PROGRAM MATERIALS
Program #3016
March 25, 2020

The Empire State of Cannabis: A look into the Future of New York Cannabis Regulation

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March 25, 2020

The Empire State of Cannabis

A Look into the Future of New York State Cannabis Regulation

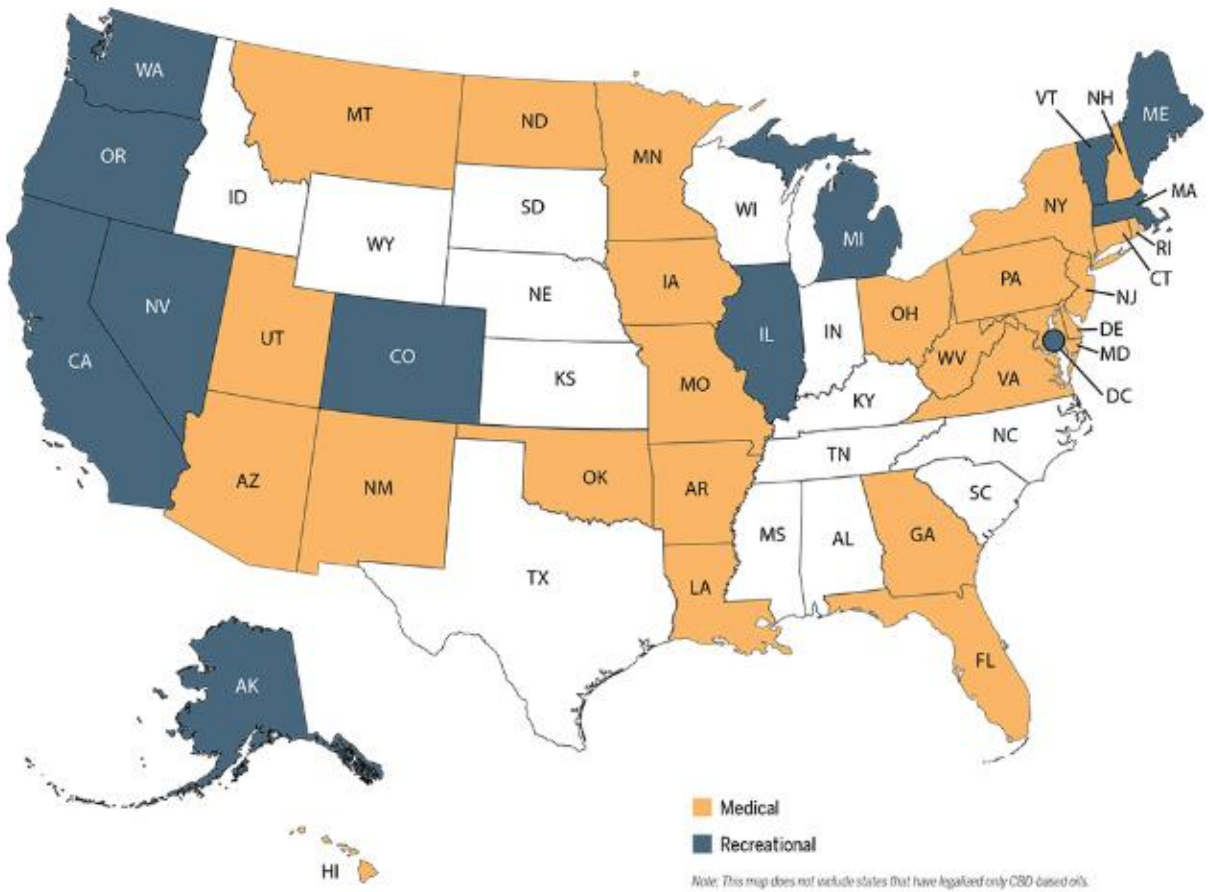
WILSON ELSER

Neil M. Willner, Associate in Wilson Elser's Cannabis Law Practice

OVERVIEW

- New York's Medical Marijuana Program
  - The Compassionate Care Act
- New York's Hemp Program
  - Dep't of Agriculture and Markets Regulations
  - S. 6184 – signed into law by Gov. Cuomo in December 2019
  - CBD in foods/dietary supplements
    - 2018 Farm Bill
    - FDA guidance
- CRTA
- MRTA
- FDA compliance and CBD litigation

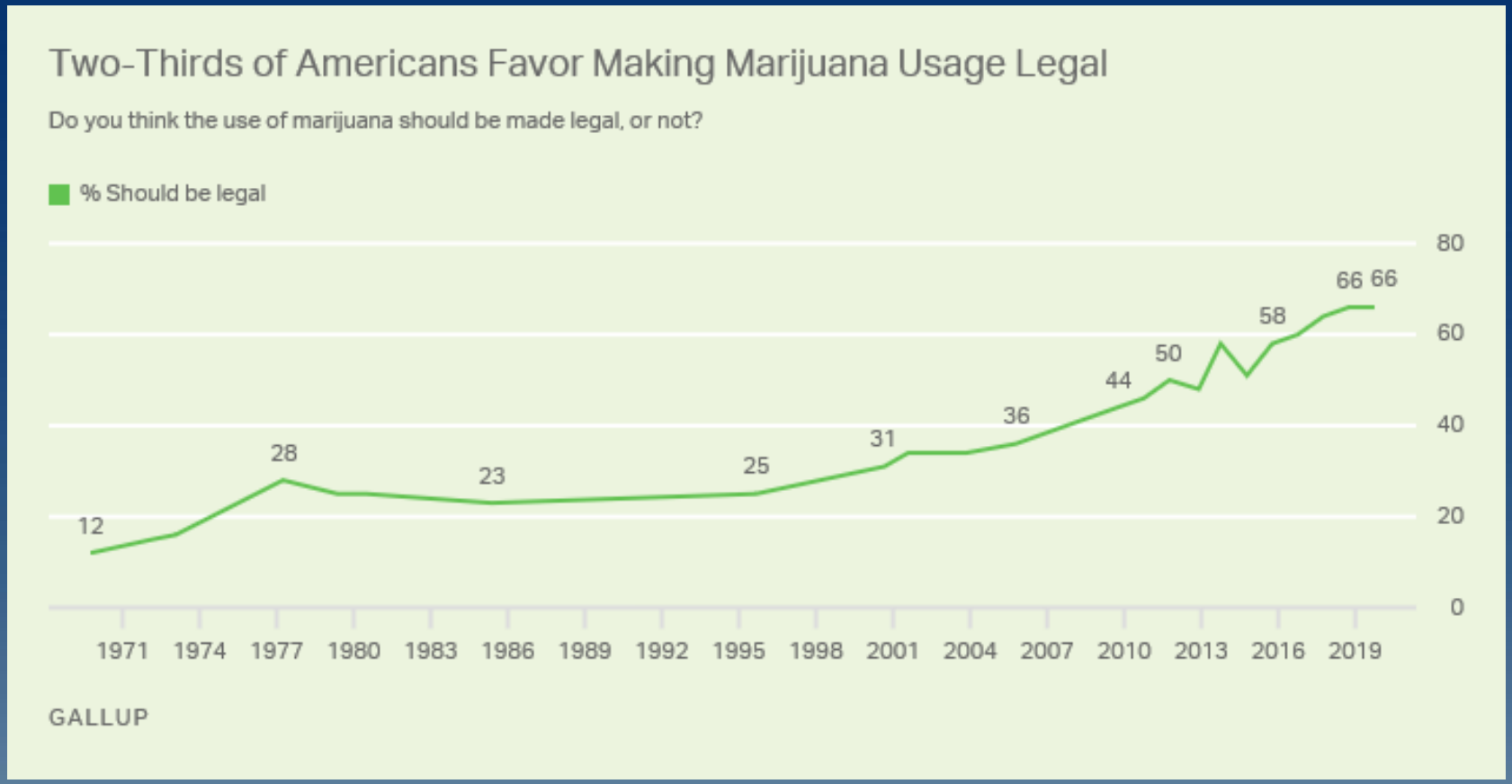
Legalization Across the Country



Data is current as of March 6, 2020.

Social Acceptance

National Support for Marijuana



Support for Making Marijuana Legal, by Political Party and Ideology

	Favor	Oppose
	%	%
Party identification		
Democrat	76	23
Independent	68	30
Republican	51	47
Political ideology		
Liberal	82	17
Moderate	72	27
Conservative	48	50

Combined data from three 2018-2019 polls

GALLUP

NEW YORK POST

Support for legalizing marijuana in New York reaches all-time high

By Bernadette Hogan

January 21, 2020 | 9:52am

Shutterstock

ALBANY — They're stoked to smoke.

New Yorkers are itching for Democratic lawmakers to legalize recreational pot statewide, according to a Siena College poll released Tuesday.

Voters are high on the measure by a 58 to 38 percent margin — the best numbers recorded to date in a Siena survey on the topic.

New York's Medical Marijuana Program
The Compassionate Care Act

- Signed into law in 2014, the Compassionate Care Act legalized medical marijuana in New York for "certified patients" with qualified "serious conditions."
- The bill originally created 5 licenses for "registered organizations."
- "Registered Organizations" are required to be vertically integrated meaning they must grow, cultivate, manufacture, process, transport, and distribute medical marijuana.
- There are currently 10 "registered organizations" in NY, each with 4 dispensary locations across the state.

Program Overview

New York State Medical Marijuana Program

Practitioners

Educate
Practitioner takes approved course.

Register Online
Practitioner registers online using the Health Commerce System.

Certify
Practitioner can now issue certifications to patients with qualifying medical conditions.

Patients

Register Online
Certified patient registers online and can name up to two caregivers. Patients who can't give consent, including children, must have a caregiver.

Receive ID Card
Patient gets Temporary ID Card to use right away. Permanent ID Card arrives in 7-10 business days. Caregivers get ID cards too.

Purchase
Patient and/or caregiver can buy medical marijuana from a Registered Organization's dispensing facility.

Dispensing facilities are found across New York State. All are registered and regulated by the Department of Health, and all products are tested for quality assurance.

Medical marijuana is only available in smoke-free and non-food product forms. This ensures the safest delivery methods for patients.

Product examples:

Capsules | Oral Spray | Oils | Vaporization

For more information health.ny.gov/mmp 1-844-863-9312

NEW YORK STATE Department of Health

#1083 12/18

Qualifying Conditions

Patients are eligible for medical marijuana if they have been diagnosed with:

- Cancer
- HIV infection or AIDS
- ALS
- Parkinson's Disease
- Multiple sclerosis
- Spinal cord injury
- Epilepsy
- Inflammatory bowel disease
- Neuropathy
- Huntington's disease
- PTSD
- Chronic Pain
- Pain that degrades health and functional capability as an alternative to opioid use or substance use disorder

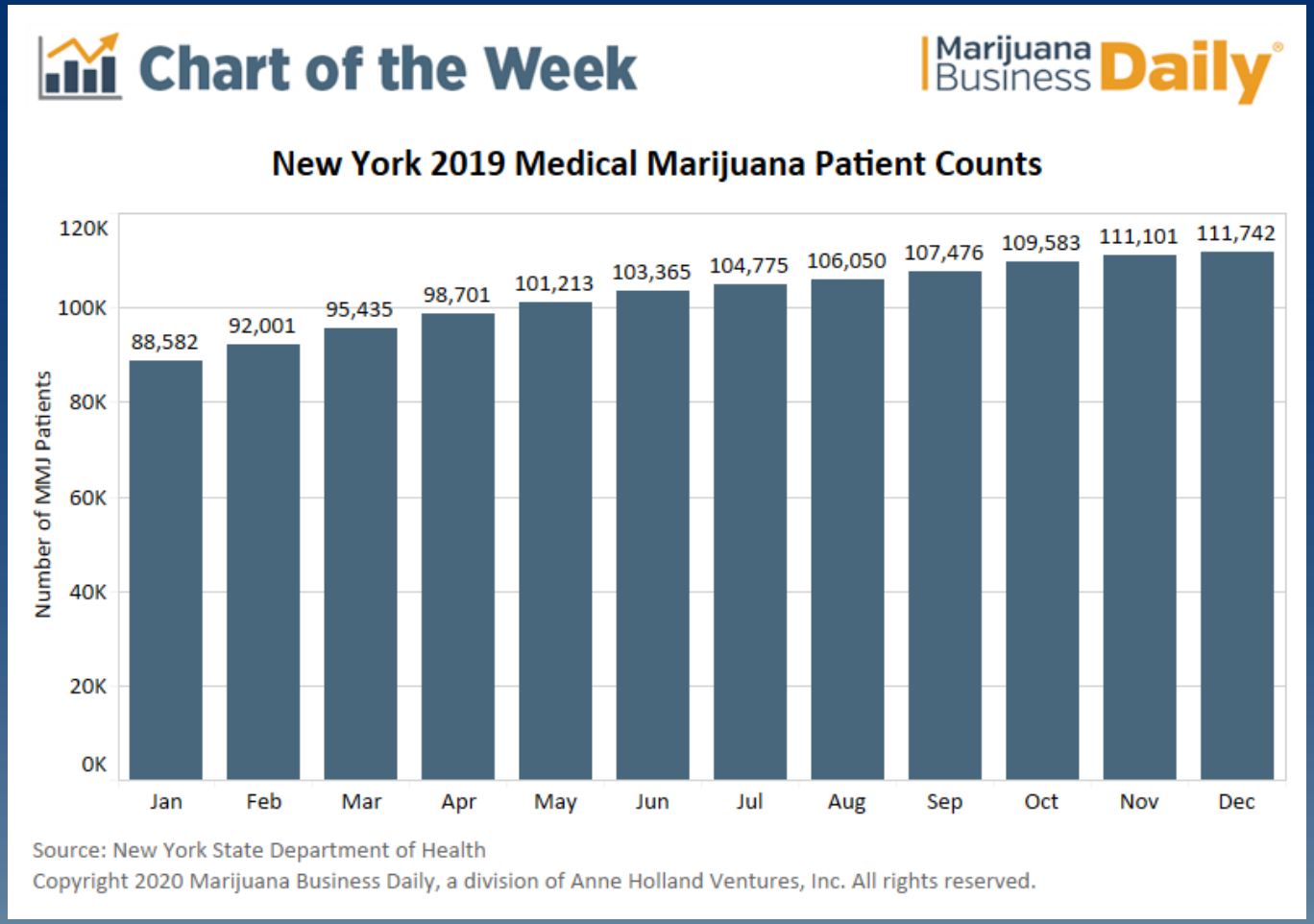
The severe debilitating or life-threatening condition must also be accompanied by one or more of the following associated or complicating conditions: cachexia or wasting syndrome, severe or chronic pain, severe nausea, seizures, or severe or persistent muscle spasms, PTSD or opioid use disorder.

Registered Organizations

- There are currently 10 registered organizations in NY. Each registered organization is permitted to have up to 4 dispensary locations and 1 manufacturing location. RO's include:

Citiva Medical
Columbia Care
Curaleaf NY
Etain
Fiorello Pharmaceuticals
MedMen
Acreage Holdings
PharmaCann
Vireo Health
Cresco Labs

Certified Patients



ROs' NYC Dispensary Locations

ROs' Long Island Dispensary Locations

COVID-19 Response

NEW YORK STATE OF OPPORTUNITY. Department of Health

ANDREW M. CUOMO
Governor

HOWARD A. ZUCKER, M.D., J.D.
Commissioner

SALLY DRESLIN, M.S., R.N.
Executive Deputy Commissioner

Novel Coronavirus (COVID-19) Guidance for Registered Organizations

Several registered organizations have reached out to the Department for guidance regarding Novel Coronavirus (COVID-19). The Department recognizes that registered patients may have severe debilitating or life-threatening conditions and are often immunocompromised and would like to share the following direction:

1. **Registered Organizations are considered essential businesses**
   - In the event non-essential businesses are forced to shut-down due to COVID-19, Registered Organizations in the Medical Marijuana Program will be considered essential and allowed to remain open because they are considered medical providers.
2. **Dispensing Modification requests**
   - The Department has received multiple requests from ROs to dispense medical marijuana products at the door of the dispensing facility to limit potential exposure to RO staff and other patients. ROs may dispense from the doors of the dispensing facilities provided that you maintain compliance with all current laws, rules and regulations including but not limited to dispensing on camera, checking the PMP as required and validating registry ID cards.
3. **Home Delivery**
   - **To help facilitate social distancing, the Department directs that until April 16, 2020, registered organizations who have been approved to deliver medical marijuana products to the homes of registered patients and designated caregivers may expand delivery services statewide without seeking the Department's prior written approval.**

COVID-19 Response

4. **Schedule appointments whenever possible**
   - Provided that your registered organization is equipped to do so, please encourage patients to schedule an appointment before coming into a dispensing facility to avoid overcrowding.

5. **Have a plan in place if staff become ill.**
   - Postpone large meetings and gatherings
   - Encourage staff to stay home if they are feeling sick or have a sick individual in their home
   - If a member of your staff tests positive or may have been exposed to COVID-19, please refer to the following link on the DOH website: https://health.ny.gov/diseases/communicable/coronavirus/docs/guidance_for_employers.pdf
6. **Supply chain issues**
   - Notify the Department as soon as possible of any existing and/or anticipated disruptions to your organization's supply chain and ability to manufacture medical marijuana products.
7. **Sanitation**
   - Increase and continue the use of general sanitation across all registered facilities:
     - All registered facilities should continue to perform routine cleaning and sanitizing of all areas including high contact surfaces such as counters, telephones, computer mice and keyboards, light switches, handrails and doorknobs
     - Regular cleaning and laundering of uniforms and other linens
     - Frequent waste removal
     - Increased handwashing with soap and water for a minimum of 20 seconds
     - When soap and water are not available, use an alcohol-based hand sanitizer that contains at least 70% alcohol
     - Cover coughs and sneezes with tissues or elbow
     - Dispose of soiled tissues immediately
8. **Post cleaning guidance.**
   - Please reference the attached *COVID-19 General Building Cleaning Guidance* and post the information in a conspicuous location on the premises of each manufacturing and dispensing facility.

Registered Organization Regulation

10 NYCRR 1004.11(n)

- (n) No synthetic marihuana additives nor any cannabinoid preparation not produced by a registered organization in an approved manufacturing facility shall be used in the production of any medical marihuana product[.]; provided, however, that a registered organization may use hemp, or extracts derived from hemp, grown and processed under the authority of the New York State Department of Agriculture and Markets in the manufacturing of medical marihuana products.

What is Hemp?

Photo credit: Greenbrier Hemp

2018 Farm Bill

Hemp: The plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis

2018 Farm Bill and USDA Regulation

USDA issued an interim final rule effective October 31, 2019.

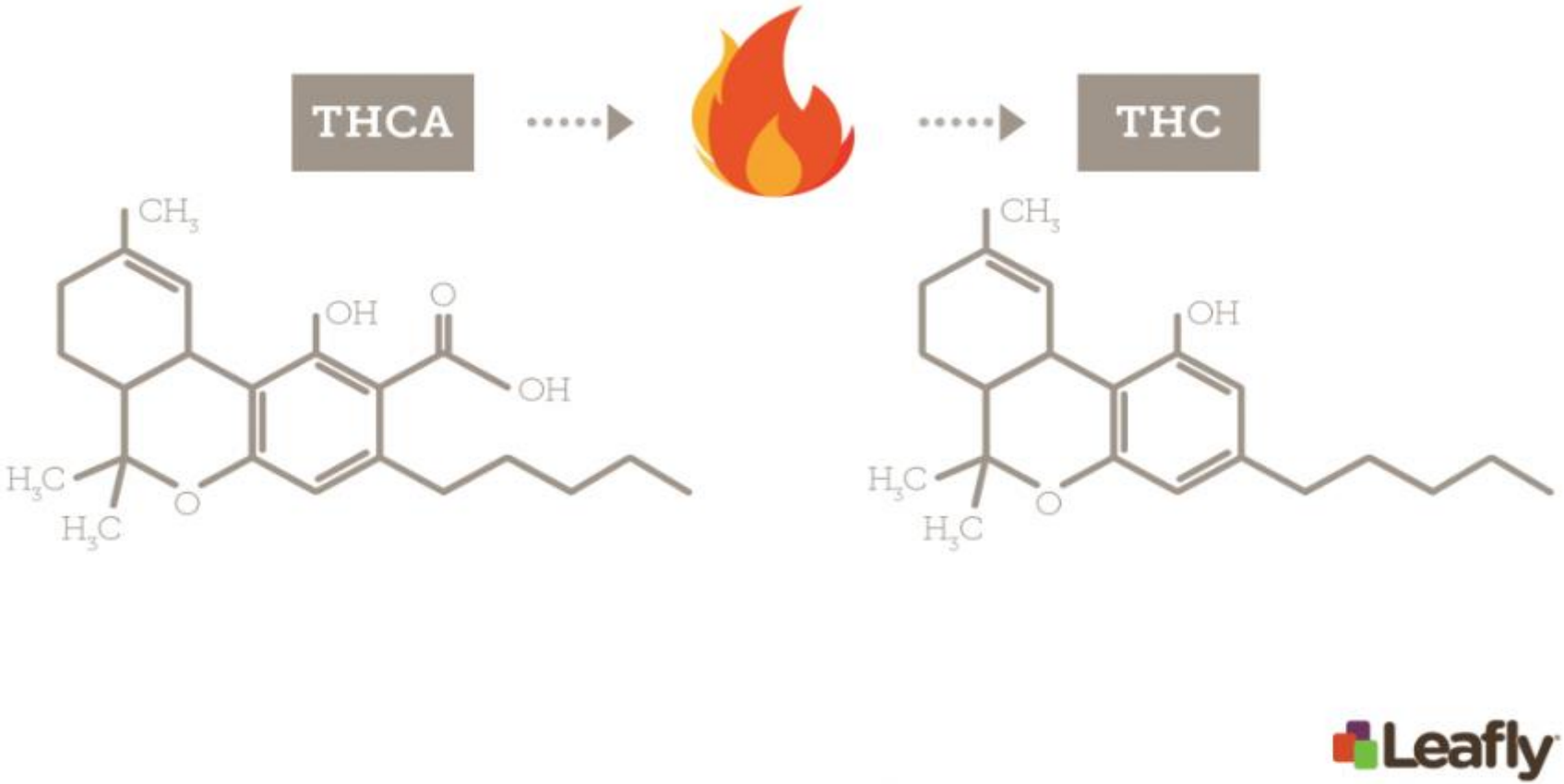
USDA will use the 2020 growing season as a chance to test drive the interim rule to help guide any adjustments that will be made to the final rule.

Provides guidance on basic provisions needed from States/Tribes to obtain plan approval:

Procedures for tracking land where hemp is grown;

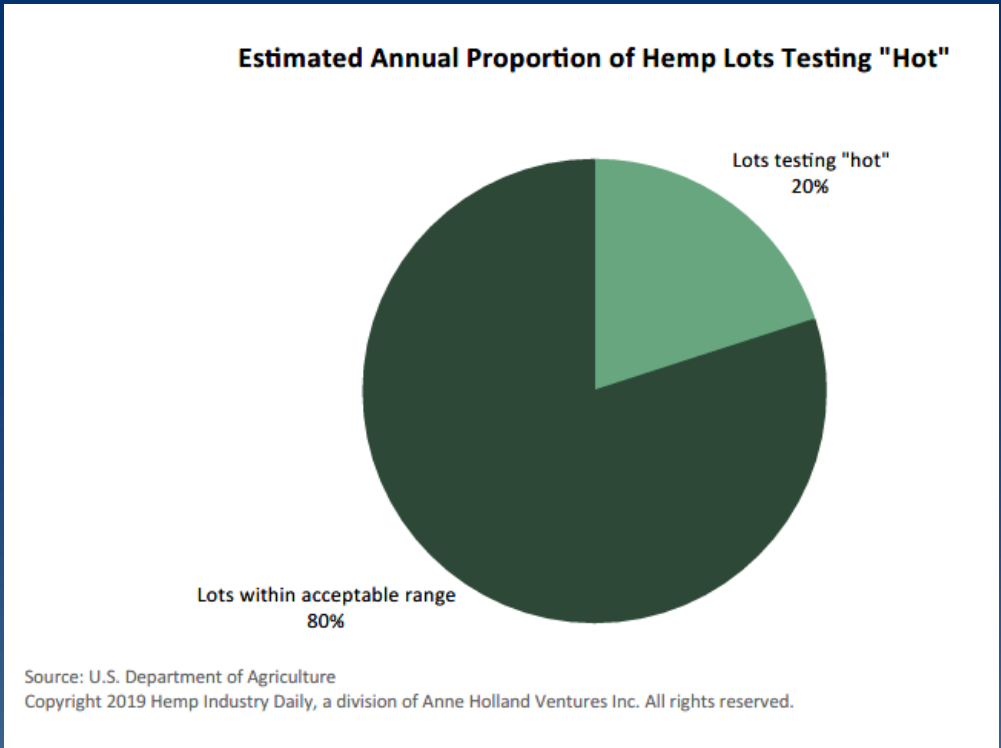
- Procedures for testing, using post-decarboxylation or other similarly reliable methods (i.e. “total THC”);
- Requires testing labs to be “DEA Registered” (not applicable for 2020 growing season);
- Sampling – States/Tribes must ensure that a representative sample of the hemp production is physically collected;
- Sampling must be conducted within 15 days prior to anticipated harvest;
- If a test result is up to 0.5% THC the result is not considered a negligent violation but the crop must be destroyed.

