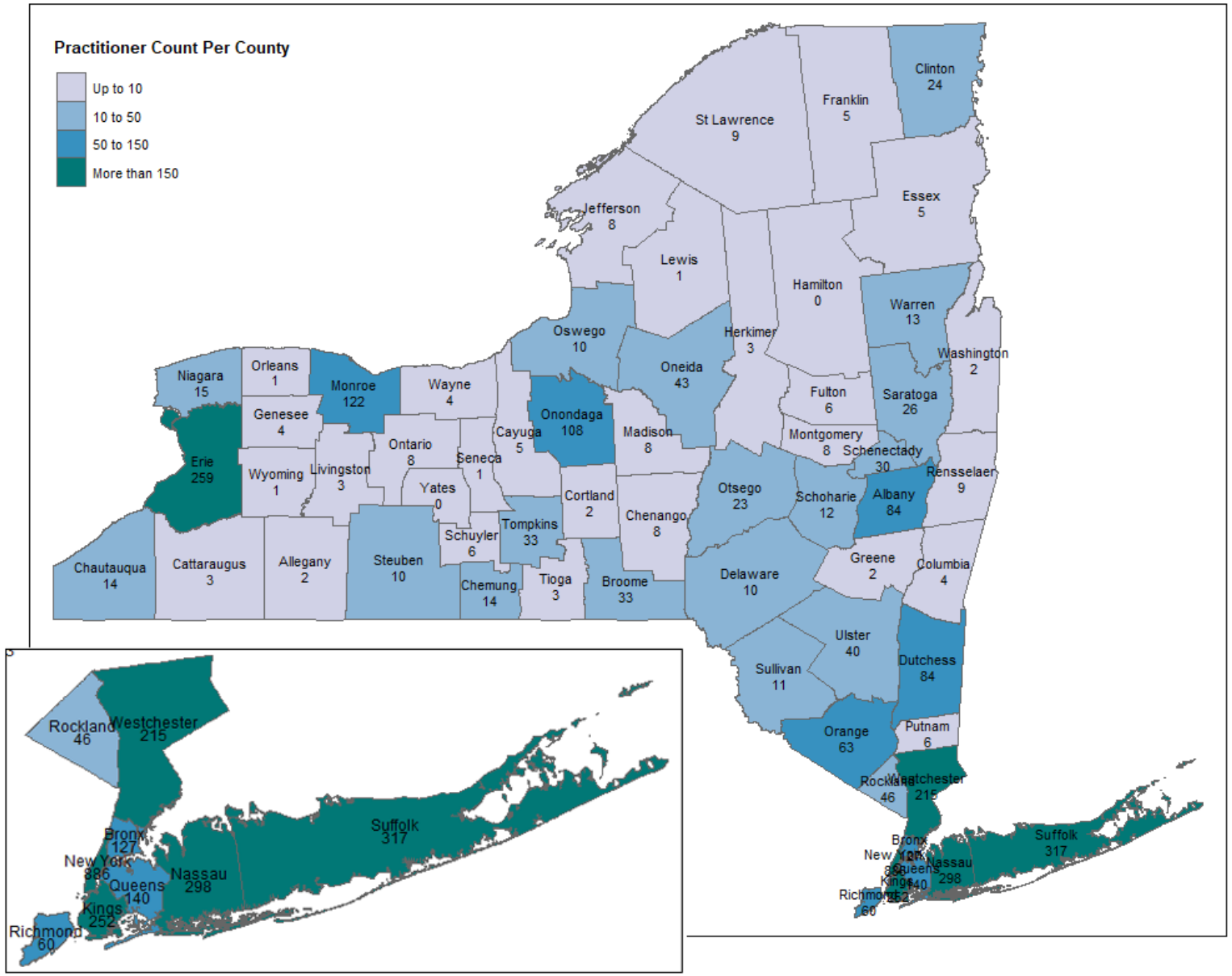
Appendix 3: Patient Registrations by Age and Primary Qualifying Condition as of December 31, 2022