Delta 9 THC vs. Total THC



Leafly

Testing “Hot”



Disposal of non-compliant hemp:

- Plowing under
- Mulching/composting
- Disking
- Bush Mower / Chopper
- Deep Burial
- Burning

USDA is delaying enforcement of the requirement that producers use a DEA-registered reverse distributor or law enforcement to dispose of non-compliant plants (7 C.F.R. § § 990.3(a)(3)(iii)(E) and 990.27

New York's Hemp Program

Under the 2018 Farm Bill, states must submit hemp programs to the USDA for approval. For the 2020 growing season, states can continue to operate under the 2014 Farm Bill but beginning in 2021, all states must submit a hemp plan to the USDA for approval.

New York is operating under the 2014 Farm Bill pilot program for the 2020 growing season.

- Licensed growers
- Licensed processors
- Licensed CBD processors

NY's pilot program will terminate on November 1, 2020.

New York's Hemp Program

- Industrial hemp means the "plant Cannabis sativa L. and any part of such plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis." (NY AGM § 505)

- In 2019, NY's hemp program had 99 processors, 537 growers, and over 25,000 acres of registered hemp production

New York's Hemp Program

Application requirements:

- A description and map of each location where industrial hemp will be cultivated, by physical address and by GPS co-ordinates, visually depicting the buildings, structures, and improvements on the premises and identifying their use, and describing the relevant activities conducted at the location
- A detailed research plan and summary of the issues and matters that the applicant intends to study in conjunction with growing or cultivating of industrial hemp
- A marketing plan
- A seed/propagule acquisition plan
- Statement of relevant experience of the individual responsible for the research project
- A nonrefundable $500 application fee

New York's Hemp Program

- Growers and Processors are governed by a "research partner agreement" that they enter into with the Department of Agriculture and Markets.
- Agreements set forth growth and cultivation standards, processing standards, penalties, reporting requirements, etc.

DEPARTMENT-CONDUCTED RESEARCH PARTNER AGREEMENT

INDUSTRIAL HEMP GROWERS

This Department-Conducted Research Partner Agreement for Industrial Hemp Growers ("Research Agreement"), dated _____between the State of New York, acting by and through the New York State Department of Agriculture and Markets, or another agency, department or authority of New York State subsequently designated by the State (the "Department") and _____(the "Research Partner").

WHEREAS, pursuant to Title 7 U.S.C. § 5940 and New York State Agriculture and Markets Law § 505, et seq., the Commissioner of the New York State Department of Agriculture and Markets has been granted the authority to approve sites for the study of the growth and cultivation, sale, distribution, transportation and processing of hemp and products derived from such hemp as part of an agricultural pilot program conducted by the Department; and

New York's Hemp Program
Regulation of Hemp Extraction

Hemp Extract means all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers derived from hemp, used or intended for human consumption, for its cannabinoid content, with a delta-9 tetrahydrocannabinol concentration of not more than an amount determined by the department in regulation. For the purpose of this article, hemp extract excludes (a) any food, food ingredient or food additive that is generally recognized as safe pursuant to federal law; or (b) any hemp extract that is not used for human consumption. Such excluded substances shall not be regulated pursuant to the provisions of this article but are subject to other provisions of applicable state law, rules and regulations

NY CLS Pub Health § 3398(5) (effective May 1, 2020)

New York's Hemp Program
Regulation of Hemp Extraction

- Cannabinoid related hemp extract licensing (Effective May 1, 2020):
  - **Cannabinoid grower license:**
    - Authorizes the acquisition, possession, cultivation and sale of hemp extract grown or used for its cannabinoid content on the licensed premises of the grower.
  - **Cannabinoid manufacturer license:**
    - Authorizes the licensee's acquisition, possession, and manufacture of hemp extract from a licensed cannabinoid grower or cannabinoid extractor for the processing of hemp extract or the production of hemp extract products marketed or sold for cannabinoid content and used or intended for human or animal consumption.
  - **Cannabinoid extractor license:**
    - Authorizes the licensee's acquisition, possession, extraction and manufacture of hemp extract from a licensed cannabinoid grower for the processing of hemp extract or the production of hemp extract products or the production of hemp extract products marketed, or sold for cannabinoid content and used for human or animal consumption.

New York's Hemp Program
CBD in Food, Beverages and Dietary Supplements

NEW YORK STATE OF OPPORTUNITY. Agriculture and Markets

Enforcement

No food or beverage product may be made or sold in New York State if it contains CBD as a food, a food additive, or an ingredient. Food or beverage products that are found by Department inspectors, in either a processing facility or in the marketplace, to contain CBD are considered adulterated. These products are subject to enforcement actions taken by the Department or the US Food and Drug Administration. Enforcement actions may include:

- Voluntary removal of products
- Seizure and/or destruction of products
- Issuance of a fine and/or a failing sanitary inspection

Q: Why can't CBD be added to food?
A: CBD has not been approved as a food, a food additive or ingredient by the FDA. Under both federal (FD&C Act, sec. 301(b)) and state Agriculture and Markets law (AML sec. 200), the addition of CBD to food is prohibited.

Q: Is it legal to sell foods with CBD added?
A: No. CBD is not an approved food, food additive or ingredient. Currently federal (FD&C Act, sec. 301(b) and State Agriculture and Markets law (AML sec. 200) prohibit the sale of food products containing CBD.

Q: What about beverages? Can CBD be added to beverages and be sold?
A: No. CBD cannot be added to beverages and cannot be sold.

New York's Hemp Program
CBD in Food, Beverages and Dietary Supplements

Packaging and labeling of hemp extracts by NY licensed processors:

- Hemp extracts intended for human consumption will be regulated like dietary supplements.
- Department authorized to promulgate rules governing the packing and labeling of hemp extracts. Regulations must include:
  - Requiring labels warning consumers of any potential impact on human health resulting from the consumption of hemp extract products
  - Requiring labels to have a QR code
  - Establishing methods for determining service sizes, active cannabinoid concentration per service size, number of services per container, and the growing region, state or country of origin if not from the US
  - Requiring a supplemental facts panel

NY CLS Pub Health § 3398 -n (effective May 1, 2020)

New York's Hemp Program
Processing of Cannabinoid Hemp and Hemp Extract

- No processor shall sell or agree to sell or deliver in the state any cannabinoid hemp, hemp extract or product derived therefrom, used for human consumption, except in sealed containers containing quantities in accordance with size standards pursuant to rules adopted by the commissioner. Such containers shall have affixed thereto such labels as may be required by the rules of the department;
- All cannabinoid hemp, hemp extract, and products derived therefrom used for human consumption shall be extracted and processed in according with current good manufacturing processes (cGMP);
- Processors shall ensure that the cannabinoid hemp or hemp extract used in their operation has only been grown with pesticides that are registered by the department of environmental conservation or that specifically meed the US environmental protection agency registration exemption criteria.
- NY CLS Pub Health § 3398-n (effective May 1, 2020)

New York's Hemp Program
Hemp Extract Prohibitions

Effective January 1, 2021, the following prohibitions will apply in NY:

- Except as authorized by the FDA, the processing of cannabinoid hemp or hemp extract used for human consumption is prohibited within the state unless the processor is licensed in NY;

- Cannabinoid hemp and hemp extracts used for human consumption and grown or processed outside the state shall not be distributed or sold at retail within the state, unless they meet all standards established for cannabinoid hemp under state law and regulations;

- The retail sale of cannabinoid hemp is prohibited in this state unless the retailer Is licensed under this article.

NY CLS Pub Health § 3398-s

Proposed Adult-Use Legislation
Cannabis Regulation and Taxation Act

- As part of his FY 2021 proposed budget, Governor Cuomo included legislation to legalize adult-use cannabis called the “Cannabis Regulation and Taxation Act.”
- CRTA includes:
  - Social justice initiatives to help those communities disproportionally affected by the drug war
  - Creates a three-tiered licensing scheme similar to NY’s Alcoholic Beverage Control Law
  - Permit on-site cannabis consumption
  - Create a centralized Office of Cannabis Management to oversee NY’s medical marijuana program, adult-use program, and hemp program

CRTA (continued)

Economic Equity Plan

- The Office of Cannabis Management must create a plan to actively promote racial, ethnic, and gender diversity. The plan must:
  - Prioritize applicants who qualify as a minority, a women-owned business, a social equity application or disadvantaged farmer; and
  - Positively impact areas that have been harmed through disproportionate enforcement of the war on drugs.

CRTA (continued)

- CRTA creates six license categories:
  - Cultivator license
  - Processor license
  - Cooperative license
  - Distributor license
  - Retail dispensary license
  - On-site consumption license

- Like NY's ABCL, CRTA prohibits vertical integration, banning overlapping ownership interest across multiple license categories.
  - E.g., persons or entities holding cultivator licenses are prohibited form holding a retail dispensary license and cannot have nay direct or indirect interest in one

CRTA (continued)

- Cultivators can plant, grow, close, harvest, dry, cure and trim adult-use cannabis. Licensees can also have one processor's license and one distributor's license.
- Processors can blend, extract, infuse, package, label, brand and sell cannabis products to lessened distributors.
- Distributors can distribute and sell cannabis from a licensed processor to a licensed dispensary.
- Retail Dispensaries can sell cannabis on their premises to retail consumers. Retailers can have up to three retail locations.
  - can also have an on-site consumption license.

CRTA (continued)

- Special-use permits:
  - Nursery permit to produce clones, immature plants and seeds;
  - Solicitor's and broker's permit to solicit cannabis orders and broker transactions for commissions;
  - Delivery permit to cannabis dispensary licensees or third parties to deliver cannabis directly to consumers;
  - Caterer's permit to authorize the service of cannabis products at a function or event in a hotel, restaurant, club or ballroom

CRTA (continued)

Miscellaneous provisions

- Counties or cities can opt out of adult-use plan but they must have 100,000 or more residents and adopt a local law or ordinance by a majority vote of the governing body;
- The 10 ROs with medical marijuana licenses will not be automatically grandfathered into the program. The Executive Director will have authority to grant some or all of the ROS the ability to cultivate, process, distribute and sell adult-use cannabis products without abiding by restrictions that prohibit overlapping ownership interests across tiers.

Proposed Adult-Use Legislation
Marijuana Regulation and Taxation Act

The Marijuana Regulation and Taxation Act (MRTA)

- Re-introduced by Assembly Majority Leader Crystal Peoples-Stoke and Senator Liz Krueger in March 12, 2020. The bill currently has 22 co-sponsors in the Senate and 43 co-sponsors in the Assembly;

- Bill focuses on social justice initiatives, establishing a chief equity officer, providing for automatic expungements for those with prior cannabis convictions, and includes low or zero-interest loans for qualifying equity application;

- Includes recreational home grow for up to six plans

MRTA (continued)

- Taxation under MRTA
  - Bill taxes cannabis sales at 18%
  - After covering costs of implementation, revenue from those taxes would go towards three areas:
    - 25% for the sate lottery fund, so long as its designated for the Department of Education;
    - 25% for a drug treatment and public education fund; and
    - 50% for a community grants reinvestment fund.

FDA Compliance and CBD-related Litigation

FDA Warning Letters – Rooted Apothecary (October 10, 2019)

Dietary Supplement Labeling

In addition, information on your website and social media account indicates that you market your "Hemp Capsules, 750 mg" and "Hemp Oil" products as dietary supplements that contain CBD. However, these products cannot be dietary supplements, because they do not meet the definition of a dietary supplement under section 201(ff) of the FD&C Act, 21 U.S.C. 321(ff). FDA has concluded that, based on available evidence, CBD products are excluded from the dietary supplement definition under sections 201(ff)(3)(B)(i) and (ii) of the FD&C Act, 21 U.S.C. 321(ff)(3)(B)(i) and (ii). Under those provisions, if an article (such as CBD) is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act, 21 U.S.C. 355, or has been authorized for investigation as a new drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, then products containing that article are outside the definition of a dietary supplement. There is an exception if the substance was "marketed as" a dietary supplement or as a conventional food before the new drug investigations were authorized; however, based on the evidence available, FDA has concluded that this is not the case for CBD.[3] FDA is not aware of any evidence that would call into question its current conclusion that CBD products are excluded from the dietary supplement definition under sections 201(ff)(3)(B)(i) and (ii) of the FD&C Act, but you may present FDA with any evidence that has bearing on this issue.[4]

FDA Compliance and CBD-related Litigation

FDA Warning Letters – Curaleaf (July 22, 2019)

This letter is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your website at the Internet address https://curaleafhemp.com in April and June 2019 and has determined that you take orders there for the products "CBD Lotion," "CBD Pain-Relief Patch," "CBD Tincture" (5 versions), "CBD Disposable Vape Pen" (5 versions) and "Bido CBD for Pets" (3 versions), all of which you promote as products containing cannabidiol (CBD).[1] We have also reviewed your social media websites at www.facebook.com/CuraleafHemp and https://twitter.com/curaleafhemp; these websites direct consumers to your website, https://curaleafhemp.com, to purchase your products. FDA has determined that your "CBD Lotion," "CBD Pain-Relief Patch," "CBD Tincture," and "CBD Disposable Vape Pen" products are unapproved new drugs sold in violation of sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), 21 U.S.C. 355(a) and 331(d). Furthermore, these products are misbranded drugs under section 502(f)(1) of the FD&C Act, 21 U.S.C. 352(f)(1). FDA has also determined that your "Bido CBD for Pets" products are unapproved new animal drugs that are unsafe under section 512(a) of the FD&C Act, 21 U.S.C. 360b(a), and adulterated under section 501(a)(5) of the FD&C Act, 21 U.S.C. 351(a)(5). As explained further below, introducing or delivering these products for introduction into interstate commerce for such uses violates the FD&C Act. You can find the FD&C Act and FDA regulations through links on FDA's home page at www.fda.gov.

On your webpage titled "CBD Benefits: Top 5 Research-Backed Benefits of CBD"

- "CBD has also been shown to be effective in treating Parkinson's disease."
- "CBD has been linked to the effective treatment of Alzheimer's disease . . .."
- "CBD is being adopted more and more as a natural alternative to pharmaceutical-grade treatments for depression and anxiety."
- "CBD can also be used in conjunction with opioid medications, and a number of studies have demonstrated that CBD can in fact reduce the severity of opioid-related withdrawal and lessen the buildup of tolerance."
- "CBD has been demonstrated to have properties that counteract the growth of spread of cancer."
- "CBD was effective in killing human breast cancer cells."

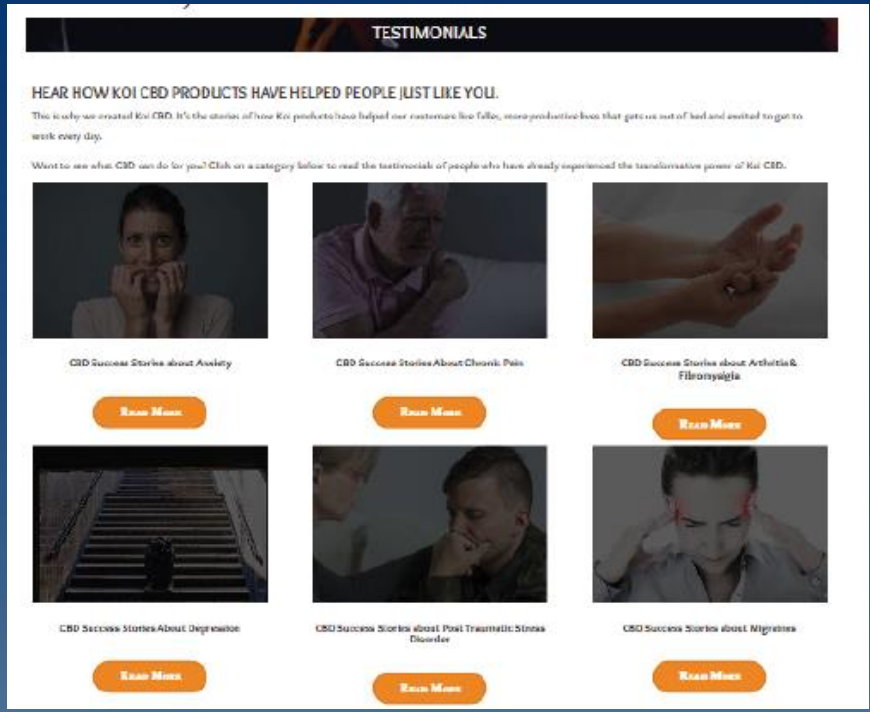
FDA Compliance and CBD-related Litigation

Thurston v. Koi CBD (LA County Sup. Court)

NATURE OF THE CASE

1. This is an action seeking damages, declaratory and injunctive relief to restrain KOI from marketing cannabidiol ("CBD") products (the "Products")[1] as drugs, purportedly able to treat a wide array of diseases and conditions, including cancer and its side effects; depression and post-traumatic stress disorder ("PTSD"); chronic pain; arthritis and other inflammation-related diseases; migraines; heart disease, asthma; liver disease; glaucoma; and epilepsy, all without the required pre-approval of the U.S. Food and Drug Administration ("FDA") as being safe and effective for these marketed purposes.

43. Linking or reposting consumer testimonials is an adoption of the testimonial for a company's own product. *See* 16 C.F.R. § 255.2(a). When a testimonial concerns a person's health, FDA considers such claim to be part of the product's labeling in determining whether it is being advertised to treat any condition or disease.[19]



FDA Compliance and CBD-related Litigation

Gaddis v. Just Brands US, Inc. (S.D. Fla.)

17. Notwithstanding that business philosophy, Defendants' CBD Claims are false and misleading. As independent lab testing reveals, the true quantity of CBD in the CBD Products is only a small fraction of Defendants' representations. Plaintiff's counsel commissioned Anresco Laboratories to perform independent testing of Defendants' products, which show that the Products do not contain the amount of CBD promised in the CBD Claims. Specifically, pursuant

Skibbe v. Curaleaf Holdings, Inc. (E.D.N.Y.)

35. During the Class Period, Defendants, individually and in concert, directly or indirectly, disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

High-quality CBD pet drops and soft-baked bites support a pet's overall health

WAKEFIELD, Mass., May 10, 2019 /PRNewswire/ -- Curaleaf Holdings, Inc. (CSE: CURA) (OTCQX: CURLF) ("Curaleaf"), a leading vertically integrated cannabis operator in the United States, today announced the launch of Bido, hemp-based CBD products for pets. CBD is a non-intoxicating, non-psychoactive compound from the cannabis sativa plant. ***CBD has been shown in initial third-party studies to support a pet's overall wellness including the potential to help manage pain and anxiety***. Bido pet drops come in three varieties, bacon, salmon and unflavored "pure," and Bido soft-baked bites are available in apple chicken, peanut butter bacon, and honey sweet potato. All Bido products can be purchased online at www.curaleafhemp.com.

Links to Articles

1. NY Compassionate Care Act (see document below)
2. NY Medical Marijuana Regulations (see document below)
3. NY decriminalization bill (see document below)
4. NY Registered Organization COVID19 guidance (see document below)
5. NY Medical Marijuana rule amendment (see document below)
6. USDA Interim final hemp rule
7. NY Hemp Legislation (see document below)
8. NY Hemp Program Guidance (see document below)
9. NY Hemp Program FAQ (see document below)
10. NY Hemp Grower sample research partner agreement (see document below)
11. CRTA
12. MRTA
13. 2nd Times a Charm (see article below)
14. Designated Access to Cannabis as Essential during COVID19 Pandemic (see article below)
15. FDA Report Brings Hope for CBD Dietary Supplements (see article below)
16. The Empire State of Cannabis (see article below)
17. NY Medical Marijuana Guidance for opioid use disorder (see document below)

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A06357 Summary:

BILL NO A06357E

SAME AS SAME AS

SPONSOR Gottfried (MS)

COSPNSR Lupardo, Cahill, Clark, Cymbrowitz, Dinowitz, Hevesi, Lavine, Paulin, Peoples-Stokes, Rosenthal, Titone, Arroyo, Bronson, Brook-Krasny, Cook, Crespo, DenDekker, Fahy, Jaffee, Kavanagh, Lifton, Otis, Rivera, Roberts, Skartados, Steck, Weprin, Zebrowski, Sepulveda, Katz, Miller, O'Donnell

MLTSPNSR Abinanti, Aubry, Braunstein, Brennan, Buchwald, Farrell, Galef, Glick, Hikind, Jacobs, Kellner, Magee, Markey, McDonald, Millman, Mosley, Moya, Perry, Pretlow, Robinson, Rodriguez, Scarborough, Schimel, Sweeney, Walter, Weisenberg, Wright

Add Art 33 Title 5-A SS3360 - 3369-e, amd S3371, Pub Health L; add Art 20-B SS490 & 491, amd S171-a, Tax L; add S89-h, St Fin L; amd S853, Gen Bus L; amd S221.00, add Art 179 SS179.00 - 179.15, Pen L; amd SS216.00 & 410.91, CP L

Relates to the medical use of marihuana; legalizes the possession, manufacture, use, delivery, transport or administration of medical marihuana by a designated caregiver for a certified medical use; prescribes procedures for such possession, acquisition, etc. including certification of patients by their practitioner, and that, in the practitioner's professional judgment, the patient would receive therapeutic or palliative benefit from use of medical marihuana.

A06357 Actions:

BILL NO A06357E

03/26/2013 referred to health
04/16/2013 reported referred to codes
04/30/2013 reported referred to ways and means
05/29/2013 reported
05/31/2013 advanced to third reading cal.477
06/03/2013 passed assembly
06/03/2013 delivered to senate
06/03/2013 REFERRED TO HEALTH
06/17/2013 recalled from senate
06/17/2013 RETURNED TO ASSEMBLY
06/17/2013 vote reconsidered - restored to third reading
06/17/2013 amended on third reading 6357a
01/08/2014 referred to health
01/14/2014 reported referred to codes
05/20/2014 reported referred to ways and means
05/21/2014 amend and recommit to ways and means
05/21/2014 print number 6357b
05/27/2014 reported referred to rules
05/27/2014 reported
05/27/2014 rules report cal.41
05/27/2014 ordered to third reading rules cal.41
05/27/2014 passed assembly
05/27/2014 delivered to senate
05/27/2014 REFERRED TO CODES
06/09/2014 recalled from senate
06/09/2014 RETURNED TO ASSEMBLY
06/09/2014 vote reconsidered - restored to third reading
06/09/2014 amended on third reading 6357c
06/16/2014 recommitted to rules
06/16/2014 amend and recommit to rules 6357d
06/19/2014 amend (t) and recommit to rules
06/19/2014 print number 6357e
06/19/2014 reported
06/19/2014 rules report cal.598
06/19/2014 ordered to third reading rules cal.598
06/19/2014 message of necessity - 3 day message
06/19/2014 repassed assembly
06/19/2014 returned to senate
06/19/2014 REFERRED TO RULES
06/20/2014 SUBSTITUTED FOR S7923
06/20/2014 3RD READING CAL.1659
06/20/2014 MESSAGE OF NECESSITY - 3 DAY MESSAGE
06/20/2014 PASSED SENATE
06/20/2014 RETURNED TO ASSEMBLY
06/24/2014 delivered to governor
07/05/2014 signed chap.90

A06357 Memo:

NEW YORK STATE ASSEMBLY
MEMORANDUM IN SUPPORT OF LEGISLATION
submitted in accordance with Assembly Rule III, Sec 1(f)

BILL NUMBER: A6357E

SPONSOR: Gottfried (MS)

TITLE OF BILL: An act to amend the public health law, the tax law, the state finance law, the general business law, the penal law and the criminal procedure law, in relation to medical use of marihuana; and providing for the repeal of such provisions upon expiration thereof

PURPOSE:

This bill would comprehensively regulate the manufacture, sale and use of medical marihuana. It would strike the right balance between potentially relieving the pain and suffering of those in desperate need of a

treatment and protecting the public against risks to its health and safety. The balance would be maintained by granting discretion to physicians to prescribe in accordance with regulatory requirements and medical norms, empowering the Department of Health to oversee the regimen of medical marihuana usage and leaving to the Governor, the final say in seeing that the public's safety and health are protected by authorizing him to discontinue the program, in whole or in part, should risks to the public so warrant.

SUMMARY OF PROVISIONS:

The bill would create a new Title V-A in Article 33 of the Public Health Law entitled "Medical Use of Marihuana," a comprehensive regulatory structure governing every aspect of the medical use of marihuana.

Certification: A patient would have to be certified by a practitioner in order to obtain medical marihuana. A practitioner would be a physician, trained by and registered with the Department of Health (DOH), licensed

by the State and qualified to treat the serious condition for which the patient is seeking treatment. A certification could be issued only to a patient with a serious condition, which is limited to a defined list of conditions. The Commissioner of Health (Commissioner) may add additional conditions or symptoms to the list. The patient would have to be under the practitioner's continuing care for the serious condition.

The bill would establish the form of the certification. In making the certification, the practitioner must consider the appropriate form and dosage of medical marihuana. Any form of medical marihuana not approved by the Commissioner would be prohibited, and smoking would be prohibited. The dosage must be consistent with guidance issued by the Commissioner, and the patient would not be allowed to possess an amount of medical marihuana in excess of a 30 day supply of the dosage. Additionally, the patient would be required to keep the medical marihuana in

the original packaging in which it was dispensed.

Registry Identification Cards: Upon approval of the certification, DOH would issue registration identification cards. Patients or designated caregivers would have to apply to DOH for a card, on an application determined by the Commissioner. If a patient wishes to change or terminate a certified caregiver, the patient would be required to notify the Department, which would notify the caregiver that the caregiver's card is invalid and must be returned to the Department.

The registry identification card would expire one year after the date the certification is signed. The card would contain any recommendation or limitation on form or dosage imposed by the practitioner as well as other information. A patient or caregiver would have to notify the Department of any change in name or address or if the patient ceases to have the serious condition noted on the certification, at which point

the card would have to be returned to the Department. A patient would be required to carry his or her registration card when in possession of the medical marihuana.

The Department would maintain a confidential list of persons issued a registry identification card, and individual identifying information obtained by the Department would be exempt from disclosure under Article Six of the Public Officers Law. The Department would be able to suspend or revoke the card of a patient or caregiver who willfully violates any provision of the new Title.

Registered Organizations: A registered organization would be a for-profit business entity or not-for-profit corporation that would acquire, possess, manufacture, sell, deliver, transport, distribute, or dispense medical marihuana. Registered organizations would be able to dispense medical marihuana to individuals who present a registry identification card and would provide the patient or caregiver with a receipt, which

would also be provided to the Department. A safety insert would also be

provided to the patient or caregiver. The organization would not be able to dispense an amount greater than a thirty day supply to a patient. The medical marihuana would be dispensed in a sealed and properly labeled package. All manufacturing and dispensing of medical marihuana by registered organizations would take place in New York State. The Commissioner is authorized to promulgate regulations restricting the advertising and marketing of medical marihuana.

Registered organizations would register with the Department on a form determined by the Commissioner. Registered organizations would also be under a continuing obligation to report any changes in facts or circumstances reflected in the application either during the application process or once registration has been granted. The Commissioner would grant applications only when the Commissioner is satisfied that the applicant

would be able to conform to a delineated list of requirements. Registrations would be valid for two years at a time and would be renewable. A registration will be suspended or revoked if the organization fails to comply with applicable state laws. The Commissioner would be able to register up to five organizations that each operate four dispensaries, and would be able to allow additional registered organizations and dispensaries.

Registered organizations would be required to file reports with the Department and would have to comply with security and record keeping requirements determined through regulation by the Commissioner.

OTHER PROVISIONS:

*Health insurers would not be required to provide coverage for medical marihuana.

*The Commissioner would have authority to issue any necessary regulations to implement the Title's provisions and would also set a price for medical marihuana.

*Registration identifications and registrations for organizations would be issued 18 months after the effective date of the bill, unless the Commissioner certifies that the Title could not be implemented in accordance with public health and safety interests. The Governor would also be allowed to suspend or terminate any provisions of the Title based on the recommendations of the Commissioner or Superintendent.

*The medical marihuana program would be integrated into the successful existing I-STOP program.

*There would be a new article in the Tax Law, Article 20-B, which would impose an excise tax on every sale of medical marihuana by a registered organization to a certified patient or designated caregiver. The excise tax, which would be charged against and paid by the organization, would equal 7% of the gross receipts attributable to the sale of the medical marihuana to the certified patient or designated caregiver. The

provisions in proposed new Article 20-B also include the procedural rules necessary to administer and enforce the new excise tax.

*The bill would establish the Medical Marihuana Trust Fund - in Section 89-h of the State Finance Law that would consist of the proceeds of the excise tax. The moneys of the medical marihuana trust fund, following appropriation by the Legislature, would be allocated as follows: 22.5% to the counties in New York in which the medical marihuana was manufactured; 22.5% to the counties in New York in which the medical marihuana was dispensed; 5% to the Office of Alcoholism and Substance Abuse Services to be used for additional drug abuse prevention, counseling and treatment services; and 5% to the Division of Criminal Justice Services to be used for a program of discretionary grants to state and local law enforcement agencies that demonstrate a need relating to Title V-A of Article 33 of the Public Health Law.

*The Penal Law would be amended to create a class E felony for a practitioner to issue a certification when the practitioner knows or has reason to know that the patient has no medical need for the certification, or that the certification was requested for a purpose other than to treat a serious condition. It would be a class B misdemeanor for a person to transfer medical marihuana to an individual who the person knows or has reasonable grounds to know is not authorized to possess medical marihuana. It would be a class A misdemeanor for patients or caregivers to retain an amount of marihuana in excess of the amount they are authorized to possess.

EXISTING LAW:

Article 221 of the Penal Law governs the possession and sale of marihuana.

JUSTIFICATION:

Medical marihuana has the potential to alleviate the pain and suffering of New Yorkers afflicted with serious illnesses. Numerous other states

have recognized the therapeutic and palliative benefits of medical mari-

huana. Any system allowing medical marihuana, however, must be strictly regulated to avoid any undue risks or negative consequences to the public health and public safety. This bill would create a comprehensive, regulated framework for providing medical marihuana to individuals who stand to benefit most from its use.
The bill would regulate practitioners, patients and organizations that participate in the medical marihuana system. It would also provide that the program would not begin until the Commissioner and the Superintendent of State Police certify that the system can be administered consistent with public health and safety interests. It would also provide the Commissioner substantial regulatory authority to ensure the system is administered safely.

Notably, this bill prohibits smoking medical marihuana. The negative health consequences of smoking of marihuana are well-established. As the

National Institute for Drug Abuse notes, "The smoke of marijuana, like that of tobacco, consists of a toxic mixture of gases and particulates, many of which are known to be harmful to the lungs." In addition to its direct negative effects on users' health, the widespread smoking of medical marihuana has the potential to undermine New York State's decades-long and successful effort to decrease smoking more broadly. However well-intentioned, any effort that reduces the stigma associated with smoking, and that has the potential to lead to an increase in smoking rates among New Yorkers, especially young New Yorkers, presents an unwarranted public health risk. This legislation would avoid that risk.

LEGISLATIVE HISTORY:

This is a new bill.

BUDGET IMPLICATIONS:

Any State Fiscal Year 2014-2015 expenses associated with this bill would be paid for by existing state resources, and ongoing expenses would be

funded through the excise tax revenues and application fees.

EFFECTIVE DATE:
This bill would take effect immediately, subject to the necessary certifications by the Commissioner and Superintendent. This bill would sunset in 7 years.

A06357 Text:

STATE OF NEW YORK

6357--E

2013-2014 Regular Sessions

IN ASSEMBLY

March 26, 2013

Introduced by M. of A. GOTTFRIED, LUPARDO, CAHILL, CLARK, CYMBROWITZ, DINOWITZ, HEVESI, LAVINE, PAULIN, PEOPLES-STOKES, ROSENTHAL, TITONE, ARROYO, BRONSON, BROOK-KRASNY, COOK, CRESPO, DenDEKKER, FAHY, JAFFEE, KAVANAGH, LIFTON, OTIS, RIVERA, ROBERTS, SKARTADOS, STECK, WEPRIN, ZEBROWSKI, SEPULVEDA, KATZ, MILLER, O'DONNELL -- Multi-Sponsored by --

M. of A. ABINANTI, AUBRY, BRAUNSTEIN, BRENNAN, BUCHWALD, FARRELL, GALEF, GLICK, HIKIND, JACOBS, KELLNER, MAGEE, MARKEY, McDONALD, MILLMAN, MOSLEY, MOYA, PERRY, PRETLOW, ROBINSON, RODRIGUEZ, SCARBOROUGH, SCHIMEL, SWEENEY, WALTER, WEISENBERG, WRIGHT -- (at request of the Governor) -- read once and referred to the Committee on Health -- reported and referred to the Committee on Codes -- reported and referred to the Committee on Ways and Means -- passed by Assembly and delivered to the Senate, recalled from the Senate, vote reconsidered, bill amended, ordered reprinted, retaining its place on the order of third reading -- recommitted to the Committee on Health in accordance with Assembly Rule 3, sec. 2 -- reported and referred to the Committee on Codes -- reported and referred to the Committee on Ways and Means

-- committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee -- reported and referred to the Committee on Rules -- passed by Assembly and delivered to the Senate, recalled from the Senate, vote reconsidered, bill amended, ordered reprinted, retaining its place on the special order of third reading -- recommitted to the Committee on Rules -- Rules Committee discharged, bill amended, ordered reprinted as amended and recommitted to the Committee on Rules -- again reported from said committee with amendments, ordered reprinted as amended and recommitted to said committee

AN ACT to amend the public health law, the tax law, the state finance law, the general business law, the penal law and the criminal procedure law, in relation to medical use of marihuana; and providing for

the repeal of such provisions upon expiration thereof

EXPLANATION--Matter in *italics* (underscored) is new; matter in brackets [-] is old law to be omitted.

LBD01604-31-4

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

Section 1. Article 33 of the public health law is amended by adding a new title 5-A to read as follows:

TITLE V-A

MEDICAL USE OF MARIHUANA

Section 3360. Definitions.
3361. Certification of patients.
3362. Lawful medical use.
3363. Registry identification cards.
3364. Registered organizations.
3365. Registering of registered organizations.
3366. Reports by registered organizations.
3367. Evaluation; research programs; report by department.
3368. Relation to other laws.
3369. Protections for the medical use of marihuana.
3369-a. Regulations.
3369-b. Effective date.
3369-c. Suspend; terminate.
3369-d. Pricing.
3369-e. Severability.

§ 3360. Definitions. As used in this title, the following terms shall have the following meanings, unless the context clearly requires otherwise:

1. "Certified medical use" means the acquisition, possession, use, or, transportation of medical marihuana by a certified patient, or the acquisition, possession, delivery, transportation or administration of medical marihuana by a designated caregiver, for use as part of the treatment of the patient's serious condition, as authorized in a certification under this title including enabling the patient to tolerate treatment for the serious condition. A certified medical use does not include smoking.

2. "Caring for" means treating a patient, in the course of which the practitioner has completed a full assessment of the patient's medical history and current medical condition.

3. "Certified patient" means a patient who is a resident of New York state or receiving care and treatment in New York state as determined by the commissioner in regulation, and is certified under section thirty-three hundred sixty-one of this title.

4. "Certification" means a certification, made under section thirty-three hundred sixty-one of this title.

5. "Designated caregiver" means the individual designated by a certified patient in a registry application. A certified patient may designate up to two designated caregivers.

6. "Public place" means a public place as defined in regulation by the commissioner.

7. (a) "Serious condition" means:

(i) having one of the following severe debilitating or life-threatening conditions: cancer, positive status for human immunodeficiency virus or acquired immune deficiency syndrome, amyotrophic lateral sclerosis, Parkinson's disease, multiple sclerosis, damage to the nervous tissue of the spinal cord with objective neurological indication of intractable spasticity, epilepsy, inflammatory bowel disease, neuropathies, Huntington's disease, or as added by the commissioner; and

(ii) any of the following conditions where it is clinically associated with, or a complication of, a condition under this paragraph or its treatment: cachexia or wasting syndrome; severe or chronic pain; severe nausea; seizures; severe or persistent muscle spasms; or such conditions as are added by the commissioner.

(b) No later than eighteen months from the effective date of this section, the commissioner shall determine whether to add the following serious conditions: Alzheimer's, muscular dystrophy, dystonia, post-traumatic stress disorder and rheumatoid arthritis.

8. "Medical marihuana" means marihuana as defined in subdivision twenty-one of section thirty-three hundred two of this article, intended for a certified medical use, as determined by the commissioner in his or her sole discretion. Any form of medical marihuana not approved by the commissioner is expressly prohibited.

9. "Registered organization" means a registered organization under sections thirty-three hundred sixty-four and thirty-three hundred sixty-five of this title.

10. "Registry application" means an application properly completed and filed with the department by a certified patient under section thirty-three hundred sixty-three of this title.

11. "Registry identification card" means a document that identifies a certified patient or designated caregiver, as provided under section thirty-three hundred sixty-three of this title.

12. "Practitioner" means a practitioner who (i) is a physician licensed by New York state and practicing within the state, (ii) who by training or experience is qualified to treat a serious condition as defined in subdivision seven of this section; and (iii) has completed a two to four hour course as determined by the commissioner in regulation and registered with the department; provided however, a registration shall not be denied without cause. Such course may count toward board certification requirements. The commissioner shall consider the inclusion of nurse practitioners under this title based upon considerations including access and availability. After such consideration the commissioner is authorized to deem nurse practitioners as practitioners under this title.

13. "Terminally ill" means an individual has a medical prognosis that the individual's life expectancy is approximately one year or less if the illness runs its normal course.

14. "Labor peace agreement" means an agreement between an entity and a labor organization that, at a minimum, protects the state's proprietary interests by prohibiting labor organizations and members from engaging in picketing, work stoppages, boycotts, and any other economic interference with the registered organization's business.

15. "Individual dose" means a single measure of raw medical marihuana or non-infused concentrates to be determined and clearly identified by a patient's practitioner for the patient's specific certified condition. For ingestible or sub-lingual medical marihuana products, no individual dose may contain more than ten milligrams of tetrahydrocannabinol.

16. "Form of medical marihuana" means characteristics of the medical marihuana recommended or limited for a particular certified patient, including the method of consumption and any particular strain, variety, and quantity or percentage of marihuana or particular active ingredient.

17. "Applicant" means a for-profit entity or not-for-profit corporation and includes: board members, officers, managers, owners, partners, principal stakeholders and members who submit an application to become a registered organization.

§ 3361. Certification of patients. 1. A patient certification may only be issued if: (a) a practitioner has been registered with the department to issue a certification as determined by the commissioner; (b) the patient has a serious condition, which shall be specified in the patient's health care record; (c) the practitioner by training or experience is qualified to treat the serious condition; (d) the patient is under the practitioner's continuing care for the serious condition; and (e) in the practitioner's professional opinion and review of past treatments, the patient is likely to receive therapeutic or palliative benefit from the primary or adjunctive treatment with medical use of marihuana for the serious condition.

2. The certification shall include (a) the name, date of birth and address of the patient; (b) a statement that the patient has a serious condition and the patient is under the practitioner's care for the serious condition; (c) a statement attesting that all requirements of subdivision one of this section have been satisfied; (d) the date; and (e) the name, address, federal registration number, telephone number, and the handwritten signature of the certifying practitioner. The commissioner may require by regulation that the certification shall be on a form provided by the department. The practitioner may state in the certification that, in the practitioner's professional opinion, the patient would benefit from medical marihuana only until a specified date. The practitioner may state in the certification that, in the practitioner's professional opinion, the patient is terminally ill and that the certification shall not expire until the patient dies.

3. In making a certification, the practitioner shall consider the form of medical marihuana the patient should consume, including the method of consumption and any particular strain, variety, and quantity or percentage of marihuana or particular active ingredient, and appropriate dosage. The practitioner shall state in the certification any recommendation or limitation the practitioner makes, in his or her professional opinion, concerning the appropriate form or forms of medical marihuana and dosage.

4. Every practitioner shall consult the prescription monitoring drug program registry prior to making or issuing a certification, for the purpose of reviewing a patient's controlled substance history. For purposes of this section, a practitioner may authorize a designee to consult the prescription monitoring program registry on his or her behalf, provided that such designation is in accordance with section thirty-three hundred forty-three-a of this article.

5. The practitioner shall give the certification to the certified patient, and place a copy in the patient's health care record.

6. No practitioner shall issue a certification under this section for himself or herself.

7. A registry identification card based on a certification shall expire one year after the date the certification is signed by the practitioner.

8. (a) If the practitioner states in the certification that, in the practitioner's professional opinion, the patient would benefit from medical marihuana only until a specified earlier date, then the registry identification card shall expire on that date;

(b) If the practitioner states in the certification that in the practitioner's professional opinion the patient is terminally ill and that the certification shall not expire until the patient dies, then the registry identification card shall state that the patient is terminally

ill and that the registration card shall not expire until the patient dies;

(c) If the practitioner re-issues the certification to terminate the certification on an earlier date, then the registry identification card shall expire on that date and shall be promptly returned by the certified patient to the department;

(d) If the certification so provides, the registry identification card shall state any recommendation or limitation by the practitioner as to the form or forms of medical marihuana or dosage for the certified patient; and

(e) The commissioner shall make regulations to implement this subdivision.

§ 3362. Lawful medical use. 1. The possession, acquisition, use, delivery, transfer, transportation, or administration of medical marihuana by a certified patient or designated caregiver possessing a valid registry identification card, for certified medical use, shall be lawful under this title; provided that:

(a) the marihuana that may be possessed by a certified patient shall not exceed a thirty day supply of the dosage as determined by the practitioner, consistent with any guidance and regulations issued by the commissioner, provided that during the last seven days of any thirty day period, the certified patient may also possess up to such amount for the next thirty day period;

(b) the marihuana that may be possessed by designated caregivers does not exceed the quantities referred to in paragraph (a) of this subdivision for each certified patient for whom the caregiver possesses a valid registry identification card, up to five certified patients;

(c) the form or forms of medical marihuana that may be possessed by the certified patient or designated caregiver pursuant to a certification shall be in compliance with any recommendation or limitation by the practitioner as to the form or forms of medical marihuana or dosage for the certified patient in the certification; and

(d) the medical marihuana shall be kept in the original package in which it was dispensed under subdivision twelve of section thirty-three hundred sixty-four of this title, except for the portion removed for immediate consumption for certified medical use by the certified patient.

2. Notwithstanding subdivision one of this section:

(a) possession of medical marihuana shall not be lawful under this title if it is smoked, consumed, vaporized, or grown in a public place, regardless of the form of medical marihuana stated in the patient's certification.

(b) a person possessing medical marihuana under this title shall possess his or her registry identification card at all times when in immediate possession of medical marihuana.

§ 3363. Registry identification cards. 1. Upon approval of the certification, the department shall issue registry identification cards for certified patients and designated caregivers. A registry identification card shall expire as provided in section thirty-three hundred sixty-one of this title or as otherwise provided in this section. The department shall begin issuing registry identification cards as soon as practicable after the certifications required by section thirty-three hundred sixty-nine-b are granted. The department may specify a form for a registry application, in which case the department shall provide the form on request, reproductions of the form may be used, and the form shall be available for downloading from the department's website.

2. To obtain, amend or renew a registry identification card, a certified patient or designated caregiver shall file a registry application with the department. The registry application or renewal application shall include:

(a) in the case of a certified patient:

(i) the patient's certification (a new written certification shall be provided with a renewal application);

(ii) the name, address, and date of birth of the patient;

(iii) the date of the certification;

(iv) if the patient has a registry identification card based on a current valid certification, the registry identification number and expiration date of that registry identification card;

(v) the specified date until which the patient would benefit from medical marihuana, if the certification states such a date;

(vi) the name, address, federal registration number, and telephone number of the certifying practitioner;

(vii) any recommendation or limitation by the practitioner as to the form or forms of medical marihuana or dosage for the certified patient; and

(viii) other individual identifying information required by the department;

(b) in the case of a certified patient, if the patient designates a designated caregiver, the name, address, and date of birth of the designated caregiver, and other individual identifying information required by the department;

(c) in the case of a designated caregiver:

(i) the name, address, and date of birth of the designated caregiver;

(ii) if the designated caregiver has a registry identification card, the registry identification number and expiration date of that registry identification card; and

(iii) other individual identifying information required by the department;

(d) a statement that a false statement made in the application is punishable under section 210.45 of the penal law;

(e) the date of the application and the signature of the certified patient or designated caregiver, as the case may be;

(f) a fifty dollar application fee, provided, that the department may waive or reduce the fee in cases of financial hardship; and

(g) any other requirements determined by the commissioner.

3. Where a certified patient is under the age of eighteen:

(a) The application for a registry identification card shall be made by an appropriate person over twenty-one years of age. The application shall state facts demonstrating that the person is appropriate.

(b) The designated caregiver shall be (i) a parent or legal guardian of the certified patient, (ii) a person designated by a parent or legal guardian, or (iii) an appropriate person approved by the department upon a sufficient showing that no parent or legal guardian is appropriate or available.

4. No person may be a designated caregiver if the person is under twenty-one years of age unless a sufficient showing is made to the department that the person should be permitted to serve as a designated caregiver. The requirements for such a showing shall be determined by the commissioner.

5. No person may be a designated caregiver for more than five certified patients at one time.

6. If a certified patient wishes to change or terminate his or her designated caregiver, for whatever reason, the certified patient shall notify the department as soon as practicable. The department shall issue a notification to the designated caregiver that their registration card is invalid and must be promptly returned to the department. The newly designated caregiver must comply with all requirements set forth in this section.

7. If the certification so provides, the registry identification card shall contain any recommendation or limitation by the practitioner as to the form or forms of medical marihuana or dosage for the certified patient.

8. The department shall issue separate registry identification cards for certified patients and designated caregivers as soon as reasonably practicable after receiving a complete application under this section, unless it determines that the application is incomplete or factually inaccurate, in which case it shall promptly notify the applicant.

9. If the application of a certified patient designates an individual as a designated caregiver who is not authorized to be a designated caregiver, that portion of the application shall be denied by the department but that shall not affect the approval of the balance of the application.

10. A registry identification card shall:

(a) contain the name of the certified patient or the designated caregiver as the case may be;

(b) contain the date of issuance and expiration date of the registry identification card;

(c) contain a registry identification number for the certified patient or designated caregiver, as the case may be and a registry identification number;

(d) contain a photograph of the individual to whom the registry identification card is being issued, which shall be obtained by the department in a manner specified by the commissioner in regulations; provided, however, that if the department requires certified patients to submit photographs for this purpose, there shall be a reasonable accommodation of certified patients who are confined to their homes due to their medical conditions and may therefore have difficulty procuring photographs;

(e) be a secure document as determined by the department;

(f) plainly state any recommendation or limitation by the practitioner as to the form or forms of medical marihuana or dosage for the certified patient; and

(g) any other requirements determined by the commissioner.

11. A certified patient or designated caregiver who has been issued a registry identification card shall notify the department of any change in his or her name or address or, with respect to the patient, if he or she ceases to have the serious condition noted on the certification within ten days of such change. The certified patient's or designated caregiver's registry identification card shall be deemed invalid and shall be returned promptly to the department.

12. If a certified patient or designated caregiver loses his or her registry identification card, he or she shall notify the department and submit a twenty-five dollar fee within ten days of losing the card to maintain the registration. The department may establish higher fees for issuing a new registry identification card for second and subsequent replacements for a lost card, provided, that the department may waive or reduce the fee in cases of financial hardship. The department shall

issue a new registry identification card as soon as practicable, which may contain a new registry identification number, to the certified patient or designated caregiver, as the case may be. The certified patient or designated caregiver shall not be able to obtain medical marihuana until the certified patient receives a new card.