As of December 31,2022	Patient Age in Years										
Medical Condition	**0-5**	**6-12**	**13-17**	**18-30**	**31-40**	**41-50**	**51-60**	**61-70**	**71+**	**Total**	**Percent Of Total**
Alzheimer's	0	0	0	0	0	1	3	4	41	49	0.04%
Amyotrophic lateral sclerosis (ALS)	0	0	0	3	6	8	48	82	41	188	0.15%
Autism	5	36	16	63	15	3	1	1	0	140	0.11%
Cancer	4	26	21	213	599	1170	2361	3554	4212	12160	9.88%
Dystonia	0	0	0	6	44	6	8	10	9	43	0.04%
Epilepsy	4	25	30	267	252	166	83	59	25	911	0.74%
HIV/AIDS	0	0	0	39	97	88	130	102	21	477	0.39%
Huntington's disease	0	0	0	2	3	2	1	8	2	18	0.01%
Inflammatory bowel disease	0	4	9	553	613	512	313	219	105	2328	1.89%
Multiple sclerosis	0	0	0	71	243	318	335	246	89	1302	1.06%
Muscular dystrophy	0	0	0	0	7	5	5	6	4	27	0.02%
Neuropathy	0	7	8	355	673	875	1245	1256	992	5411	4.40%
Opioid alternative for pain that degrades health and functional capability	0	0	8	1931	3114	3126	3321	2897	1880	16277	13.23%
Other	4	19	61	9132	13828	13660	12744	11603	6852	67903	55.18%
Parkinson's disease	0	0	0	3	6	18	58	159	251	495	0.40%
Post-traumatic stress disorder	0	2	35	3581	4160	2823	1646	1057	362	13666	11.11%
Rheumatoid arthritis	0	0	0	35	78	135	170	242	125	785	0.64%
Spinal cord nerve injury with intractable spasticity	0	0	0	29	53	72	112	85	44	395	0.32%
Substance use disorder	0	0	0	115	199	96	40	18	9	477	0.39%
Total	17	119	188	16398	23950	23084	22624	21608	15064	123052	
Percent Of Total	0.01%	0.10%	0.15%	13.33%	19.46%	18.76%	18.39%	17.56%	12.24%		

Appendix 4: Patients Registered as Terminally Ill by Age and Primary Qualifying Condition as of December 31, 2022

As of December 31,2022	**Patient Age in Years**										
Medical Condition	**0-5**	**6-12**	**13-17**	**18-30**	**31-40**	**41-50**	**51-60**	**61-70**	**71+**	**Total**	**Percent Of Total**
Alzheimer's	0	0	0	0	0	0	0	0	3	3	0.04%
Amyotrophic lateral sclerosis (ALS)	0	0	0	3	4	7	38	72	37	161	2.13%
Autism	0	0	0	0	0	0	0	0	0	0	0.00%
Cancer	3	17	10	66	177	400	998	1747	2787	6205	82.10%
Dystonia	0	0	0	0	0	0	0	0	0	0	0.00%
Epilepsy	1	6	7	27	10	5	3	2	4	65	0.86%
HIV/AIDS	0	0	0	1	4	3	7	10	0	25	0.33%
Huntington's disease	0	0	0	0	0	0	1	3	0	4	0.05%
Inflammatory bowel disease	0	0	0	1	2	0	1	1	3	8	0.11%
Multiple sclerosis	0	0	0	2	3	2	6	11	6	30	0.40%
Muscular dystrophy	0	0	0	0	0	0	0	0	0	0	0.00%
Neuropathy	0	2	0	2	5	5	19	31	41	105	1.39%
Opioid alternative for pain that degrades health and functional capability	0	0	0	3	1	3	5	13	31	56	0.74%
Other	1	2	0	26	43	57	94	174	367	764	10.11%
Parkinson's disease	0	0	0	0	0	1	1	14	54	70	0.92%
Post-traumatic stress disorder	0	0	0	4	8	6	6	6	20	50	0.66%
Rheumatoid arthritis	0	0	0	0	0	0	0	0	0	0	0.00%
Spinal cord nerve injury with intractable spasticity	0	0	0	1	3	1	1	4	2	12	0.16%
Substance use disorder	0	0	0	0	0	0	0	0	0	0	0.00%
Total	5	27	17	136	26	490	1180	2088	3355	7558	
Percent Of Total	0.07%	0.36%	0.22%	1.80%	3.44%	6.48%	15.61%	27.63%	44.39%		

Appendix 5: Number of Registered Practitioners by County as of December 31, 2022



Appendix 6: Number of Registered Patients by County as of December 31, 2022