13. The department shall maintain a confidential list of the persons to whom it has issued registry identification cards. Individual identifying information obtained by the department under this title shall be confidential and exempt from disclosure under article six of the public officers law. Notwithstanding this subdivision, the department may notify any appropriate law enforcement agency of information relating to any violation or suspected violation of this title.

14. The department shall verify to law enforcement personnel in an appropriate case whether a registry identification card is valid.

15. If a certified patient or designated caregiver willfully violates any provision of this title as determined by the department, his or her registry identification card may be suspended or revoked. This is in addition to any other penalty that may apply.

§ 3364. Registered organizations. 1. A registered organization shall be a for-profit business entity or not-for-profit corporation organized for the purpose of acquiring, possessing, manufacturing, selling, delivering, transporting, distributing or dispensing marihuana for certified medical use.

2. The acquiring, possession, manufacture, sale, delivery, transporting, distributing or dispensing of marihuana by a registered organization under this title in accordance with its registration under section thirty-three hundred sixty-five of this title or a renewal thereof shall be lawful under this title.

3. Each registered organization shall contract with an independent laboratory to test the medical marihuana produced by the registered organization. The commissioner shall approve the laboratory and require that the laboratory report testing results in a manner determined by the commissioner. The commissioner is authorized to issue regulation requiring the laboratory to perform certain tests and services.

4. (a) A registered organization may lawfully, in good faith, sell, deliver, distribute or dispense medical marihuana to a certified patient or designated caregiver upon presentation to the registered organization of a valid registry identification card for that certified patient or designated caregiver. When presented with the registry identification card, the registered organization shall provide to the certified patient or designated caregiver a receipt, which shall state: the name, address, and registry identification number of the registered organization; the name and registry identification number of the certified patient and the designated caregiver (if any); the date the marihuana was sold; any recommendation or limitation by the practitioner as to the form or forms of medical marihuana or dosage for the certified patient; and the form and the quantity of medical marihuana sold. The registered organization shall retain a copy of the registry identification card and the receipt for six years.

(b) The proprietor of a registered organization shall file or cause to be filed any receipt and certification information with the department by electronic means on a real time basis as the commissioner shall require by regulation. When filing receipt and certification information electronically pursuant to this paragraph, the proprietor of the registered organization shall dispose of any electronically recorded

prescription information in such manner as the commissioner shall by regulation require.

5. (a) No registered organization may sell, deliver, distribute or dispense to any certified patient or designated caregiver a quantity of medical marihuana larger than that individual would be allowed to possess under this title.

(b) When dispensing medical marihuana to a certified patient or designated caregiver, the registered organization (i) shall not dispense an amount greater than a thirty day supply to a certified patient until the certified patient has exhausted all but a seven day supply provided pursuant to a previously issued certification, and (ii) shall verify the information in subparagraph (i) of this paragraph by consulting the prescription monitoring program registry under section thirty-three hundred forty-three-a of this article.

(c) Medical marihuana dispensed to a certified patient or designated caregiver by a registered organization shall conform to any recommendation or limitation by the practitioner as to the form or forms of medical marihuana or dosage for the certified patient.

6. When a registered organization sells, delivers, distributes or dispenses medical marihuana to a certified patient or designated caregiver, it shall provide to that individual a safety insert, which will be developed and approved by the commissioner and include, but not be limited to, information on:

(a) methods for administering medical marihuana in individual doses,

(b) any potential dangers stemming from the use of medical marihuana,

(c) how to recognize what may be problematic usage of medical marihuana and obtain appropriate services or treatment for problematic usage, and

(d) other information as determined by the commissioner.

7. Registered organizations shall not be managed by or employ anyone who has been convicted of any felony of sale or possession of drugs, narcotics, or controlled substances provided that this subdivision only applies to (a) managers or employees who come into contact with or handle medical marihuana, and (b) a conviction less than ten years (not counting time spent in incarceration) prior to being employed, for which the person has not received a certificate of relief from disabilities or a certificate of good conduct under article twenty-three of the correction law.

8. Manufacturing of medical marihuana by a registered organization shall only be done in an indoor, enclosed, secure facility located in New York state, which may include a greenhouse. The commissioner shall promulgate regulations establishing requirements for such facilities.

9. Dispensing of medical marihuana by a registered organization shall only be done in an indoor, enclosed, secure facility located in New York state, which may include a greenhouse. The commissioner shall promulgate regulations establishing requirements for such facilities.

10. A registered organization shall determine the quality, safety, and clinical strength of medical marihuana manufactured or dispensed by the registered organization, and shall provide documentation of that quality, safety and clinical strength to the department and to any person or entity to which the medical marihuana is sold or dispensed.

11. A registered organization shall be deemed to be a "health care provider" for the purposes of title two-D of article two of this chapter.

12. Medical marihuana shall be dispensed to a certified patient or designated caregiver in a sealed and properly labeled package. The

labeling shall contain: (a) the information required to be included in the receipt provided to the certified patient or designated caregiver by the registered organization; (b) the packaging date; (c) any applicable date by which the medical marihuana should be used; (d) a warning stating, "This product is for medicinal use only. Women should not consume during pregnancy or while breastfeeding except on the advice of the certifying health care practitioner, and in the case of breastfeeding mothers, including the infant's pediatrician. This product might impair the ability to drive. Keep out of reach of children."; (e) the amount of individual doses contained within; and (f) a warning that the medical marihuana must be kept in the original container in which it was dispensed.

13. The commissioner is authorized to make rules and regulations restricting the advertising and marketing of medical marihuana, which shall be consistent with the federal regulations governing prescription drug advertising and marketing.

§ 3365. Registering of registered organizations. 1. Application for initial registration. (a) An applicant for registration as a registered organization under section thirty-three hundred sixty-four of this title shall include such information prepared in such manner and detail as the commissioner may require, including but not limited to:

(i) a description of the activities in which it intends to engage as a registered organization;

(ii) that the applicant:

(A) is of good moral character;

(B) possesses or has the right to use sufficient land, buildings, and other premises (which shall be specified in the application) and equipment to properly carry on the activity described in the application, or in the alternative posts a bond of not less than two million dollars;

(C) is able to maintain effective security and control to prevent diversion, abuse, and other illegal conduct relating to the marihuana;

(D) is able to comply with all applicable state laws and regulations relating to the activities in which it intends to engage under the registration;

(iii) that the applicant has entered into a labor peace agreement with a bona-fide labor organization that is actively engaged in representing or attempting to represent the applicant's employees. The maintenance of such a labor peace agreement shall be an ongoing material condition of certification.

(iv) the applicant's status under subdivision one of section thirty-three hundred sixty-four of this title; and

(v) the application shall include the name, residence address and title of each of the officers and directors and the name and residence address of any person or entity that is a member of the applicant. Each such person, if an individual, or lawful representative if a legal entity, shall submit an affidavit with the application setting forth:

(A) any position of management or ownership during the preceding ten years of a ten per centum or greater interest in any other business, located in or outside this state, manufacturing or distributing drugs;

(B) whether such person or any such business has been convicted of a felony or had a registration or license suspended or revoked in any administrative or judicial proceeding; and

(C) such other information as the commissioner may reasonably require.

2. Duty to report. The applicant shall be under a continuing duty to report to the department any change in facts or circumstances reflected

in the application or any newly discovered or occurring fact or circumstance which is required to be included in the application.

3. Granting of registration. (a) The commissioner shall grant a registration or amendment to a registration under this section if he or she is satisfied that:

(i) the applicant will be able to maintain effective control against diversion of marihuana;

(ii) the applicant will be able to comply with all applicable state laws;

(iii) the applicant and its officers are ready, willing and able to properly carry on the manufacturing or distributing activity for which a registration is sought;

(iv) the applicant possesses or has the right to use sufficient land, buildings and equipment to properly carry on the activity described in the application;

(v) it is in the public interest that such registration be granted; the commissioner may consider whether the number of registered organizations in an area will be adequate or excessive to reasonably serve the area;

(vi) the applicant and its managing officers are of good moral character;

(vii) the applicant has entered into a labor peace agreement with a bona-fide labor organization that is actively engaged in representing or attempting to represent the applicant's employees; and

(viii) the applicant satisfies any other conditions as determined by the commissioner.

(b) If the commissioner is not satisfied that the applicant should be issued a registration, he or she shall notify the applicant in writing of those factors upon which further evidence is required. Within thirty days of the receipt of such notification, the applicant may submit additional material to the commissioner or demand a hearing, or both.

(c) The fee for a registration under this section shall be a reasonable amount determined by the department in regulations; provided, however, if the registration is issued for a period greater than two years the fee shall be increased, pro rata, for each additional month of validity.

(d) Registrations issued under this section shall be effective only for the registered organization and shall specify:

(i) the name and address of the registered organization;

(ii) which activities of a registered organization are permitted by the registration;

(iii) the land, buildings and facilities that may be used for the permitted activities of the registered organization; and

(iv) such other information as the commissioner shall reasonably provide to assure compliance with this title.

(e) Upon application of a registered organization, a registration may be amended to allow the registered organization to relocate within the state or to add or delete permitted registered organization activities or facilities. The fee for such amendment shall be two hundred fifty dollars.

4. A registration issued under this section shall be valid for two years from the date of issue, except that in order to facilitate the renewals of such registrations, the commissioner may upon the initial application for a registration, issue some registrations which may remain valid for a period of time greater than two years but not exceeding an additional eleven months.

5. Applications for renewal of registrations. (a) An application for the renewal of any registration issued under this section shall be filed with the department not more than six months nor less than four months prior to the expiration thereof. A late-filed application for the renewal of a registration may, in the discretion of the commissioner, be treated as an application for an initial license.

(b) The application for renewal shall include such information prepared in the manner and detail as the commissioner may require, including but not limited to:

(i) any material change in the circumstances or factors listed in subdivision one of this section; and

(ii) every known charge or investigation, pending or concluded during the period of the registration, by any governmental or administrative agency with respect to:

(A) each incident or alleged incident involving the theft, loss, or possible diversion of marihuana manufactured or distributed by the applicant; and

(B) compliance by the applicant with the laws of the state with respect to any substance listed in section thirty-three hundred six of this article.

(c) An applicant for renewal shall be under a continuing duty to report to the department any change in facts or circumstances reflected in the application or any newly discovered or occurring fact or circumstance which is required to be included in the application.

(d) If the commissioner is not satisfied that the applicant is entitled to a renewal of the registration, he or she shall within a reasonably practicable time as determined by the commissioner, serve upon the applicant or his or her attorney of record in person or by registered or certified mail an order directing the applicant to show cause why his or her application for renewal should not be denied. The order shall specify in detail the respects in which the applicant has not satisfied the commissioner that the registration should be renewed.

(e) Within a reasonably practicable time as determined by the commissioner of such order, the applicant may submit additional material to the commissioner or demand a hearing or both. If a hearing is demanded the commissioner shall fix a date as soon as reasonably practicable.

6. Granting of renewal of registrations. (a) The commissioner shall renew a registration unless he or she determines and finds that:

(i) the applicant is unlikely to maintain or be able to maintain effective control against diversion; or

(ii) the applicant is unlikely to comply with all state laws applicable to the activities in which it may engage under the registration; or

(iii) it is not in the public interest to renew the registration because the number of registered organizations in an area is excessive to reasonably serve the area; or

(iv) the applicant has either violated or terminated its labor peace agreement.

(b) For purposes of this section, proof that a registered organization, during the period of its registration, has failed to maintain effective control against diversion, violates any provision of this article, or has knowingly or negligently failed to comply with applicable state laws relating to the activities in which it engages under the registration, shall constitute grounds for suspension or termination of the registered organization's registration as determined by the commissioner. The registered organization shall also be under a continuing duty to report to the department any material change or fact or circum-

stance to the information provided in the registered organization's application.

7. The department may suspend or terminate the registration of a registered organization, on grounds and using procedures under this article relating to a license, to the extent consistent with this title. The department shall suspend or terminate the registration in the event that a registered organization violates or terminates the applicable labor peace agreement. Conduct in compliance with this title which may violate conflicting federal law, shall not be grounds to suspend or terminate a registration.

8. The department shall begin issuing registrations for registered organizations as soon as practicable after the certifications required by section thirty-three hundred sixty-nine-b of this title are given.

9. The commissioner shall register no more than five registered organizations that manufacture medical marihuana with no more than four dispensing sites wholly owned and operated by such registered organization. The commissioner shall ensure that such registered organizations and dispensing sites are geographically distributed across the state. The commission may register additional registered organizations.

§ 3366. Reports by registered organizations. 1. The commissioner shall, by regulation, require each registered organization to file reports by the registered organization during a particular period. The commissioner shall determine the information to be reported and the forms, time, and manner of the reporting.

2. The commissioner shall, by regulation, require each registered organization to adopt and maintain security, tracking, record keeping, record retention and surveillance systems, relating to all medical marihuana at every stage of acquiring, possession, manufacture, sale, delivery, transporting, distributing, or dispensing by the registered organization, subject to regulations of the commissioner.

§ 3367. Evaluation; research programs; report by department. 1. The commissioner may provide for the analysis and evaluation of the operation of this title. The commissioner may enter into agreements with one or more persons, not-for-profit corporations or other organizations, for the performance of an evaluation of the implementation and effectiveness of this title.

2. The department may develop, seek any necessary federal approval for, and carry out research programs relating to medical use of marihuana. Participation in any such research program shall be voluntary on the part of practitioners, patients, and designated caregivers.

3. 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 marihuana under this title and make appropriate recommendations.

§ 3368. Relation to other laws. 1. (a) The provisions of this article shall apply to this title, except that where a provision of this title conflicts with another provision of this article, this title shall apply.

(b) Medical marihuana shall not be deemed to be a "drug" for purposes of article one hundred thirty-seven of the education law.

2. Nothing in this title shall be construed to require an insurer or health plan under this chapter or the insurance law to provide coverage for medical marihuana. Nothing in this title shall be construed to require coverage for medical marihuana under article twenty-five of this chapter or article five of the social services law.

§ 3369. Protections for the medical use of marihuana. 1. Certified patients, designated caregivers, practitioners, registered organizations and the employees of registered organizations shall not be subject to arrest, prosecution, or penalty in any manner, or denied any right or privilege, including but not limited to civil penalty or disciplinary action by a business or occupational or professional licensing board or bureau, solely for the certified medical use or manufacture of marihuana, or for any other action or conduct in accordance with this title.

2. Non-discrimination. Being a certified patient shall be deemed to be having a "disability" under article fifteen of the executive law (human rights law), section forty-c of the civil rights law, sections 240.00, 485.00, and 485.05 of the penal law, and section 200.50 of the criminal procedure law. This subdivision shall not bar the enforcement of a policy prohibiting an employee from performing his or her employment duties while impaired by a controlled substance. This subdivision shall not require any person or entity to do any act that would put the person or entity in violation of federal law or cause it to lose a federal contract or funding.

3. The fact that a person is a certified patient and/or acting in accordance with this title, shall not be a consideration in a proceeding pursuant to applicable sections of the domestic relations law, the social services law and the family court act.

4. Certification applications, certification forms, any certified patient information contained within a database, and copies of registry identification cards shall be deemed exempt from public disclosure under sections eighty-seven and eighty-nine of the public officers law.

§ 3369-a. Regulations. The commissioner shall make regulations to implement this title.

§ 3369-b. Effective date. Registry identification cards or registered organization registrations shall be issued or become effective no later than eighteen months from signing or until such time as the commissioner and the superintendent of state police certify that this title can be implemented in accordance with public health and safety interests, whichever event comes later.

§ 3369-c. Suspend; terminate. Based upon the recommendation of the commissioner and/or the superintendent of state police that there is a risk to the public health or safety, the governor may immediately terminate all licenses issued to registered organizations.

§ 3369-d. Pricing. 1. Every sale of medical marihuana shall be at the price determined by the commissioner. Every charge made or demanded for medical marihuana not in accordance with the price determined by the commissioner, is prohibited.

2. The commissioner is hereby authorized to set the per dose price of each form of medical marihuana sold by any registered organization. In setting the per dose price of each form of medical marihuana, the commissioner shall consider the fixed and variable costs of producing the form of marihuana and any other factor the commissioner, in his or her discretion, deems relevant to determining the per dose price of each form of medical marihuana.

§ 3369-e. Severability. If any clause, sentence, paragraph, section or part of this act shall be adjudged by any court of competent jurisdiction to be invalid, the judgment shall not affect, impair, or invalidate the remainder thereof, but shall be confined in its operation to the clause, sentence, paragraph, section or part thereof directly involved in the controversy in which the judgment shall have been rendered.

§ 3. Subdivision 2 of section 3371 of the public health law, as added by section 5 of part A of chapter 447 of the laws of 2012, is amended to read as follows:

2. The prescription monitoring program registry may be accessed, under such terms and conditions as are established by the department for purposes of maintaining the security and confidentiality of the information contained in the registry, by:

(a) a practitioner, or a designee authorized by such practitioner pursuant to paragraph (b) of subdivision two of section thirty-three hundred forty-three-a **or section thirty-three hundred sixty-one** of this article, for the purposes of: (i) informing the practitioner that a patient may be under treatment with a controlled substance by another practitioner; (ii) providing the practitioner with notifications of controlled substance activity as deemed relevant by the department, including but not limited to a notification made available on a monthly or other periodic basis through the registry of controlled substances activity pertaining to his or her patient; (iii) allowing the practitioner, through consultation of the prescription monitoring program registry, to review his or her patient's controlled substances history as required by section thirty-three hundred forty-three-a **or section thirty-three hundred sixty-one** of this article; and (iv) providing to his or her patient, or person authorized pursuant to paragraph (j) of subdivision one of this section, upon request, a copy of such patient's controlled substance history as is available to the practitioner through the prescription monitoring program registry; or

(b) a pharmacist, pharmacy intern or other designee authorized by the pharmacist pursuant to paragraph (b) of subdivision three of section thirty-three hundred forty-three-a of this article, for the purposes of: (i) consulting the prescription monitoring program registry to review the controlled substances history of an individual for whom one or more prescriptions for controlled substances **or certifications for marihuana** is presented to the pharmacist, pursuant to section thirty-three hundred forty-three-a of this article; and (ii) receiving from the department such notifications of controlled substance activity as are made available by the department[~~.~~]**; or**

(c) an individual employed by a registered organization for the purpose of consulting the prescription monitoring program registry to review the controlled substances history of an individual for whom one or more certifications for marihuana is presented to that registered organization, pursuant to section thirty-three hundred sixty-four of this article. Unless otherwise authorized by this article, an individual employed by a registered organization will be provided access to the prescription monitoring program in the sole discretion of the commissioner.

§ 4. The tax law is amended by adding a new article 20-B to read as follows:

ARTICLE 20-B

EXCISE TAX ON MEDICAL MARIHUANA

Section 490. Definitions.

491. Returns to be secret.

§ 490. Definitions. 1. (a) All definitions of terms applicable to title five-A of article thirty-three of the public health law shall apply to this article.

(b) As used in this section, where not otherwise specifically defined and unless a different meaning is clearly required "gross receipt" means the amount received in or by reason of any sale, conditional or other-

wise, of medical marihuana or in or by reason of the furnishing of medical marihuana from the sale of medical marihuana provided by a registered organization to a certified patient or designated caregiver. Gross receipt is expressed in money, whether paid in cash, credit or property of any kind or nature, and shall be determined without any deduction therefrom on account of the cost of the service sold or the cost of materials, labor or services used or other costs, interest or discount paid, or any other expenses whatsoever. "Amount received" for the purpose of the definition of gross receipt, as the term gross receipt is used throughout this article, means the amount charged for the provision of medical marihuana.

2. There is hereby imposed an excise tax on the gross receipts from the sale of medical marihuana by a registered organization to a certified patient or designated caregiver, to be paid by the registered organization, at the rate of seven percent. The tax imposed by this article shall be charged against and be paid by the registered organization and shall not be added as a separate charge or line item on any sales slip, invoice, receipt or other statement or memorandum of the price given to the retail customer.

3. The commissioner may make, adopt and amend rules, regulations, procedures and forms necessary for the proper administration of this article.

4. Every registered organization that makes sales of medical marihuana subject to the tax imposed by this article shall, on or before the twentieth date of each month, file with the commissioner a return on forms to be prescribed by the commissioner, showing its receipts from the retail sale of medical marihuana during the preceding calendar month and the amount of tax due thereon. Such returns shall contain such further information as the commissioner may require. Every registered organization required to file a return under this section shall, at the time of filing such return, pay to the commissioner the total amount of tax due on its retail sales of medical marihuana for the period covered by such return. If a return is not filed when due, the tax shall be due on the day on which the return is required to be filed.

5. Whenever the commissioner shall determine that any moneys received under the provisions of this article were paid in error, he may cause the same to be refunded, with interest, in accordance with such rules and regulations as he may prescribe, except that no interest shall be allowed or paid if the amount thereof would be less than one dollar. Such interest shall be at the overpayment rate set by the commissioner pursuant to subdivision twenty-sixth of section one hundred seventy-one of this chapter, or if no rate is set, at the rate of six percent per annum, from the date when the tax, penalty or interest to be refunded was paid to a date preceding the date of the refund check by not more than thirty days. Provided, however, that for the purposes of this subdivision, any tax paid before the last day prescribed for its payment shall be deemed to have been paid on such last day. Such moneys received under the provisions of this article which the commissioner shall determine were paid in error, may be refunded out of funds in the custody of the comptroller to the credit of such taxes provided an application therefor is filed with the commissioner within two years from the time the erroneous payment was made.

6. The provisions of article twenty-seven of this chapter shall apply to the tax imposed by this article in the same manner and with the same force and effect as if the language of such article had been incorporated in full into this section and had expressly referred to the tax

imposed by this article, except to the extent that any provision of such article is either inconsistent with a provision of this article or is not relevant to this article.

7. All taxes, interest and penalties collected or received by the commissioner under this article shall be deposited and disposed of pursuant to the provisions of section one hundred seventy-one-a of this chapter, provided that an amount equal to one hundred percent collected under this article less any amount determined by the commissioner to be reserved by the comptroller for refunds or reimbursements shall be paid by the comptroller to the credit of the medical marihuana trust fund established by section eighty-nine-h of the state finance law.

8. A registered organization that dispenses medical marihuana shall provide to the department information on where the medical marihuana was dispensed and where the medical marihuana was manufactured. A registered organization that obtains marihuana from another registered organization shall obtain from such registered organization information on where the medical marihuana was manufactured.

§ 491. Returns to be secret. 1. Except in accordance with proper judicial order or as in this section or otherwise provided by law, it shall be unlawful for the commissioner, any officer or employee of the department, or any officer or person who, pursuant to this section, is permitted to inspect any return or report or to whom a copy, an abstract or a portion of any return or report is furnished, or to whom any information contained in any return or report is furnished, or any person engaged or retained by such department on an independent contract basis or any person who in any manner may acquire knowledge of the contents of a return or report filed pursuant to this article to divulge or make known in any manner the contents or any other information relating to the business of a distributor, owner or other person contained in any return or report required under this article. The officers charged with the custody of such returns or reports shall not be required to produce any of them or evidence of anything contained in them in any action or proceeding in any court, except on behalf of the state, the state department of health, or the commissioner in an action or proceeding under the provisions of this chapter or on behalf of the state or the commissioner in any other action or proceeding involving the collection of a tax due under this chapter to which the state or the commissioner is a party or a claimant or on behalf of any party to any action or proceeding under the provisions of this article, when the returns or the reports or the facts shown thereby are directly involved in such action or proceeding, or in an action or proceeding relating to the regulation or taxation of medical marihuana on behalf of officers to whom information shall have been supplied as provided in subdivision two of this section, in any of which events the court may require the production of, and may admit in evidence so much of said returns or reports or of the facts shown thereby as are pertinent to the action or proceeding and no more. Nothing herein shall be construed to prohibit the commissioner, in his or her discretion, from allowing the inspection or delivery of a certified copy of any return or report filed under this article or of any information contained in any such return or report by or to a duly authorized officer or employee of the state department of health; or by or to the attorney general or other legal representatives of the state when an action shall have been recommended or commenced pursuant to this chapter in which such returns or reports or the facts shown thereby are directly involved; or the inspection of the returns or reports required under this article by the comptroller or duly designated officer or

employee of the state department of audit and control, for purposes of the audit of a refund of any tax paid by a registered organization or other person under this article; nor to prohibit the delivery to a registered organization, or a duly authorized representative of such registered organization, a certified copy of any return or report filed by such registered organization pursuant to this article, nor to prohibit the publication of statistics so classified as to prevent the identification of particular returns or reports and the items thereof.

2. The commissioner, in his or her discretion and pursuant to such rules and regulations as he or she may adopt, may permit the commissioner of internal revenue of the United States, or the appropriate officers of any other state which regulates or taxes medical marihuana, or the duly authorized representatives of such commissioner or of any such officers, to inspect returns or reports made pursuant to this article, or may furnish to such commissioner or other officers, or duly authorized representatives, a copy of any such return or report or an abstract of the information therein contained, or any portion thereof, or may supply such commissioner or any such officers or such representatives with information relating to the business of a registered organization making returns or reports hereunder. The commissioner may refuse to supply information pursuant to this subdivision to the commissioner of internal revenue of the United States or to the officers of any other state if the statutes of the United States, or of the state represented by such officers, do not grant substantially similar privileges to the commissioner, but such refusal shall not be mandatory. Information shall not be supplied to the commissioner of internal revenue of the United States or the appropriate officers of any other state which regulates or taxes medical marihuana, or the duly authorized representatives of such commissioner or of any of such officers, unless such commissioner, officer or other representatives shall agree not to divulge or make known in any manner the information so supplied, but such officers may transmit such information to their employees or legal representatives when necessary, who in turn shall be subject to the same restrictions as those hereby imposed upon such commissioner, officer or other representatives.

3. (a) Any officer or employee of the state who willfully violates the provisions of subdivision one or two of this section shall be dismissed from office and be incapable of holding any public office in this state for a period of five years thereafter.

(b) Cross-reference: For criminal penalties, see article thirty-seven of this chapter.

§ 5. The state finance law is amended by adding a new section 89-h to read as follows:

§ 89-h. Medical marihuana trust fund. 1. There is hereby established in the joint custody of the state comptroller and the commissioner of taxation and finance a special fund to be known as the "medical marihuana trust fund."

2. The medical marihuana trust fund shall consist of all moneys required to be deposited in the medical marihuana trust fund pursuant to the provisions of section four hundred ninety of the tax law.

3. The moneys in the medical marihuana trust fund shall be kept separate and shall not be commingled with any other moneys in the custody of the commissioner of taxation and finance and the state comptroller.

4. The moneys of the medical marihuana trust fund, following appropriation by the legislature, shall be allocated upon a certificate of approval of availability by the director of the budget as follows: (a) Twenty-two and five-tenths percent of the monies shall be transferred to

the counties in New York state in which the medical marihuana was manufactured and allocated in proportion to the gross sales originating from medical marihuana manufactured in each such county; (b) twenty-two and five-tenths percent of the moneys shall be transferred to the counties in New York state in which the medical marihuana was dispensed and allocated in proportion to the gross sales occurring in each such county; (c) five percent of the monies shall be transferred to the office of alcoholism and substance abuse services, which shall use that revenue for additional drug abuse prevention, counseling and treatment services; and (d) five percent of the revenue received by the department shall be transferred to the division of criminal justice services, which shall use that revenue for a program of discretionary grants to state and local law enforcement agencies that demonstrate a need relating to title five-A of article thirty-three of the public health law; said grants could be used for personnel costs of state and local law enforcement agencies. For purposes of this subdivision, the city of New York shall be deemed to be a county.

§ 6. Subdivision 1 of section 171-a of the tax law, as amended by section 1 of part R of chapter 60 of the laws of 2004, is amended to read as follows:

1. All taxes, interest, penalties and fees collected or received by the commissioner or the commissioner's duly authorized agent under articles nine (except section one hundred eighty-two-a thereof and except as otherwise provided in section two hundred five thereof), nine-A, twelve-A (except as otherwise provided in section two hundred eighty-four-d thereof), thirteen, thirteen-A (except as otherwise provided in section three hundred twelve thereof), eighteen, nineteen, twenty (except as otherwise provided in section four hundred eighty-two thereof), twenty-B twenty-one, twenty-two, twenty-six, twenty-six-B, twenty-eight (except as otherwise provided in section eleven hundred two or eleven hundred three thereof), twenty-eight-A, thirty-one (except as otherwise provided in section fourteen hundred twenty-one thereof), thirty-two, thirty-three and thirty-three-A of this chapter shall be deposited daily in one account with such responsible banks, banking houses or trust companies as may be designated by the comptroller, to the credit of the comptroller. Such an account may be established in one or more of such depositories. Such deposits shall be kept separate and apart from all other money in the possession of the comptroller. The comptroller shall require adequate security from all such depositories. Of the total revenue collected or received under such articles of this chapter, the comptroller shall retain in the comptroller's hands such amount as the commissioner may determine to be necessary for refunds or reimbursements under such articles of this chapter and article ten thereof out of which amount the comptroller shall pay any refunds or reimbursements to which taxpayers shall be entitled under the provisions of such articles of this chapter and article ten thereof. The commissioner and the comptroller shall maintain a system of accounts showing the amount of revenue collected or received from each of the taxes imposed by such articles. The comptroller, after reserving the amount to pay such refunds or reimbursements, shall, on or before the tenth day of each month, pay into the state treasury to the credit of the general fund all revenue deposited under this section during the preceding calendar month and remaining to the comptroller's credit on the last day of such preceding month, (i) except that the comptroller shall pay to the state department of social services that amount of overpayments of tax imposed by article twenty-two of this chapter and the interest on

such amount which is certified to the comptroller by the commissioner as the amount to be credited against past-due support pursuant to subdivision six of section one hundred seventy-one-c of this chapter, (ii) and except that the comptroller shall pay to the New York state higher education services corporation and the state university of New York or the city university of New York respectively that amount of overpayments of tax imposed by article twenty-two of this chapter and the interest on such amount which is certified to the comptroller by the commissioner as the amount to be credited against the amount of defaults in repayment of guaranteed student loans and state university loans or city university loans pursuant to subdivision five of section one hundred seventy-one-d and subdivision six of section one hundred seventy-one-e of this chapter, (iii) and except further that, notwithstanding any law, the comptroller shall credit to the revenue arrearage account, pursuant to section ninety-one-a of the state finance law, that amount of overpayment of tax imposed by article nine, nine-A, twenty-two, thirty, thirty-A, thirty-B, thirty-two or thirty-three of this chapter, and any interest thereon, which is certified to the comptroller by the commissioner as the amount to be credited against a past-due legally enforceable debt owed to a state agency pursuant to paragraph (a) of subdivision six of section one hundred seventy-one-f of this article, provided, however, he shall credit to the special offset fiduciary account, pursuant to section ninety-one-c of the state finance law, any such amount creditable as a liability as set forth in paragraph (b) of subdivision six of section one hundred seventy-one-f of this article, (iv) and except further that the comptroller shall pay to the city of New York that amount of overpayment of tax imposed by article nine, nine-A, twenty-two, thirty, thirty-A, thirty-B, thirty-two, or thirty-three of this chapter and any interest thereon that is certified to the comptroller by the commissioner as the amount to be credited against city of New York tax warrant judgment debt pursuant to section one hundred seventy-one-l of this article, (v) and except further that the comptroller shall pay to a non-obligated spouse that amount of overpayment of tax imposed by article twenty-two of this chapter and the interest on such amount which has been credited pursuant to section one hundred seventy-one-c, one hundred seventy-one-d, one hundred seventy-one-e, one hundred seventy-one-f or one hundred seventy-one-l of this article and which is certified to the comptroller by the commissioner as the amount due such non-obligated spouse pursuant to paragraph six of subsection (b) of section six hundred fifty-one of this chapter; and (vi) the comptroller shall deduct a like amount which the comptroller shall pay into the treasury to the credit of the general fund from amounts subsequently payable to the department of social services, the state university of New York, the city university of New York, or the higher education services corporation, or the revenue arrearage account or special offset fiduciary account pursuant to section ninety-one-a or ninety-one-c of the state finance law, as the case may be, whichever had been credited the amount originally withheld from such overpayment, and (vii) with respect to amounts originally withheld from such overpayment pursuant to section one hundred seventy-one-l of this article and paid to the city of New York, the comptroller shall collect a like amount from the city of New York.

§ 7. Subdivision 1 of section 171-a of the tax law, as amended by section 54 of part A of chapter 59 of the laws of 2014, is amended to read as follows:

1. All taxes, interest, penalties and fees collected or received by the commissioner or the commissioner's duly authorized agent under articles nine (except section one hundred eighty-two-a thereof and except as otherwise provided in section two hundred five thereof), nine-A, twelve-A (except as otherwise provided in section two hundred eighty-four-d thereof), thirteen, thirteen-A (except as otherwise provided in section three hundred twelve thereof), eighteen, nineteen, twenty (except as otherwise provided in section four hundred eighty-two thereof), **twenty-B,** twenty-one, twenty-two, twenty-six, twenty-six-B, twenty-eight (except as otherwise provided in section eleven hundred two or eleven hundred three thereof), twenty-eight-A, thirty-one (except as otherwise provided in section fourteen hundred twenty-one thereof), thirty-three and thirty-three-A of this chapter shall be deposited daily in one account with such responsible banks, banking houses or trust companies as may be designated by the comptroller, to the credit of the comptroller. Such an account may be established in one or more of such depositories. Such deposits shall be kept separate and apart from all other money in the possession of the comptroller. The comptroller shall require adequate security from all such depositories. Of the total revenue collected or received under such articles of this chapter, the comptroller shall retain in the comptroller's hands such amount as the commissioner may determine to be necessary for refunds or reimbursements under such articles of this chapter out of which amount the comptroller shall pay any refunds or reimbursements to which taxpayers shall be entitled under the provisions of such articles of this chapter. The commissioner and the comptroller shall maintain a system of accounts showing the amount of revenue collected or received from each of the taxes imposed by such articles. The comptroller, after reserving the amount to pay such refunds or reimbursements, shall, on or before the tenth day of each month, pay into the state treasury to the credit of the general fund all revenue deposited under this section during the preceding calendar month and remaining to the comptroller's credit on the last day of such preceding month, (i) except that the comptroller shall pay to the state department of social services that amount of overpayments of tax imposed by article twenty-two of this chapter and the interest on such amount which is certified to the comptroller by the commissioner as the amount to be credited against past-due support pursuant to subdivision six of section one hundred seventy-one-c of this article, (ii) and except that the comptroller shall pay to the New York state higher education services corporation and the state university of New York or the city university of New York respectively that amount of overpayments of tax imposed by article twenty-two of this chapter and the interest on such amount which is certified to the comptroller by the commissioner as the amount to be credited against the amount of defaults in repayment of guaranteed student loans and state university loans or city university loans pursuant to subdivision five of section one hundred seventy-one-d and subdivision six of section one hundred seventy-one-e of this article, (iii) and except further that, notwithstanding any law, the comptroller shall credit to the revenue arrearage account, pursuant to section ninety-one-a of the state finance law, that amount of overpayment of tax imposed by article nine, nine-A, twenty-two, thirty, thirty-A, thirty-B or thirty-three of this chapter, and any interest thereon, which is certified to the comptroller by the commissioner as the amount to be credited against a past-due legally enforceable debt owed to a state agency pursuant to paragraph (a) of subdivision six of section one hundred seventy-one-f of this article, provided, however, he

shall credit to the special offset fiduciary account, pursuant to section ninety-one-c of the state finance law, any such amount creditable as a liability as set forth in paragraph (b) of subdivision six of section one hundred seventy-one-f of this article, (iv) and except further that the comptroller shall pay to the city of New York that amount of overpayment of tax imposed by article nine, nine-A, twenty-two, thirty, thirty-A, thirty-B or thirty-three of this chapter and any interest thereon that is certified to the comptroller by the commissioner as the amount to be credited against city of New York tax warrant judgment debt pursuant to section one hundred seventy-one-l of this article, (v) and except further that the comptroller shall pay to a non-obligated spouse that amount of overpayment of tax imposed by article twenty-two of this chapter and the interest on such amount which has been credited pursuant to section one hundred seventy-one-c, one hundred seventy-one-d, one hundred seventy-one-e, one hundred seventy-one-f or one hundred seventy-one-l of this article and which is certified to the comptroller by the commissioner as the amount due such non-obligated spouse pursuant to paragraph six of subsection (b) of section six hundred fifty-one of this chapter; and (vi) the comptroller shall deduct a like amount which the comptroller shall pay into the treasury to the credit of the general fund from amounts subsequently payable to the department of social services, the state university of New York, the city university of New York, or the higher education services corporation, or the revenue arrearage account or special offset fiduciary account pursuant to section ninety-one-a or ninety-one-c of the state finance law, as the case may be, whichever had been credited the amount originally withheld from such overpayment, and (vii) with respect to amounts originally withheld from such overpayment pursuant to section one hundred seventy-one-l of this article and paid to the city of New York, the comptroller shall collect a like amount from the city of New York.

§ 7-a. Section 853 of the general business law is amended by adding a new subdivision 3 to read as follows:

3. This article shall not apply to any sale, furnishing or possession which is for a lawful purpose under title five-A of article thirty-three of the public health law.

§ 8. Section 221.00 of the penal law, as added by chapter 360 of the laws of 1977, is amended to read as follows:

§ 221.00 Marihuana; definitions.

Unless the context in which they are used clearly otherwise requires, the terms occurring in this article shall have the same meaning ascribed to them in article two hundred twenty of this chapter. **Any act that is lawful under title five-A of article thirty-three of the public health law is not a violation of this article.**

§ 9. The penal law is amended by adding a new article 179 to read as follows:

ARTICLE 179

CRIMINAL DIVERSION OF MEDICAL MARIHUANA

Section 179.00 Criminal diversion of medical marihuana; definitions.
179.05 Criminal diversion of medical marihuana; limitations.
179.10 Criminal diversion of medical marihuana in the first degree.
179.11 Criminal diversion of medical marihuana in the second degree.
179.15 Criminal retention of medical marihuana.

§ 179.00 Criminal diversion of medical marihuana; definitions.
The following definitions are applicable to this article:

1. "Medical marihuana" means medical marihuana as defined in subdivision eight of section thirty-three hundred sixty of the public health law.
2. "Certification" means a certification, made under section thirty-three hundred sixty-one of the public health law.

§ 179.05 Criminal diversion of medical marihuana; limitations.
The provisions of this article shall not apply to:
1. a practitioner authorized to issue a certification who acted in good faith in the lawful course of his or her profession; or
2. a registered organization as that term is defined in subdivision nine of section thirty-three hundred sixty of the public health law who acted in good faith in the lawful course of the practice of pharmacy; or
3. a person who acted in good faith seeking treatment for medical condition or assisting another person to obtain treatment for a medical condition.

§ 179.10 Criminal diversion of medical marihuana in the first degree.
A person is guilty of criminal diversion of medical marihuana in the first degree when he or she is a practitioner, as that term is defined in subdivision twelve of section thirty-three hundred sixty of the public health law, who issues a certification with knowledge of reasonable grounds to know that (i) the recipient has no medical need for it, or (ii) it is for a purpose other than to treat a serious condition as defined in subdivision seven of section thirty-three hundred sixty of the public health law.
Criminal diversion of medical marihuana in the first degree is a class E felony.

§ 179.11 Criminal diversion of medical marihuana in the second degree.
A person is guilty of criminal diversion of medical marihuana in the second degree when he or she sells, trades, delivers, or otherwise provides medical marihuana to another with knowledge or reasonable grounds to know that the recipient is not registered under title five-A of article thirty-three of the public health law.
Criminal diversion of medical marihuana in the second degree is a class B misdemeanor.

§ 179.15 Criminal retention of medical marihuana.
A person is guilty of criminal retention of medical marihuana when, being a certified patient or designated caregiver, as those terms are defined in subdivisions three and five of section thirty-three hundred sixty of the public health law, respectively, he or she knowingly obtains, possesses, stores or maintains an amount of marihuana in excess of the amount he or she is authorized to possess under the provisions of title five-A of article thirty-three of the public health law.
Criminal retention of medical marihuana is a class A misdemeanor.

§ 10. The opening paragraph of subdivision 1 of section 216.00 of the criminal procedure law, as added by section 4 of part AAA of chapter 56 of the laws of 2009, is amended to read as follows:
"Eligible defendant" means any person who stands charged in an indictment or a superior court information with a class B, C, D or E felony offense defined in article one hundred seventy-nine, two hundred twenty or two hundred twenty-one of the penal law or any other specified offense as defined in subdivision four of section 410.91 of this chapter, provided, however, a defendant is not an "eligible defendant" if he or she:

§ 11. Subdivision 5 of section 410.91 of the criminal procedure law, as amended by section 8 of part AAA of chapter 56 of the laws of 2009, is amended to read as follows:

5. For the purposes of this section, a "specified offense" is an offense defined by any of the following provisions of the penal law: burglary in the third degree as defined in section 140.20, criminal mischief in the third degree as defined in section 145.05, criminal mischief in the second degree as defined in section 145.10, grand larceny in the fourth degree as defined in subdivision one, two, three, four, five, six, eight, nine or ten of section 155.30, grand larceny in the third degree as defined in section 155.35 (except where the property consists of one or more firearms, rifles or shotguns), unauthorized use of a vehicle in the second degree as defined in section 165.06, criminal possession of stolen property in the fourth degree as defined in subdivision one, two, three, five or six of section 165.45, criminal possession of stolen property in the third degree as defined in section 165.50 (except where the property consists of one or more firearms, rifles or shotguns), forgery in the second degree as defined in section 170.10, criminal possession of a forged instrument in the second degree as defined in section 170.25, unlawfully using slugs in the first degree as defined in section 170.60, **criminal diversion of medical marihuana in the first degree as defined in section 179.10** or an attempt to commit any of the aforementioned offenses if such attempt constitutes a felony offense; or a class B felony offense defined in article two hundred twenty where a sentence is imposed pursuant to paragraph (a) of subdivision two of section 70.70 of the penal law; or any class C, class D or class E controlled substance or marihuana felony offense as defined in article two hundred twenty or two hundred twenty-one.

§ 12. This act shall take effect immediately and shall expire and be deemed repealed seven years after such date; provided that the amendments to section 171-a of the tax law made by section seven of this act shall take effect on the same date and in the same manner as section 54 of part A of chapter 59 of the laws of 2014 takes effect; and provided, further, that the amendments to subdivision 5 of section 410.91 of the criminal procedure law made by section eleven of this act shall not affect the expiration and repeal of such section and shall expire and be deemed repealed therewith.

Part 1004 - Medical Use of Marihuana

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Wednesday, February 26, 2020
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Public Health Law, Section 3369-a

Section 1004.1 - Practitioner registration

1004.1 Practitioner registration.

(a) No practitioner shall be authorized to issue a patient certification as set forth in section 1004.2 unless the practitioner:

(1) is qualified to treat patients with one or more of the serious conditions set forth in subdivision 1004.2(a)(8) of this Part;

(2) is licensed, in good standing as a physician and practicing medicine, as defined in article 131 of the Education Law, in New York State, or is certified, in good standing as a nurse practitioner and practicing, as defined in article 139 of the Education Law, in New York State, or is licensed, in good standing as a physician assistant and practicing in New York State, as defined in article 131-B of the Education Law, under the supervision of a physician registered under this Part;

(3) has completed a two to four hour course approved by the commissioner as set forth in subdivision (b) of this section;

(4) has applied to the department for a registration or a renewal of registration to issue patient certifications in a manner and format determined by the commissioner; and

(5) has been granted such registration by the department.

(b) The commissioner shall approve at least one, if not more, courses for practitioners seeking to become registered, which shall be two to four hours in duration. The educational content of such course shall include: the pharmacology of marihuana; contraindications; side effects; adverse reactions; overdose prevention; drug interactions; dosing; routes of administration; risks and benefits; warnings and precautions; abuse and dependence; and such other components as determined by the commissioner.

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Section 1004.2 - Practitioner issuance of certification

1004.2 Practitioner issuance of certification.

(a) Requirements for Patient Certification. A practitioner who is registered pursuant to 1004.1 of this part may issue a certification for the use of an approved medical marihuana product by a qualifying patient subject to completion of subdivision (e) of this section. Such certification shall contain:

(1) the practitioner's name, business address, telephone number and email address;

(2) the practitioner's license number as issued by the New York State Department of Education;

(3) the practitioner's Drug Enforcement Administration registration number;

(4) a statement that the practitioner is licensed and in good standing in New York State and possesses an active registration with the Drug Enforcement Administration;

(5) a statement that the practitioner is registered with the department to issue the certification;

(6) a statement that the practitioner is caring for the patient in relation to the patient's serious condition;

(7) the patient's name, date of birth, address, telephone number and email address if available;

(8) the patient's diagnosis, limited solely to the specific severe debilitating or life-threatening condition(s) listed below;

(i) cancer;

(ii) positive status for human immunodeficiency virus or acquired immune deficiency syndrome, provided that the practitioner has obtained from the patient consent for disclosure of this information that meets the requirements set forth in sections twenty-seven hundred eighty and twenty-seven hundred eighty-two of the public health law;

(iii) amyotrophic lateral sclerosis;

(iv) Parkinson's disease;

(v) multiple sclerosis;

(vi) damage to the nervous tissue of the spinal cord with objective neurological indication of intractable spasticity;

(vii) epilepsy;

(viii) inflammatory bowel disease;

(ix) neuropathies;

(x) Huntington's disease;

(xi) any severe debilitating pain that the practitioner determines degrades health and functional capability; where the patient has contraindications, has experienced intolerable side effects, or has experienced failure of one or more previously tried therapeutic options; and where there is documented medical evidence of such pain having lasted three months or more beyond onset, or the practitioner reasonably anticipates such pain to last three months or more beyond onset;

(xii) post-traumatic stress disorder;

(xiii) pain that degrades health and functional capability where the use of medical marihuana is an alternative to opioid use, provided that the precise underlying condition is expressly stated on the patient's certification; or

(xiv) substance use disorder; or

(xv) any other condition added by the commissioner.

(9) The condition or symptom that is clinically associated with, or is a complication of the severe debilitating or life-threatening condition listed in paragraph (8) of this subdivision. Clinically associated conditions, symptoms or complications, as defined in subdivision 7 of section 3360 of the public health law are limited solely to:

(i) Cachexia or wasting syndrome;

(ii) severe or chronic pain resulting in substantial limitation of function;

(iii) severe nausea;

(iv) seizures;

(v) severe or persistent muscle spasms;

(vi) post-traumatic stress disorder;

(vii) opioid use disorder; or

(viii) such other conditions, symptoms or complications as added by the commissioner.

(10) a statement that by training or experience, the practitioner is qualified to treat the serious condition, which encompasses the severe debilitating or life-threatening condition listed pursuant to paragraph (8) of this subdivision and the clinically associated condition, symptom or complication listed pursuant to paragraph (9) of this subdivision;

(i) for purposes of this subdivision, a practitioner must hold a federal Drug Addiction Treatment Act of 2000 (DATA 2000) waiver to be qualified to treat patients with substance use disorder or opioid use disorder.

(11) a statement that in the practitioner's professional opinion and review of past treatments, the patient is likely to receive therapeutic or palliative benefit from the primary or adjunctive treatment with medical marihuana for the serious condition;

(12) any recommendations or limitations the practitioner makes to the certified patient and/or the patient's designated caregiver concerning:

(i) the authorized brand, authorized form, administration method, dosage and any limitations in the use of the approved medical marihuana product; and

(ii) the total amount of usable approved medical marihuana product that may be dispensed to the patient, in measurable controlled doses, which shall not exceed a thirty (30) day supply, if used as directed;

(13) a statement that the practitioner has explained the potential risks and benefits of the use of medical marihuana to the qualifying patient and has documented in the patient's medical record that such explanation has been provided to the patient.

(14) to the extent that a practitioner is seeking to authorize the use of an approved medical marihuana product by a patient who is under the age of eighteen or a person who is otherwise incapable of consenting to medical

treatment, the practitioner shall explain the potential risks and benefits of medical marihuana to the patient's parent or legal guardian, and if appropriate, to the minor patient. The practitioner shall document in the patient's medical record that such explanation has been provided as required herein; and

(15) a statement that the patient, or the patient's parent or legal guardian if applicable, has provided informed consent; and

(16) to the extent that a practitioner seeks to authorize the use of an approved medical marihuana product by a patient who temporarily resides in New York State for the purpose of receiving care and treatment from the practitioner, the practitioner shall so state on the patient's certification.

(b) Expiration of Certification.

(1) The certification shall state the date upon which the certification shall expire, which shall be no longer than one year after the date it was issued, unless the patient is terminally ill.

(2) If the practitioner issues a certification to a patient who is terminally ill, the certification shall not expire until the patient's death or the practitioner revokes the certification.

(3) If the practitioner issues a certification to a patient who is not a resident of New York but is receiving care and treatment in this state, the certification shall be valid for a period of time which is no longer than the applicant is reasonably anticipated to be residing in New York State for the purposes of care and treatment, but in no event shall it be valid for more than one year after the date it was issued.

(c) Submission of Certification to the Department. Practitioners shall utilize a form, which may be in an electronic format, developed by the department for the certification required in subdivision (a) of this section. The practitioner shall submit to the department, the information required by subdivision (a) of this section, in a manner determined by the department, including by electronic transmission through a secure website. In the instance that a practitioner submits this information to the department electronically, the practitioner shall retain, for a period of 5 years, a printed copy of the electronic certification that shall contain the information required in subdivision (a).

(d) Medical Record Retention. The practitioner shall date and place his or her handwritten signature upon the printed certification, and provide the printed certification to the patient. The practitioner shall also maintain a copy of the signed certification in the patient's medical record.

(e) Consultation of Prescription Monitoring Program Registry. Prior to issuing, modifying or renewing a certification, the practitioner shall consult the prescription monitoring program registry pursuant to section 3343-a of the Public Health Law for the purpose of reviewing a patient's controlled substance history. Practitioners may authorize a designee to consult the prescription monitoring program registry on their behalf, provided that such designation is in accordance with section 3343-a of the Public Health Law.

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Public Health Law, Sections 3360 and 3369-a

Section 1004.3 - Application for registration as a certified patient

1004.3 Application for registration as a certified patient.

(a) A person applying for issuance or renewal of a registration as a certified patient shall:

(1) be a resident of New York State, or be receiving care and treatment in New York State; and

(2) possess a certification issued by a registered practitioner.

(b) New York State residents. An applicant shall demonstrate his or her New York State residency by submitting to the department a copy of information concerning his or her New York State Driver's License or New York State Identification Card. If the applicant does not possess or cannot obtain a valid New York State Driver's License or New York State Identification Card, the applicant shall submit a copy of one or more of the following forms of documentation to establish that he or she is a New York resident:

(1) a copy of a government-issued identification card that contains the applicant's name and New York State address. If the applicant is under the age of eighteen, the parent or legal guardian applying on behalf of the applicant shall submit a copy of the parent or legal guardian's state or government issued identification and a copy of the applicant's birth certificate;

(2) a copy of a utility bill or other document indicating an applicant's residency issued within the previous two months that contains the applicant's name and address;

(3) a copy of a current lease or similar document indicating an applicant's residency within New York State; or

(4) such other documentation as approved by the department containing sufficient information to show proof of residency in New York State.

(c) Non-New York State Residents. An applicant applying for registration who is not a resident of New York State but is receiving care and treatment in this state, may qualify for registration as a certified patient if the applicant otherwise meets the requirements of article thirty-three of the public health law and this part, and is temporarily residing in New York State for the purpose of receiving care and treatment from a practitioner registered with the department.

(1) The applicant shall submit a copy of the following forms of documentation along with the application for registration:

(i) a copy of a state or government issued identification card that contains the applicant's name and permanent address. If the applicant is under the age of eighteen, the parent or legal guardian applying on behalf of the applicant shall submit a copy of the parent or legal guardian's state or government issued identification and a copy of the applicant's birth certificate;

(ii) proof of temporary residence in New York State, including, but not limited to a copy of a lease, utility bill, hospital bill, or such other documentation as approved by the department containing sufficient information to show proof of temporary residency in New York State. If the applicant is under the age of eighteen, the parent or legal guardian applying on behalf of the applicant shall submit a copy of such documentation to show sufficient proof of the applicant's temporary residency in New York State.

(2) Nothing in this part shall be construed to grant to the applicant authorization to transport approved medical marihuana products outside of New York State.

(d) Application for a registry identification card. To obtain, amend or renew a registry identification card, a certified patient shall file a registry application with the department, on a form or in a manner determined by the department, which shall include:

(1) the documentation required in subdivisions (b) and (c) of this section, as applicable;

(2) the information required in section thirty-three hundred sixty-three of the public health law;

(3) for new applicants, if the applicant does not have a current valid New York State Driver's license, New York State Identification Card, or government issued identification containing a photograph, the applicant shall provide a recent passport-style color photograph of the applicant's face, taken against a white background or backdrop. The photograph shall be a true likeness of the applicant's actual appearance on the date the photograph was taken and shall not be altered to change any aspect of the applicant's physical appearance. The photograph shall have been taken not more than thirty (30) days prior to the date of the application. The photograph shall be submitted in a form and manner described by the department, including as a digital file (.jpeg) when appropriate, provided, however, the department may waive the requirements of this paragraph upon good cause shown. For amendments and renewal applications, the department may utilize a previously submitted photograph if the applicant attests it is a true likeness of the applicant on the date the amendment or renewal application is submitted;

(4) a nonrefundable application fee of fifty dollars; provided, however, that the department may waive or reduce the fee in cases of financial hardship as determined by the department; and

(5) acknowledgement that a false statement in the application is punishable under section 210.45 of the penal law;

(e) If the applicant for a registry identification card is under the age of eighteen or a person who is otherwise incapable of consenting to medical treatment, the application shall be made by an appropriate person over twenty-one years of age. In preparing the application, the applicant may designate up to two proposed designated caregivers who shall be either: (i) a parent or legal guardian of the certified patient; (ii) a person designated by a parent or legal guardian, or (iii) an appropriate person approved by the department upon a sufficient showing that no parent or legal guardian is appropriate or available.

(1) As a condition of registration of a certified patient who is a minor or is incapable of medical decision-making, the applicant shall consent, in a manner determined by the department, to the certified patient's use of an approved medical marihuana product, and shall acknowledge that the parent, legal guardian or other appropriate person, as applicable, will control the acquisition and possession of the medical marihuana and any device used for its administration.

(2) Once the certified patient who is a minor or is incapable of medical decision-making is registered, the proposed designated caregiver(s) may apply for and, if approved, receive a designated caregiver registration in accordance with the requirements of section thirty-three hundred sixty-three of the public health law and section 1004.4 of this part.

(f) Prior to issuing or renewing a registry identification card, the department may verify the information submitted by the applicant. The applicant shall provide, at the department's request, such information and documentation, including any consents or authorizations to contact treating practitioners that may be necessary for the department to verify the information.

(g) The department shall approve, deny, or determine incomplete or inaccurate an application to issue or renew a registry identification card within thirty (30) days of receipt of the application. If the application is approved within the 30 day period, the department shall issue a registry identification card as soon as is reasonably practicable.

(h) The department shall notify the applicant in writing, by email, by telephone, or in another manner as determined appropriate by the department, if an application is incomplete or factually inaccurate, and shall explain what documents or information is necessary for the department to consider the application complete and accurate.

(i) An applicant shall have thirty (30) days from the date of a notification of an incomplete or factually inaccurate application to submit the materials required to complete, revise, or substantiate information in the application. If the applicant fails to submit the required materials within such thirty day time period, the application shall be denied by the department.

(j) Applicants whose applications are denied may submit a new application for an initial or renewal of a registry identification card, together with the applicable fee as set forth herein.

(k) A certified patient may designate up to two designated caregivers either on the application for issuance or renewal of a registry identification card or in another manner determined by the department. A designated caregiver may be either a natural person or a facility. For purposes of this section, a "facility" shall mean: a general hospital or residential health care facility operating pursuant to Article 28 of the Public Health Law; an adult care facility operating pursuant to Title 2 of Article 7 of the Social Services Law; a community mental health residence established pursuant to section 41.44 of the Mental Hygiene Law; a hospital operating pursuant to section 7.17 of the Mental Hygiene Law; a mental hygiene facility operating pursuant to Article 31 of the Mental Hygiene Law; an inpatient or residential treatment program certified pursuant to Article 32 of the Mental Hygiene Law; a residential facility for the care and treatment of persons with developmental disabilities operating pursuant to Article 16 of the Mental Hygiene Law; a residential treatment facility for children and youth operating pursuant to Article 31 of the Mental Hygiene Law; or a private or public school. Further, within each of the facilities listed above, each division, department, component, floor or other unit of such facility shall be entitled to be considered to be a "facility" for purposes of this section. The application for issuance or renewal of a registry identification card shall include the following information:

(1) name of the proposed designated caregiver(s);

(2) address of the proposed designated caregiver(s);

(3) date of birth of the proposed designated caregiver(s), unless the proposed designated caregiver is not a natural person;

(4) any other individual identifying information concerning the proposed designated caregiver(s) required by the department.

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Section 1004.4 - Designated caregiver registration

1004.4 Designated caregiver registration.

(a) A certified patient's designation of a designated caregiver shall not be valid unless and until the proposed designated caregiver successfully applies for and receives a designated caregiver registry identification card.

(b) A facility or natural person selected by a certified patient as a designated caregiver may apply to the department for a registry identification card or renewal of such card on a form or in a manner determined by the department. The proposed designated caregiver shall submit an application to the department which shall contain the following information and documentation:

(1) For a proposed designated caregiver that is a natural person, the individual shall submit:

(i) the applicant's full name, address, date of birth, telephone number, email address if available, and signature;

(ii) if the applicant has a registry identification card, the registry identification number;

(iii) a nonrefundable application fee of fifty ($50) dollars, provided, however that the department may waive or reduce the fee in cases of financial hardship as determined by the department;

(iv) a statement that the applicant is not the certified patient's practitioner;

(v) a statement that the applicant agrees to secure and ensure proper handling of all approved medical marihuana products;

(vi) acknowledgement that a false statement in the application is punishable under section 210.45 of the penal law;

(vii) proof that the applicant is a New York State resident, consisting of a copy of either:

(a) a New York State issued driver's license; or

(b) a New York State non-driver identification card;

(viii) If the documentation submitted by the applicant in accordance with paragraph (vii) of this subdivision does not contain a photograph of the applicant or the photograph on the documentation is not a true likeness of the applicant, the applicant shall provide one recent passport-style color photograph of the applicant's face taken against a white background or backdrop. The photograph shall be a true likeness of the applicant's appearance on the date the photograph was taken and shall not be altered to change any aspect of the applicant's physical appearance. The photograph shall have been taken not more than thirty (30) days prior to the date of the application. The photograph shall be submitted in a form and manner as directed by the department, including as a digital file (.jpeg).

(ix) Identification of all certified patients for which the applicant serves, has served or has an application pending to serve as a designated caregiver and a statement that the applicant is not currently a designated caregiver for five current certified patients, and that he/she has not submitted an application which is pending and, if approved, would cause the applicant to be a designated caregiver for a total of five current certified patients;

(2) For a proposed designated caregiver that is an entire facility that is licensed or operated pursuant to an authority set forth in subdivision (k) of section 1004.3 of this Part, the designated caregiver shall submit:

(i) the facility's full name, address, operating certificate or license number where appropriate, email address, and printed name, title, and signature of an authorized facility representative;

(ii) if the facility has a registry identification card, the registry identification number;

(iii) a statement that the facility agrees to secure and ensure proper handling of all approved medical marihuana products; and

(iv) an acknowledgement that a false statement in the application is punishable under section 210.45 of the penal law;

(3) For a proposed designated caregiver that is a division, department, component, floor or other unit pursuant to subdivision (k) of section 1004.3 of this Part, the designated caregiver shall submit:

(i) the parent facility's full name, address, operating certificate or license number where appropriate, email address, and printed name, title and signature of an authorized representative of the parent facility and of an authorized representative of the division, department, component, floor or other unit;

(ii) if the parent facility, division, department, component, floor or other unit has a registry identification card, the registry identification number;

(iii) a statement that the parent facility, and the division, department, component, floor or other unit, agree to secure and ensure proper handling of all approved medical marihuana products; and

(iv) an acknowledgement that a false statement in the application is punishable under section 210.45 of the penal law.

(c) Prior to issuing or renewing a registry identification card, the department may verify the information submitted by the applicant. The applicant shall provide, at the department's request, such information and documentation, including any consents or authorizations that may be necessary for the department to verify the information.

(d) The department shall approve, deny or determine incomplete or inaccurate an initial or renewal application within thirty (30) days of receipt of the application. If the application is approved within the 30 day period, the department shall issue a registry identification card as soon as is reasonably practicable.

(e) The department shall notify the applicant in writing, by email, by telephone, or in another manner as determined appropriate by the department if an application is incomplete or factually inaccurate, and shall explain what documents or information is necessary for the department to consider the application complete and accurate.

(f) An applicant shall have thirty (30) days from the date of a notification of an incomplete or factually inaccurate application to submit the materials required to complete, revise or substantiate information in the application. If the applicant fails to submit the required materials within such thirty day time period, the application shall be denied by the department.

(g) Applicants whose applications are denied pursuant to subdivision (f) of this section may submit a new initial or renewal application for a registry identification card, together with the applicable fee as set forth herein.

(h) The department shall deny a registry identification card for an applicant who:

(1) is already a designated caregiver for five currently certified patients or has an application pending that, if approved, would cause the proposed designated caregiver to be a designated caregiver for more than five currently certified patients; or

(2) in accordance with subdivision (e) of this section, fails to provide complete or factually accurate information in support of his or her initial or renewal application.

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Section 1004.5 - Application for initial registration as a registered organization

1004.5 Application for initial registration as a registered organization.

(a) No person or entity shall produce, grow or sell medical marihuana or hold itself out as a New York State registered organization unless it has complied with article 33 of the public health law and this part and is registered by the department.

(b) In order to operate as a registered organization, an entity shall file an application on forms or in a manner prescribed by the commissioner. The application shall be signed by the chief executive officer duly authorized by the board of a corporate applicant, or a general partner or owner of a proprietary applicant. The application shall set forth or be accompanied by the following:

(1) the name, address, phone and email address of the applicant;

(2) identification of all real property, buildings and facilities that will be used in manufacturing, as defined in Section 1004.11 of this part, and dispensing of the medical marihuana products;

(3) identification of all equipment that will be used to carry out the manufacturing, processing, transportation, distributing, sale and dispensing activities described in the application and operating plan;

(4) an operating plan that includes a detailed description of the applicant's manufacturing processes, transporting, distributing, sale and dispensing policies or procedures. The operating plan shall also include:

(i) a detailed description of any devices used with approved medical marihuana products to be offered or sold by the registered organization;

(ii) policies and procedures related to security and control measures that will be in place to prevent diversion, abuse, and other illegal or unauthorized conduct relating to medical marihuana and are consistent with provisions set forth in this part;

(iii) a standard operating procedure manual for all methods used from cultivation of the medical marihuana through packaging, sealing and labeling of each lot of medical marihuana product. The procedures shall include use of good agricultural practices (GAPs) and must conform to all applicable laws and rules of New York State. Standard operating procedures shall be able to be validated to demonstrate that the applicant will be able to produce and dispense consistent and reproducible medical marihuana product such that, for each form of each brand produced, there is homogeneity, absence of contamination and reproducibility of the brand profile in each lot as defined in section 1004.11 of this part.

(iv) quality assurance plans, including but not limited to plans to detect, identify and prevent dispensing errors;

(v) policies and procedures to document and investigate approved medical marihuana product returns, complaints and adverse events, and to provide for rapid voluntary or involuntary recalls of any lot of medical marihuana product. Such policies and procedures shall include a plan for any retesting of returned approved medical marihuana products, storage and disposal of marihuana and any manufactured medical marihuana products not passing requirements, and a requirement that adverse events and total recalls are reported to the department within twenty-four hours of their occurrence;

(vi) a quality assurance program to track contamination incidents and document the investigated source of such incidents, and the appropriate corrective action(s) taken.

(vii) detailed description of plans, procedures and systems adopted and maintained for tracking, record keeping, record retention and surveillance systems, relating to all medical marihuana at every stage including cultivating, possessing of marihuana, and manufacturing, delivery, transporting, distributing, sale and dispensing by the proposed registered organization.

(viii) proposed hours of operation for the manufacturing and dispensing facilities;

(5) copies of the organizational and operational documents of the applicant, including but not limited to, as applicable: the certificate of incorporation, bylaws, articles of organization, partnership agreement, operating agreement and other applicable documents and agreements, and all amendments thereto;

(6) the name, residence address and title of each of the board members, officers, managers, owners, partners, principal stakeholders, directors and any person or entity that is a member of the applicant. Each such person (if an individual, or lawful representative, if a legal entity) shall submit an affidavit with the application setting forth: (i) any position of management or ownership during the preceding ten years of a ten percent or greater interest in any other business, located in or outside New York State, manufacturing or distributing drugs; and (ii) whether such person or any such business has been convicted of a felony or had a registration or license suspended or revoked in any administrative or judicial proceeding. In addition, any managers who may come in contact with or handle medical marihuana, including medical marihuana products, shall be subject to a fingerprinting process as part of a criminal history background check in compliance with the procedures established by Division of Criminal Justice Services and submission of the applicable fee;

(7) documentation that the applicant has entered into a labor peace agreement, as required by subdivision one of section thirty-three hundred sixty five of the public health law, with a bona-fide labor organization that is actively engaged in representing or attempting to represent the applicant's employees. The maintenance of such a labor peace agreement shall be an ongoing material condition of registration;

(8) a statement that the applicant is able to comply with all applicable state and local laws and regulations relating to the activities in which it intends to engage under the registration;

(9) copies of all applicable executed and proposed deeds, leases, and rental agreements or executed option contracts related to the organization's real property interests, that shows that the applicant possesses or has the right to use sufficient land, buildings, and other premises as specified in the application and equipment to properly carry on the activities for which registration is sought. In the alternative, the applicant shall post a bond of not less than two million dollars; provided, however, that if the applicant posts a bond in lieu of providing the documentation requested herein, the applicant's submission of the applicable executed deeds, leases and rental agreements shall be required prior to the issuance of a registration to the applicant, if selected; and, provided further that whenever any applicant proposes to lease

premises for the activities described in its operating plan, the lease

agreement shall clearly set forth as a purpose the manufacturing and/or dispensing of medical marihuana, as applicable, and include the following language:
"The landlord acknowledges that its rights of reentry into the premises set forth in this lease

do not confer on it the authority to manufacture and/or dispense on the premises medical marihuana in accordance with article 33 of the Public Health Law and agrees to provide the New York State Department of Health, Mayor Erastus Corning 2nd Tower, The Governor Nelson A. Rockefeller Empire State Plaza, Albany, N.Y. 12237, with notification by certified mail of its intent to reenter the premises or to initiate dispossess proceedings or that the lease

is due to expire, at least 30 days prior to the date on which the landlord intends to exercise a right of reentry or to initiate such proceedings or at least 60 days before expiration of the lease."

(10) a financial statement setting forth all elements and details of any business transactions connected with the application, including but not limited to all agreements and contracts for consultation and/or arranging for the assistance in preparing the application;

(11) architectural program and sketches of the applicant's proposed manufacturing and dispensing facility(ies) including the following:

(i) site plans;

(ii) schematic architectural and engineering design drawings and single line sketches in an appropriate scale showing the relationship of various buildings to each other, room configurations, major exit corridors, exit stair locations, and circulation along with existing buildings if additions or alterations are part of the project;

(iii) outline specifications for the type of construction proposed including a description of energy sources, type and location of engineering systems proposed for heating, cooling, ventilation and electrical distribution, water supply and sewage;

(iv) a security plan indicating how the applicant will comply with the requirements of article 33 of the Public Health Law, this part and any other applicable law, rule, or regulation; and

(v) the registered organization shall submit detailed floor plans indicating the activities performed in each area and security plans (physical and cyber) consistent with the requirements of section 1004.13 of this part.

(12) a construction timetable;

(13) a statement as to whether the applicant, any controlling person of the applicant, any manager, any sole proprietor applicant, any general partner of a partnership applicant, any officer and member of the board of directors of a corporate applicant, and corporate general partner had a prior discharge in bankruptcy or was found insolvent in any court action;

(14) if any controlling person of the applicant, any manager, any sole proprietor applicant, any general partner of a partnership applicant, any officer and member of the board of directors of a corporate applicant, or corporate general partner or a combination of such persons collectively, maintains a ten percent interest or greater in any firm, association, foundation, trust, partnership, corporation, or other entity or if such entity maintains a ten percent interest or greater in the applicant, and such entity will or may provide goods, leases, or services to the registered organization, the value of which is or would be five hundred dollars or more within any one year, the name and address of the entity shall be disclosed together with a description of the goods, leases or services and the probable or anticipated cost to the registered organization;

(15) if the applicant is a corporate subsidiary or affiliate of another corporation, disclosure of the parent or affiliate corporation including the name and address of the parent or affiliate, the primary activities of the parent or affiliate, the interest in the applicant held by the parent or affiliate and the extent to which the parent will be responsible for the financial and contractual obligations of the subsidiary;

(16) the most recent certified financial statement of the applicant, audited by an independent certified public accountant and prepared in accordance with generally accepted accounting principles (GAAP) applied on a consistent basis, including a balance sheet as of the end of the applicant's last fiscal year and income statements for the past two fiscal years, or such shorter period of time as the applicant has been in operation;

(17) if construction, lease, rental or purchase of the manufacturing or dispensing facility has not been completed, a statement indicating the anticipated source and application of the funds to be used in such purchase, lease, rental or construction;

(18) a staffing plan for staff involved in activities related to the cultivation of marihuana, the manufacturing and/or dispensing of approved medical marihuana products and/or staff with oversight responsibilities for such activities, which shall include:

(i) a senior staff member with a minimum of one (1) year experience in good agricultural practices (GAP);

(ii) a quality assurance officer who shall exercise oversight of the organization’s practices and procedures and who has documented training and experience in quality assurance and quality control procedures;

(iii) a requirement that all staff be twenty-one (21) years of age or older;

(iv) a requirement that all staff involved in the manufacturing be trained in and conform to general sanitary practices; and

(v) policies and procedures to ensure that the proposed registered organization shall not employ anyone who would come in contact with or handle medical marihuana who has been convicted of any felony of sale or

possession of drugs, narcotics, or controlled substances in accordance with the requirements of section thirty-three hundred sixty-four of the public health law.

(19) any other information as may be required by the commissioner.

(c) An application under this section may be amended while the matter is pending before the commissioner, if approved by the commissioner upon good cause shown.

(d) The applicant shall verify the truth and accuracy of the information contained in the application. The department, in its discretion, may reject an application if it determines that information contained therein is not true and accurate.

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Section 1004.6 - Consideration of registered organization applications

1004.6 Consideration of registered organization applications.

(a) Applicants for approval to operate as registered organizations shall submit an application to the department, containing the information required in section 1004.5, in a manner and format determined by the department.

(1) Applications shall be accompanied by a non-refundable application fee in the amount of $10,000.

(2) The registration fee for the registration period shall be $200,000. Applicants shall submit the registration fee by certified check, or another method approved by the Department, at the time of submission of the application. The registration fee shall be returned to the applicant if the applicant is not granted a registration under this part.

(3) Only applications completed in accordance with this part as determined by the department and for which the application and registration fees have been submitted shall be considered if submitted in a timely manner. The department shall return the fee for $200,000 to all applicants who are not granted a registration.

(b) The department shall initially register up to five applicants as registered organizations. In deciding whether to grant an application, or amendment to a registration, the department shall consider whether:

(1) the applicant will be able to manufacture approved medical marihuana products, each with a consistent cannabinoid profile (the concentration of total tetrahydrocannabinol (THC) and total cannabidiol (CBD) will define the brand) and each able to pass the required quality control testing;

(2) the applicant will produce sufficient quantities of approved medical marihuana products as necessary to meet the needs of certified patients;

(3) the applicant will be able to maintain effective control against diversion of marihuana and medical marihuana products;

(4) the applicant will be able to comply with all applicable state and local laws and regulations;

(5) the applicant is ready, willing and able to properly carry on the activities set forth in this part;

(6) the applicant possesses or has the right to use sufficient real property, buildings and equipment to properly carry on the activity described in its operating plan;

(7) it is in the public interest that such registration be granted;

(8) the number of registered organizations in an area will be adequate or excessive to reasonably serve the area, including whether there is sufficient geographic distribution across the state;

(9) the moral character and competence of board members, officers, managers, owners, partners, principal stakeholders, directors, and members of the applicant's organization;

(10) the applicant has entered into a labor peace agreement with a bona-fide labor organization, as defined in section thirty-three hundred sixty of the public health law, that is actively engaged in representing or attempting to represent the applicant's employees; and

(11) evaluation of the applicant's proposed operating plan and suitability of the proposed manufacturing and dispensing facilities, including but not limited to the suitability of the location and architectural and engineering design of the proposed facilities. Department approval of the applicant's operating plan and architectural and engineering design of the proposed facilities shall be required for issuance of a registration.

(c) The applicant shall allow reasonable access to the department and/or its authorized representatives for the purpose of conducting an on-site survey or inspection of the applicant's proposed manufacturing and/or dispensing facilities.

(d) If the commissioner is not satisfied that the applicant should be issued a registration, he or she shall notify the applicant in writing of those factors upon which further evidence is required. Within 30 days of the receipt of such notification, the applicant may submit additional material to the commissioner or demand a hearing, or both.

(e) Upon application to the department, a registered organization's registration may be amended to allow the registered organization to relocate within the state or to add or delete permitted registered organization activities or facilities. The department shall consider whether to grant or deny the application for amendment of the registration utilizing the criteria set forth in subdivision (b) of this section. The fee for such amendment shall be $250.

(f) Registrations issued shall be valid for two years from the date of issuance. To facilitate renewals of registrations, the commissioner may upon the initial application for a registration, issue some registrations which may remain valid for a period of time greater than two years, but not exceeding an additional eleven months. The registration fee will be prorated for the additional time exceeding two years.

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Section 1004.7 - Applications for renewal of registration as registered organization

1004.7 Applications for renewal of registration as registered organization

(a) An application to renew any registration issued under this part shall be filed with the department not more than six months nor less than four months prior to the expiration thereof. If a renewal application is not filed

at least four months prior to the expiration thereof, the department may determine that the registration shall have expired and become void on such expiration date.

(b) Applications shall be accompanied by a non-refundable application fee in the amount of $10,000. Applications shall also be accompanied by a registration fee in the amount of $200,000 made by certified check. Only applications completed in accordance with this part as determined by the department and for which the application and registration fees have been submitted shall be considered if submitted in a timely manner. The registration fee shall be returned to the applicant if the applicant is not granted a renewal registration under this section.

(c) The application for renewal shall include such information prepared in the manner and detail as the commissioner may require, including but not limited to:

(1) any material change as determined by the department in the information, circumstances or factors listed in section 1004.5 of this part;

(2) every known complaint, charge or investigation, pending or concluded during the period of the registration, by any governmental or administrative agency with respect to:

(i) each incident or alleged incidence involving the theft, loss, or possible diversion of medical marihuana manufactured, distributed, or dispensed by the registered organization; and

(ii) compliance by the applicant with local or state laws, or regulations of the department, including but not limited to, with respect to any substance listed in section thirty-three hundred six of the public health law;

(3) information concerning the applicant’s ability to carry on the manufacturing and distributing activity for which it is registered, including but not limited to approved medical marihuana product shortages or wait lists occurring during the registration period; and

(4) a summary of quality assurance testing for all medical marihuana products produced in the prior year including but not limited to the percentage of lots of each brand and form passing all required testing, the percentage of lots failing contaminant testing, the percentage of lots failing brand requirements, all recalls of product lots and all adverse events reported.

(d) The department shall consider applications for renewal in accordance with the criteria set forth in section thirty-three hundred sixty-five of the public health law.

(e) If the department determines that the applicant’s registration should not be renewed, the department shall serve upon the applicant or his or her attorney of record, in person or by registered or certified mail, an order directing the applicant to show cause why his or her application for renewal should not be denied. The order shall specify in detail the respects in which the applicant has not satisfied the department that the registration should be renewed.

(1) within ten (10) business days of receipt of such an order, the applicant may submit additional material to the department or demand a hearing, or both. If a hearing is demanded, the commissioner shall fix a date as soon as reasonably practicable.

(2) If the applicant fails to submit additional material to the department within ten (10) business days as requested, and the applicant does not demand a hearing within such time period, the application for renewal of registration shall be denied.

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Section 1004.8 - Registrations non-transferable

1004.8 Registrations non-transferable.

(a) Registrations issued under this part shall be effective only for the registered organization and shall specify:

(1) the name and address of the registered organization;

(2) name of the contact person for the registered organization;

(3) the activities the registered organization is permitted to perform under the registration for each approved location; and

(4) the real property, buildings and facilities that may be used for the permitted activities of the registered organization.

(b) Registrations are not transferable or assignable, including, without limitation, to another registered organization.

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Section 1004.9 - Failure to operate

1004.9 Failure to operate.

(a) A registration shall be surrendered to the department upon written notice and demand if the registered organization fails to begin operations, to the satisfaction of the department, of a manufacturing and/or dispensing facility within six months of the date of issuance of the registration.

(b) A registered organization who is required to surrender its registration in accordance with this section shall not be entitled to any refund of fees paid to the department.

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Section 1004.10 - Registered organizations; general requirements

1004.10 Registered organizations; general requirements

(a) In addition to the requirements in public health law and as otherwise set forth in this part, a registered organization shall:

(1) make its books, records and manufacturing and dispensing facilities available to the department or its authorized representatives for monitoring, on-site inspection, and audit purposes, including but not limited to

periodic inspections and/or evaluations of facilities, methods, procedures, materials, staff and equipment to assess compliance with requirements set forth in article 33 of the public health law and this part;

(i) Any deficiencies documented in a statement of findings by the department shall require that the registered organization submit a written plan of correction in a format acceptable to the department within 15 calendar days of the issue date of the statement of findings. A plan of correction shall address all deficiencies or areas of noncompliance cited in the statement of findings and shall:

(*a*) contain an assessment and analysis of the events and/or circumstances that led to the noncompliance;

(*b*) contain a procedure addressing how the registered organization intends to correct each area of noncompliance;

(*c*) contain an explanation of how proposed corrective actions will be implemented and maintained to ensure noncompliance does not recur;

(*d*) contain the proposed date by which each area of noncompliance shall be corrected;

(*e*) address any inspection finding which the department determines jeopardizes the immediate health, safety, or well-being of certified patients, designated caregivers or the public. Such a finding shall be deemed a critical deficiency and shall require immediate corrective action to remove the immediate risk, followed by the submission of a corrective action plan within 24 hours of notification by the department of the critical deficiency. The department will acknowledge receipt within 24 hours and respond as soon as practicable to notify if the plan is accepted or needs modification. If the corrective action plan needs modification, the registered organization shall modify the plan until it is accepted by the department.

(ii) Upon written approval of the department, the registered organization shall implement the plan of correction.

(2) only manufacture and dispense approved medical marihuana products in New York State in accordance with article 33 of the public health law and this part;

(3) only manufacture and dispense approved medical marihuana products in an indoor, enclosed, secure facility located in New York State which may include greenhouses;

(4) submit approved medical marihuana product samples and manufacturing materials to the department upon request, for but not limited to, quality assurance testing or investigation of an adverse event. A subset of each lot of medical marihuana product shall be retained by the registered organization to allow for testing in the future if requested by the department and shall be stored unopened as indicated on the label and in the original packaging. This subset of medical marihuana product must be readily identifiable as belonging to its specific lot. The quantity retained shall be a statistically representative number of samples to allow for complete testing of the product at least two times and shall be retained by the registered organization for at least thirty days following the date of expiration.

(5) implement policies and procedures to notify the department within 24 hours of the following:

(i) any adverse events;

(ii) any incident involving theft, loss or possible diversion of medical marihuana products;

(iii) any suspected or known security breach or other facility event that may compromise public health and/or safety, or which requires response by public safety personnel or law enforcement; and

(iv) any vehicle accidents or incidents occurring during transport of medical marihuana products.

(6) Within ten days of the occurrence of one of the above events, the registered organization shall submit a complete written incident report to the department detailing the circumstances of the event, any corrective actions taken, and where applicable, confirmation that appropriate law enforcement authorities were notified

(7) quarantine any lot of medical marihuana product as directed by the department, and not transport, distribute or dispense such lot unless prior approval is obtained from the department;

(8) dispose of unusable medical marihuana products that have failed laboratory testing or any marihuana used in the manufacturing process pursuant to section 1004.24 of this Part;

(9) maintain records required by article 33 of the public health law and this part for a period of five (5) years, unless otherwise stated, and make such records available to the department upon request. Such records shall include:

(i) documentation, including lot numbers where applicable, of all materials used in the manufacturing of the approved medical marihuana product to allow tracking of the materials including but not limited to soil, soil amendment, nutrients, hydroponic materials, fertilizers, growth promoters, pesticides, fungicides, and herbicides;

(ii) cultivation, manufacturing, packaging and labeling production records; and

(iii) laboratory testing results.

(10) post the certificate of registration issued by the department in a conspicuous location on the premises of each manufacturing facility and dispensing facility.

(b) Registered organizations shall not:

(1) dispense approved medical marihuana products from the same location where the marihuana is grown or manufactured;

(2) grow marihuana or produce medical marihuana at any site other than a facility or site approved by the department and set forth in the registered organization’s registration;

(3) distribute products or samples at no cost except as may be allowed by the commissioner;

(4) make substantial alterations to the structure or architectural design of a manufacturing or dispensing facility without prior written approval of the department;

(5) change the composition of the entity which is the registered organization, including but not limited to, a change in sole proprietor, partner, director, stockholder, member or membership interest of the registered organization without the prior written approval of the department;

(6) materially modify or revise its operating plan, including its policies and procedures related to cultivation, processing, manufacturing, distributing or dispensing policies or procedures, without prior written approval of the department.

(7) locate a dispensing facility on the same street or avenue and within one thousand feet of a building occupied exclusively as a school, church, synagogue or other place of worship. The measurements in this paragraph of this subdivision are to be taken in straight lines from the center of the nearest entrance of the premises sought to be used as a dispensing facility to the center of the nearest entrance of such school, church, synagogue or other place of worship; or

(8) be managed by or employ anyone who has been convicted of any felony of sale or possession of drugs, narcotics, or controlled substances provided that this provision only applies to:

(i) managers or employees who come into contact with or handle medical marihuana; and

(ii) a conviction less than ten years (not counting time spent in incarceration) prior to being employed, for which the person has not received a certificate of relief from disabilities or a certificate of good conduct under article 23 of the correction law.

(c) In the event that a registered organization elects to cease operation of all permitted activities and to surrender its registration, the following provisions shall apply:

(1) The registered organization shall notify the department in writing at least 120 days prior to the anticipated date of closure of the manufacturing and each dispensing facility.

(2) Such written notice shall include a proposed plan for closure. The plan shall be subject to department approval in accordance with department protocols, and shall include timetables and describe the procedures and actions the registered organization shall take to:

(i) notify affected certified patients and designated caregivers of the closure;

(ii) properly destroy, transfer or otherwise dispose of all the registered organization's supply of medical marihuana and medical marihuana products;

(iii) maintain and make available to the department all records required to be maintained under this part for a period of five years; and

(iv) maintain compliance with these regulations and any other conditions required by the commissioner until the approved closure date.

(3) A registered organization shall take no action to close a manufacturing and dispensing facility prior to department approval of the plan for closure.

(4) A registered organization's failure to notify the department of intent to cease any operations, failure to submit an approvable plan, and/or to execute the approved plan may result in the imposition of civil penalties, not to exceed $2,000, and shall be a basis for the department to revoke the registration of the registered organization under such terms as the department determines is appropriate based on public health and safety considerations. In addition, the department reserves the right to exercise any other remedies available to it.

(d) If a registered organization's application for renewal of registration is denied, the registered organization shall submit a proposed plan for closure in accordance with this section.

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Section 1004.11 - Manufacturing requirements for approved medical marihuana products

1004.11 Manufacturing requirements for approved medical marihuana products

(a) Definitions. Wherever used in this part, the following terms shall have the following meanings:

(1) "Approved medical marihuana product" is the final manufactured product delivered to the patient that represents a specific brand with a defined cannabinoid content and active and inactive ingredients, prepared in

a specific dosage and form, to be administered as recommended by the practitioner.

(2) “Brand” means a defined medical marihuana product that has a homogenous and uniform cannabinoid concentration (total THC and total CBD) and product quality, produced according to an approved and stable processing protocol and shall have the same inactive ingredients as that defined for that form of the brand.

(3) “Form” of medical marihuana shall be a type of a medical marihuana product approved by the commissioner and shall refer to the final preparation of an approved medical marihuana brand; for example, an extract in oil for sublingual administration, an extract for vaporization or an extract in a capsule for ingestion.

(4) “Lot” means a quantity of a medical marihuana extraction product that has a homogenous and uniform cannabinoid concentration and product quality, produced according to an approved and stable processing protocol specific to that brand and form of medical marihuana product, during the same cycle of manufacture.

(5) “Lot unique identifier (Lot number or bar code)” means any distinctive combination of letters, numbers, or symbols, or any combination of them, from which the complete history of manufacturing, testing, holding, distribution or recall of a lot of medical marihuana product can be determined.

(6) “Manufacturing” shall include, but not be limited to cultivation, harvesting, extraction (or other processing), packaging and labeling.

(b) A registered organization shall use either carbon dioxide (CO2, super-critical) or alcohol for cannabinoid extraction and shall only perform extraction of the leaves and flowers of female marihuana plants. A registered organization shall only use carbon dioxide that is of a supply equivalent to food or beverage grade of at least 99.5% purity; and alcohol used shall be of a grade that meets or exceeds specifications of official compendiums as defined in section 321 of Title 21 of the United States Code (USC). 21 USC §321 is available for copying and inspection at the Regulatory Affairs Unit, New York State Department of Health, Corning Tower, Empire State Plaza, Albany, New York 12237. A registered organization shall obtain prior written approval from the department if it seeks to use other extraction methods.

(c) A registered organization shall only produce such forms of medical marihuana as approved by the department according to the following requirements:

(1) Each registered organization may initially produce up to five brands of medical marihuana product with prior approval of the department. These brands may be produced in multiple forms as approved by the commissioner. Thereafter, additional brands may be approved by the department.

(2) Each medical marihuana product brand, in its final form, shall be defined as having a specific concentration of total Tetrahydrocannabinol (THC) and total Cannabidiol (CBD) and shall have a consistent cannabinoid profile. The concentration of the following cannabinoids, at a minimum, must be reported:

(i) Tetrahydrocannabinol (THC)

(ii) Tetrahydrocannabinol acid (THCA)

(iii) Tetrahydrocannabivarin (THCV)

(iv) Cannabidiol (CBD)

(v) Cannabinadiolic acid (CBDA)

(vi) Cannabidivarine (CBDV)

(vii) Cannabinol (CBN)

(viii) Cannabigerol (CBG)

(ix) Cannabichromene (CBC)

(x) Any other cannabinoid component at > 0.2 percent, for which there is a certified standard available at a customary cost.

(3) The final medical marihuana product shall not contain less than 90 percent or more than 110 percent of the concentration of total THC or total CBD indicated on the label for this brand and shall have no more than 10mg total THC per dose. However:

(i) Where the total THC concentration is less than 5 milligrams per dose, the concentration of total THC shall be within 0.5 milligrams per dose;

(ii) Where the total CBD concentration is less than 5 milligrams per dose, the concentration of total CBD shall be within 0.5 milligrams per dose; and

(iii) the concentration of total THC and CBD in milligrams per single dose for each sample of a brand lot submitted for testing must be within 25 percent of the mean concentration of total THC and CBD in milligrams per single dose for that submitted lot with the exception that, for brands with a specified total THC and CBD concentration less than 2 milligrams per single dose, the concentration of each sample for that low concentration cannabinoid shall be within 0.5 milligrams per dose of the mean concentration.

(4) The registered organization shall offer and make available to patients at least one brand that has a low THC and a high CBD content (e.g., a 1:20 ratio of THC to CBD).

(5) The registered organization shall offer and make available at least one brand that has approximately equal amounts of THC and CBD.

(6) For each brand offered, the registered organization shall only utilize a distinct name which has been approved by the department, consisting of only letters and/or numbers. The name shall not be coined or fanciful, and may not include any “street”, slang or other name. No reference shall be made to any specific medical condition.

(7) Each registered organization shall ensure the availability of at least a one year supply of any offered brand unless otherwise allowed by the department.

(d) The registered organization shall not add any additional active ingredients or materials to any approved medical marihuana product that alters the color, appearance, smell, taste, effect or weight of the product unless it has first obtained prior written approval of the department. Excipients must be pharmaceutical grade and approved by the department.

(e) A registered organization shall:

(1) use good agricultural practices (GAPs) and must conform to all applicable laws and rules of New York State;

(2) use water from a public water supply or present a plan, approved by the department, which demonstrates the ability to obtain sufficient quantities of water of equal or greater quality as that from a public water supply and to monitor the quality of such water on an ongoing basis;

(3) upon prior written notice to the department, only use pesticides that are registered by the New York State Department of Environmental Conservation or that specifically meet the United States Environmental Protection Agency registration exemption criteria for Minimum Risk Pesticides, and only in accordance with section 325.2(b) of title 6 of the NYCRR;

(4) process the leaves and flowers of the female plant only, in a safe and sanitary manner;

(5) perform visual inspection of the harvested plant material to ensure there is no mold, mildew, pests, rot or gray or black plant material;

(6) have a separate secure area for temporary storage of any medical marihuana or medical marihuana product that needs to be destroyed; and

(7) provide continual environmental monitoring for temperature, ventilation and humidity at all locations in the manufacturing facility where unprocessed leaf and flower material is stored, until further extraction or other processing is completed.

(f) Production of any approved medical marihuana product shall be in accordance with general sanitary conditions. Poisonous or toxic materials, including but not limited toinsecticides, rodenticides, detergents, sanitizers, caustics, acids and related cleaning compounds must be stored in a separate area from the marihuana and medical marihuana products in prominently and distinctly labeled containers, except that nothing herein precludes the convenient availability of detergents or sanitizers to areas where equipment, containers and utensils are washed and sanitized.

(g) Approved medical marihuana products shall be limited to the forms of administration approved by the Department, including but not limited to:

(1) metered liquid or oil preparations;

(2) solid and semisolid preparations (e.g. capsules, chewable and effervescent tablets, lozenges);

(3) metered ground plant preparations; and

(4) topical forms and transdermal patches.

(5) medical marihuana may not be incorporated into food products by the registered organization, unless approved by the commissioner.

(6) Smoking is not an approved route of administration.

(h) The registered organization shall package the final form of the approved medical marihuana product at the manufacturing site. The original seal shall not be broken except for quality testing at an approved laboratory, for adverse event investigations, by the department, by the certified patient or designated caregiver, or by the registered organization for internal quality control testing or disposal.

(i) The registered organization shall package the approved medical marihuana product such that it is child-resistant, tamper-proof/tamper-evident, light-resistant, and in a resealable package that minimizes oxygen exposure.

(j) The registered organization shall identify each lot of approved medical marihuana product with a lot unique identifier.

(k) Each approved medical marihuana product shall be affixed with a product label. Medical marihuana product labels shall be approved by the department prior to use. Each product label shall be applied at the manufacturing facility, be easily readable, firmly affixed and include:

(1) the name, address and registration number of the registered organization;

(2) the medical marihuana product form and brand designation;

(3) the single dose THC and CBD content for the product set forth in milligrams (mg);

(4) the medical marihuana product lot unique identifier (lot number or bar code);

(5) the quantity included in the package;

(6) the date packaged;

(7) the date of expiration of the unopened product, based on stability studies in accordance with section 1004.11(m)(2) of this title, or a tentative expiration date approved by the department;

(8) the proper storage conditions;

(9) language stating:

(i) “Medical marihuana products must be kept in the original container in which they were dispensed and removed from the original container only when ready for use by the certified patient”;

(ii) “Keep secured at all times”;

(iii) “May not be resold or transferred to another person”;

(iv) “This product might impair the ability to drive”;

(v) “KEEP THIS PRODUCT AWAY FROM CHILDREN (unless medical marihuana product is being given to the child under a practitioner’s care”); and

(vi) “This product is for medicinal use only. Women should not consume during pregnancy or while breastfeeding except on the advice of the certifying practitioner, and in the case of breastfeeding mothers, including the infant’s pediatrician.”

(l) For each lot of medical marihuana product produced, the registered organization shall submit a predetermined number of final medical marihuana products (e.g., sealed vials or capsules; with the number of samples submitted, based on statistical analysis, determined to be representative of the lot) to an independent laboratory/laboratories approved by the department. The laboratory verifying the cannabinoid content shall be approved for the analysis of medical marihuana product by the department in accordance with section five hundred two of the public health law and subpart 55-2 of this title. Such laboratory, or approved laboratories cumulatively, shall certify the medical marihuana product lot as passing all contaminant testing and verify that the content is consistent with the brand prior to the medical marihuana product being released from the manufacturer to any dispensing facility.

(1) Any lot not meeting the minimum standards or specifications for safety shall be rejected and destroyed by the registered organization in accordance with section 1004.24 of this Part.

(2) Any lot not meeting the minimum standards or specifications for brand consistency shall be reported to the department and not dispensed by a registered organization without prior written approval from the department.

(3) The registered organization shall keep and maintain records documenting submission of medical marihuana products to approved laboratories as required herein, and the results of the laboratory testing. The registered organization shall provide the department with such records upon request.

(m) The registered organization shall demonstrate the stability of each approved medical marihuana product produced (each brand in each form) by testing both the unopened and opened product at an approved laboratory in accordance with section 1004.14(h) of this title:

(1) the stability of opened products shall be validated under the conditions (light, temperature and humidity), specified for storage of the product and an expiration date for opened product shall be determined;

(2) the stability of unopened products (e.g., sealed packages or vials) shall be validated by ongoing stability testing and an expiration date for unopened products shall be determined.

(3) specifications regarding storage conditions must address storage at the manufacturing facility once the package is sealed, during transport, at the dispensing facility, in the patient's home and for samples retained for future testing.

(n) No synthetic marihuana additives nor any cannabinoid preparation not produced by a registered organization in an approved manufacturing facility shall be used in the production of any medical marihuana product; provided, however, that a registered organization may use hemp, or extracts derived from hemp, grown and processed under the authority of the New York State Department of Agriculture and Markets in the manufacturing of medical marihuana products.

(o) The registered organization's approved standard operating procedure for the aforementioned activities must be followed, unless otherwise approved by the department.

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Section 1004.12 - Requirements for dispensing facilities

1004.12 Requirements for dispensing facilities

(a) Medical marihuana products shall not be dispensed or handled unless an individual with an active New York State pharmacist license, as defined in article 137 of the Education Law, who has completed a four-hour course pursuant to section 1004.1 of this part, is on the premises and supervising the activity within the facility.

(b) Dispensing facilities shall only sell approved medical marihuana products, related products necessary for the approved forms of administration of medical marihuana, and items that promote health and well-being subject to disapproval of the department and only in such a manner as does not increase risks of diversion, theft or loss of approved medical marihuana products or risk physical, chemical or microbial contamination or deterioration of approved medical marihuana products.

(c) No approved medical marihuana products shall be vaporized or consumed on the premises of a dispensing facility.

(d) Dispensing facilities shall not dispense approved medical marihuana products to anyone other than a certified patient or designated caregiver.

(e) When dispensing approved medical marihuana products, the dispensing facility shall:

(1) not dispense an amount greater than a thirty (30) day supply to a certified patient, and not until the patient has exhausted all but a seven day supply provided pursuant to any previously dispensed medical marihuana product by any registered organization;

(2) ensure that medical marihuana product packaging shall not be opened by dispensing facility staff;

(3) provide a patient specific log of medical marihuana products (brand, administration form, and dosage, and dates dispensed and any return of product) to the patient, the patient's designated caregiver, if applicable, or

the patient's practitioner upon request;

(4) ensure the prescription monitoring program registry is consulted pursuant to 3343-a and section 3364 of the Public Health Law, prior to any sales transactions and dispensing of any approved medical marihuana products by the facility.

(f) The registered organization shall be responsible for maintaining the confidentiality of patients and the integrity of the security of the facility at all times. Access to medical marihuana storage areas and areas within the dispensing facility where security equipment and recordings are stored shall be restricted to:

(1) registered organization employees;

(2) employees of the department or its authorized representatives;

(3) emergency personnel responding to an emergency, and;

(4) other persons authorized by a manager of the registered organization for the sole purpose of maintaining the operations of the facility.

(i) The dispensing facility shall maintain a visitor log of all persons, other than registered organization employees or emergency personnel responding to an emergency, that access these secured areas, which shall include the name of the visitor, date, time and purpose of the visit. The visitor log shall be available to the department at all times during operating hours and upon request.

(g) the dispensing facility shall affix to the approved medical marihuana product package a patient specific dispensing label approved by the department, that is easily readable, and firmly affixed and includes:

(1) the name and registry identification number of the certified patient and designated caregiver, if any;

(2) the certifying practitioner's name;

(3) the dispensing facility name, address and phone number;

(4) the dosing and administration instructions;

(5) the quantity and date dispensed;

(6) any recommendation or limitation by the practitioner as to the use of medical marihuana; and

(7) the expiration date of the product once opened pursuant to section 1004.11(m)(1) of this Part.

(h) the dispensing facility shall place the approved medical marihuana product in a plain outer package when dispensing to the patient or designated caregiver.

(i) The dispensing facility shall ensure that each patient receives approved medical marihuana product from no more than two distinct lots for any 30-day supply dispensed.

(j) The dispensing facility shall include with each product package dispensed to a patient, a department approved package safety insert. Information provided shall include but not be limited to:

(1) the medical marihuana product and brand;

(2) a list of any excipients used;

(3) a warning if there is any potential for allergens in the medical marihuana product;

(4) contraindications;

(5) more specific dosage directions and instructions for administration;

(6) warning of adverse effects and/or any potential dangers stemming from the use of medical marihuana;

(7) instructions for reporting adverse effects as may be determined by the department;

(8) a warning about driving, operation of mechanical equipment, child care or making important decisions while under the influence of medical marihuana;

(9) information on tolerance, dependence and withdrawal and substance abuse, how to recognize what may be problematic usage of medical marihuana and obtain appropriate services or treatment;

(10) advice on how to keep the medical marihuana product secure;

(11) language stating that the certified patient may not distribute any medical marihuana product to anyone else;

(12) language stating that unwanted, excess, or contaminated medical marihuana product must be disposed of according to section 1004.20 of this part; and

(13) language stating that “this product has not been analyzed by the FDA. There is limited information on the side effects of using this product and there may be associated health risks.”

(k) The dispensing facility shall store the medical marihuana product in a manner to ensure that there is no contamination or deterioration of the medical marihuana product or its packaging.

(l) If an approved medical marihuana product is returned to the dispensing facility, the dispensing facility shall:

(1) dispose of such product pursuant to section 1004.24 of this part;

(2) provide the following information to the department:

(i) the name and registry identification number of the certified patient for whom the product was dispensed;

(ii) the date of the return;

(iii) the brand and form being returned;

(iv) the quantity and/or weight being returned;

(v) the reason for the return;

(vi) the name of the dispensing facility employee accepting the return; and

(vii) any other information required by the department;

(3) ensure the returned marihuana product is securely stored, separate from working inventory while awaiting disposal.

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Section 1004.13 - Security requirements for manufacturing and dispensing facilities

1004.13 Security requirements for manufacturing and dispensing facilities.

(a) All facilities operated by a registered organization, including any manufacturing facility and dispensing facility, shall have a security system to prevent and detect diversion, theft or loss of marihuana and/or medical marihuana products, utilizing commercial grade equipment, which shall, at a minimum, include:

(1) a perimeter alarm;

(2) motion detectors;

(3) video cameras in all areas that may contain marihuana and at all points of entry and exit, which shall be appropriate for the normal lighting conditions of the area under surveillance. The manufacturing facility or dispensing facility shall direct cameras at all approved safes, approved vaults, dispensing areas, marihuana sales areas and any other area where marihuana is being manufactured, stored, handled, dispensed or disposed of. At entry and exit points, the manufacturing facility or dispensing facility shall angle cameras so as to allow for the capture of clear and certain identification of any person entering or exiting the facility;

(4) twenty-four hour recordings from all video cameras, which the manufacturing facility or dispensing facility shall make available for immediate viewing by the department or the department's authorized representative upon request and shall be retained for at least 90 days. The registered organization shall provide the department with an unaltered copy of such recording upon request. If a registered organization is aware of a pending criminal, civil or administrative investigation or legal proceeding for which a recording may contain relevant information, the registered organization shall retain an unaltered copy of the recording until the investigation or proceeding is closed or the entity conducting the investigation or proceeding notifies the registered organization that it is not necessary to retain the recording;

(5) a duress alarm, which for purposes of this section means a silent security alarm system signal generated by the entry of a designated code into an arming station in order to signal that the alarm user is being forced to turn off the system;

(6) a panic alarm, which for purposes of this section, means an audible security alarm system signal generated by the manual activation of a device intended to signal a life threatening or emergency situation requiring a law enforcement response;

(7) a holdup alarm, which for purposes of this section, means a silent alarm signal generated by the manual activation of a device intended to signal a robbery in progress;

(8) an automatic voice dialer or digital dialer, which for purposes of this section, means any electrical, electronic, mechanical, or other device capable of being programmed to send a prerecorded voice message, when activated, over a telephone line, radio or other communication system, to a law enforcement, public safety or emergency services agency requesting dispatch, or other department approved industry standard equivalent;

(9) a failure notification system that provides an audible, text or visual notification of any failure in the surveillance system. The failure notification system shall provide an alert to the manufacturing facility or dispensing facility within five minutes of the failure, either by telephone, email, or text message;

(10) the ability to immediately produce a clear color still photo that is a minimum of 9600 dpi from any camera image (live or recorded);

(11) a date and time stamp embedded on all recordings. The date and time shall be synchronized and set correctly and shall not significantly obscure the picture; and

(12) the ability to remain operational during a power outage.

(b) A registered organization shall ensure that any manufacturing facility and dispensing facility maintains all security system equipment and recordings in a secure location so as to prevent theft, loss, destruction or alterations.

(c) In addition to the requirements listed in subdivision (a) of this section, each manufacturing facility and dispensing facility shall have a back-up alarm system approved by the department that shall detect unauthorized entry during times when no employees are present at the facility and that shall be provided by a company supplying commercial grade equipment.

(d) A registered organization shall limit access to any surveillance areas solely to persons that are essential to surveillance operations, law enforcement agencies, security system service employees, the department or the department's authorized representative, and others when approved by the department. A registered organization shall make available to the department or the department's authorized representative, upon request, a current list of authorized employees and service employees who have access to any surveillance room. A manufacturing facility and dispensing facility shall keep all on-site surveillance rooms locked and shall not use such rooms for any other function.

(e) A registered organization shall keep illuminated the outside perimeter of any manufacturing facility and dispensing facility that is operated under the registered organization's license.

(f) All video recordings shall allow for the exporting of still images in an industry standard image format (including .jpeg, .bmp, and .gif). Exported video shall have the ability to be archived in a proprietary format that ensures authentication of the video and guarantees that no alteration of the recorded image has taken place. Exported video shall also have the ability to be saved in an industry standard file format that can be played on a standard computer operating system. A registered organization shall erase all recordings prior to disposal or sale of the facility.

(g) A registered organization shall keep all security equipment in full operating order and shall test such equipment no less than semi-annually at each manufacturing facility and dispensing facility that is operated under the registered organization's registration. Records of security tests must be maintained for five years and made available to the department upon request.

(h) The manufacturing facility of the registered organization must be securely locked and protected from unauthorized entry at all times.

(1) The registered organization shall be responsible for ensuring the integrity of the security of the manufacturing facility and the maintenance of sanitary operations when permitting access to the facility.

(2) The manufacturing facility shall maintain a visitor log of all persons other than registered organization employees or emergency personnel responding to an emergency that access any secured areas, which shall include the name of the visitor, date, time and purpose of the visit. The visitor log shall be available to the department at all times during operating hours and upon request.

(i) All marihuana must be stored in a secure area or location within the registered organization accessible to the minimum number of employees essential for efficient operation and in such a manner as approved by the department in advance, to prevent diversion, theft or loss.

(1) Registered organizations shall return marihuana to its secure location immediately after completion of manufacture, distribution, transfer or analysis.

(j) All medical marihuana must be stored in such a manner as to protect against physical, chemical and microbial contamination and deterioration of the product.

(k) All approved safes, vaults or any other approved equipment or areas used for the manufacturing or storage of marihuana and approved medical marihuana products must be securely locked or protected from entry, except for the actual time required to remove or replace marihuana or approved medical marihuana products.

(l) Keys shall not be left in the locks or stored or placed in a location accessible to individuals who are not authorized access to marihuana or manufactured medical marihuana products.

(m) Security measures, such as combination numbers, passwords or biometric security systems, shall not be accessible to individuals other than those specifically authorized to access marihuana or manufactured medical marihuana products.

(n) Prior to transporting any medical marihuana, a registered organization shall complete a shipping manifest using a form determined by the department.

(1) A copy of the shipping manifest must be transmitted to the destination that will receive the products and to the department at least two business days prior to transport unless otherwise expressly approved by the department.

(2) The registered organization shall maintain all shipping manifests and make them available to the department for inspection upon request, for a period of 5 years.

(o) Approved medical marihuana products must be transported in a locked storage compartment that is part of the vehicle transporting the marihuana and in a storage compartment that is not visible from outside the vehicle.

(p) An employee of a registered organization, when transporting approved medical marihuana products, shall travel directly to his or her destination(s) and shall not make any unnecessary stops in between.

(q) A registered organization shall ensure that all approved medical marihuana product delivery times are randomized.

(r) A registered organization shall staff all transport vehicles with a minimum of two employees. At least one transport team member shall remain with the vehicle at all times that the vehicle contains approved medical marihuana products.

(s) A transport team member shall have access to a secure form of communication with employees at the registered organization’s manufacturing facility at all times that the vehicle contains approved medical marihuana products.

(t) A transport team member shall possess a copy of the shipping manifest at all times when transporting or delivering approved medical marihuana products and shall produce it to the commissioner, the commissioner’s authorized representative or law enforcement official upon request.

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Section 1004.14 - Laboratory testing requirements for medical marihuana

1004.14 Laboratory testing requirements for medical marihuana.

(a) Medical marihuana products produced by a registered organization shall be examined in a laboratory located in New York State that is licensed by the department's Bureau of Narcotic Enforcement and approved for the analysis of medical marihuana by the department in accordance with article 5 of the Public Health Law and Subpart 55-2 of this Title.

(b) No board member, officer, manager, owner, partner, principal stakeholder or member of a registered organization, or such persons' immediate family member, shall have an interest or voting rights in the laboratory performing medical marihuana testing.

(c) For final product testing, the registered organization shall submit to the laboratory a statistically significant number of samples containing the final medical marihuana product equivalent to the sealed medical marihuana product dispensed to the patient (e.g., liquid extract in a sealed bottle or intact sealed bottle of capsules). Upon prior written approval of the department, a registered organization may submit to the laboratory the final medical marihuana product sample packaged in a quantity less than that which would be provided to the patient if the sample is prepared and packaged in the identical manner as the product provided to the patient.

(d) Testing of the final medical marihuana product is mandatory. However, at the option of the registered organization, testing may be performed on components used for the production of the final medical marihuana product including but not limited to water or growing materials. Testing may also be performed on the final marihuana extract e.g. for cannabinoid profile verification or contaminant testing.

(e) Sampling and testing of each lot of final medical marihuana product shall be conducted with a statistically significant number of samples and with acceptable methodologies, approved by the department, such that there is assurance that all lots of each medical marihuana product are adequately assessed for contaminants and the cannabinoid profile is consistent throughout.

(f) Testing of the cannabinoid profile shall include, at a minimum, those analytes specified in section 1004.11(c)(2) of this part.

(g) Testing for contaminants in the final medical marihuana product shall include but shall not be limited to those analytes listed below. The department shall make available a list of required analytes and their acceptable limits as determined by the commissioner.

Analyte:

E. coli

Pseudomonas (for products to be vaporized)

Salmonella species

Enterococcus species

Bile tolerant gram negative bacteria, specifically including Klebsiella species

Clostridium botulinum

Aspergillus species

Mucor species

Penicillium species

Thermophilic Actinomycetes species

Aflatoxins B1, B2, G1, G2

Ochratoxin A

Antimony

Arsenic

Cadmium

Chromium

Copper

Lead

Nickel

Zinc

Mercury

Any pesticide used during production of the medical marihuana product

Any growth regulator used during production of the medical marihuana product

Any other analyte as required by the commissioner

(h) laboratories performing final product testing pursuant to this section must report all results to the department, in a manner and timeframe prescribed by the department.

(i) Stability testing shall be performed on each brand and form of medical marihuana product as follows:

(1) For testing of open products, stability testing shall be performed for each extract lot, at time zero when opened and then, at a minimum, at 60 days from the date of first analysis. This shall establish use of the product lot within a specified time once opened.

(2) For testing of unopened products, until stability studies have been completed, a registered organization may assign a tentative expiration date based on available stability information. The registered organization must concurrently have stability studies conducted by an approved laboratory to determine the actual expiration date of an unopened product.

(3) For stability testing of both opened and unopened products, each brand shall retain a total THC and total CBD concentration in milligrams per single dose that is consistent with section 1004.11(c)(3). If stability testing demonstrates that a product no longer retains a consistent concentration of THC and CBD pursuant to section 1004.11(a)(2) of this Part, the product shall be deemed no longer suitable for dispensing or consumption. The department may request further stability testing of a brand to demonstrate the ongoing stability of the product produced over time.

(4) The department may waive any of the requirements of this subsection upon good cause shown.

(j) The laboratory shall track and use an approved method to dispose of any quantity of medical marihuana product that is not consumed in samples used for testing. Disposal of medical marihuana shall mean that the medical marihuana has been rendered unrecoverable and beyond reclamation.

(k) Any submitted medical marihuana products that are deemed unsuitable for testing shall be returned to the registered organization under chain of custody.

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Section 1004.15 - Pricing

1004.15 Pricing.

(a) Definitions. For purposes of this section, the following terms have the following meanings:

(1) “Cost analysis” shall mean the review and evaluation of the separate cost elements and profit of a proposed price and the application of judgment to determine how well the proposed costs represent what the price per unit for approved medical marihuana products should be, assuming reasonable economy and efficiency.

(2) “Price” shall mean the cost to manufacture, market and distribute approved medical marihuana products plus a reasonable profit.

(b) Department Approval Required. A registered organization shall only charge a price for an approved medical marihuana product that has been approved by the department.

(c) Determination of Price. The department shall set the per unit price of each form of approved medical marihuana product sold by any registered organization, as follows:

(1) Registered organizations shall submit a proposed price per unit for each form of medical marihuana indicated in its registration. Registered organizations shall submit such information and documentation, in a manner and format determined by the department, sufficient for the department to perform a cost analysis of the proposed price. In particular, the registered organization shall, in a manner and format determined by the department, provide a detailed breakdown of, and submit information and documentation concerning, all costs it factored to arrive at its proposed price, including but not limited to its fixed and variable costs such as materials and services; direct labor; and indirect costs.

(2) The registered organization shall provide cost or pricing data that is accurate and reliable, and shall certify, at the time of submission of its price proposal, that to the best of its knowledge and belief, the cost or pricing data were accurate, complete, and current as of the date of submission.

(3) The department shall determine the reasonableness of the proposed costs. In making this determination, the department may consider whether the costs represent inefficient and uneconomical practices; are not costs appropriately attributable to the price; and/or are costs unsupported by sufficient documentation or information to justify their inclusion in the proposed price. If the registered organization has been granted a renewal of its registration, any relevant historical price, cost and/or sales data of the registered organization; and any other information the commissioner deems appropriate.

(4) The department may approve the proposed price, refuse approval of a proposed price, or modify or reduce the proposed price.

(d) Examination of Records for Determination of Price. The registered organization shall grant the department or the department’s authorized representative the right to examine records that formed the basis for the proposed price, including the registered organization’s books, records, documents and other types of factual information that will permit an adequate evaluation of the proposed price.

(e) Correction of Insufficient Price Data. If the registered organization or department determines that the cost or pricing data submitted is inaccurate, incomplete or noncurrent prior to the department's approval of the price, the registered organization shall submit new data to correct the deficiency, or consider the inaccuracy, incompleteness, or noncurrency of the data.

(f) Duration of Price Determination. The department's approved price shall be in effect for the entire period of the registered organization's registration; provided, however, that at the conclusion of the first year of the registration period, or prior to that time based upon documented exceptional circumstances, the registered organization may request that the price be modified based upon a material change in the registered organization's costs. The registered organization shall fully support its request with sufficient information and documentation, in a manner and format determined by the department, to justify its request. If the department denies such request, the registered organization shall only charge prices previously approved by the department.

(g) Adjustments to determined price. If the department has approved a price, the registered organization shall immediately notify the department of any cost or pricing data submitted that it determines was inaccurate, incomplete, or noncurrent as of the date of the department's approval of the price. If the registered organization provides such notice, or if the department independently learns of such inaccurate, incomplete or noncurrent data, the department may require the registered organization to provide new data to correct the deficiency, or consider the inaccuracy, incompleteness, or noncurrency of the data. The department may adjust the price per dose if the defective data significantly increased the price approved by the department.

(h) Audits. The department may perform audits, which may include site visits. The registered organization shall provide reasonable access to the department of its facilities, books and records.

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Complete

Section 1004.16 - Medical marihuana marketing and advertising by registered organizations

1004.16 Medical marihuana marketing and advertising by registered organizations

(a) All physical structures owned, leased or otherwise utilized by a registered organization, including any dispensing facility, shall:

(1) Not advertise medical marihuana brand names or utilize graphics related to marihuana or paraphernalia on the exterior of the physical structures; and

(2) Not display medical marihuana products and paraphernalia so as to be clearly visible from the exterior of a physical structure.

(b) All restrictions listed in subdivision (a) of this section shall apply to any item located on any real property on which a registered organization's physical structures is located.

(c) All restrictions listed in subdivision (a) of this section shall apply to all vehicles owned, leased or utilized by a registered organization.

(d) All advertisements, regardless of form, for approved medical marihuana products that make a statement relating to effectiveness, side effects, consequences or contraindications shall present a true and accurate statement of such information.

(e) An advertisement does not satisfy the requirement that it presents a "true and accurate statement" of information relating to effectiveness, side effects, consequences, and contraindications if it fails to present a fair balance between information relating to effectiveness, side effects, consequences, and contraindications in that the information relating to effectiveness is presented in greater scope, depth, or detail than is the information relating to side effects, consequences and contraindications, taking into account all implementing factors such as typography, layout, contrast, headlines, paragraphing, white space, and any other techniques apt to achieve emphasis.

(f) An advertisement is false, lacking in fair balance, or otherwise misleading if it:

(1) contains a representation or suggestion that one marihuana brand or form is better, more effective, useful in a broader range of conditions or patients or safer than other drugs or treatments including other marihuana brands or forms, unless such a claim has been demonstrated by substantial scientific or clinical experience;

(2) Contains favorable information or opinions about a marihuana product previously regarded as valid but which have been rendered invalid by contrary and more credible recent information;

(3) Uses a quote or paraphrase out of context or without citing conflicting information from the same source, to convey a false or misleading idea;

(4) Uses a study on persons without a debilitating medical condition without disclosing that the subjects were not suffering from a debilitating medical condition;

(5) Uses data favorable to a marihuana product derived from patients treated with a different product or dosages different from those recommended in New York State;

(6) Contains favorable information or conclusions from a study that is inadequate in design, scope, or conduct to furnish significant support for such information or conclusions; or

(7) Fails to provide adequate emphasis for the fact that two or more facing pages are part of the same advertisement when only one page contains information relating to side effects, consequences and contraindications.

(g) False or misleading information in any part of the advertisement shall not be corrected by the inclusion of a true statement in another distinct part of the advertisement.

(h) An advertisement for any approved medical marihuana product shall not contain:

(1) any statement that is false or misleading;

(2) any statement that falsely disparages a competitor's products;

(3) any statement, design, or representation, picture or illustration that is obscene or indecent;

(4) any statement, design, representation, picture or illustration that encourages or represents the use of marihuana for a condition other than a serious condition as defined in subdivision seven of section thirty-three hundred sixty of the public health law;

(5) any statement, design, representation, picture or illustration that encourages or represents the recreational use of marihuana;

(6) any statement, design, representation, picture or illustration related to the safety or efficacy of marihuana, unless supported by substantial evidence or substantial clinical data;

(7) any statement, design, representation, picture or illustration portraying anyone under the age of 18, objects suggestive of the presence of anyone under the age of 18, or containing the use of a figure, symbol or

language that is customarily associated with anyone under the age of 18;

(8) any offer of a prize, award or inducement to a certified patient, designated caregiver or practitioner related to the purchase of marihuana or a certification for the use of marihuana; or

(9) any statement that indicates or implies that the product or entity in the advertisement has been approved or endorsed by the commissioner, department, New York State or any person or entity associated with New York State provided that this shall not preclude a factual statement that an entity is a registered organization.

(i) Any advertisement for an approved medical marihuana product, which makes any claims or statements regarding efficacy, shall be submitted to the department at least 10 business days prior to the public dissemination of the advertisement.

(j) The submitter of the advertisement shall provide the following information to the department in addition to the advertisement itself:

(1) A cover letter that:

(i) provides the following subject line: Medical marihuana advertisement review package for a proposed advertisement;

(ii) provides a brief description of the format and expected distribution of the proposed advertisement; and

(iii) provides the submitter’s name, title, address, telephone number, fax number, and email address;

(2) an annotated summary of the proposed advertisement showing every claim being made in the advertisement and which references support for each claim;

(3) verification that a person identified in an advertisement as an actual patient or health care practitioner is an actual patient or health care practitioner and not a model or actor;

(4) verification that a spokesperson who is represented as an actual patient is indeed an actual patient;

(5) verification that an official translation of a foreign language advertisement is accurate;

(6) annotated references to support disease or epidemiology information, cross-referenced to the advertisement summary; and

(7) a final copy of the advertisement, including a video where applicable, in a format acceptable to the department.

(k) Advertising packages that are missing any of the elements in subdivision (j) of this section, or that fail to follow the specific instructions for submissions, shall be considered incomplete. If the department receives an incomplete package, it shall so notify the submitter.

(l) No advertisement may be disseminated if the submitter of the advertisement has received information that has not been widely publicized in medical literature that the use of any approved medical marihuana product may cause fatalities or serious damage to a patient.

(m) A registered organization, its officers, managers and employees shall not cooperate, directly or indirectly, in any advertising if such advertising has the purpose or effect of steering or influencing patient or caregiver choice with regard to the selection of a practitioner. Nothing contained within this section prevents a registered organization from educating practitioners about approved medical marihuana products offered by the registered organization.

(n) The department may:

(1) require a specific disclosure be made in the advertisement in a clear and conspicuous manner if the department determines that the advertisement would be false or misleading without such a disclosure; or

(2) require that changes be made to the advertisement that are:

(i) necessary to protect the public health, safety and welfare; or

(ii) consistent with dispensing information for the product under review.

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Complete

Section 1004.17 - Reporting dispensed medical marihuana products

1004.17 Reporting dispensed medical marihuana products.

(a) A record of all approved medical marihuana products that have been dispensed shall be filed electronically with the department, utilizing a transmission format acceptable to the department, not later than 24 hours after the marihuana was dispensed to the certified patient or designated caregiver.

(b) The information filed with the department for each approved medical marihuana product dispensed shall include but not be limited to:

(1) a serial number that will be generated by the dispensing facility for each approved medical marihuana product dispensed to the certified patient or designated caregiver;

(2) an identification number which shall be populated by a number provided by the department, to identify the registered organization’s dispensing facility;

(3) the patient name, date of birth and sex;

(4) the patient address, including street, city, state, zip code;

(5) the patient’s registry identification card number;

(6) if applicable, designated caregiver’s name and registry identification card number;

(7) the date the approved medical marihuana product was filled by the dispensing facility;

(8) the metric quantity for the approved medical marihuana product;

(9) the medical marihuana product drug code number, which shall be populated by a number provided by the department, to represent the approved medical marihuana brand that was dispensed to the certified patient or designated caregiver, as applicable;

(10) the number of days supply dispensed;

(11) the registered practitioner’s Drug Enforcement Administration number;

(12) the date the written certification was issued by the registered practitioner; and

(13) the payment method.

(c) When applicable, a registered organization shall file a zero report with the department, in a format acceptable to the department. For the purposes of this section, a zero report shall mean a report that no approved medical marihuana product was dispensed by a registered organization during the relevant period of time. A zero report shall be submitted no later than 14 days following the most recent previously reported dispensing of an approved medical marihuana product or the submission of a prior zero report.

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Section 1004.18 - Prohibition the use of approved medical marihuana products in certain places

1004.18 Prohibition the use of approved medical marihuana products in certain places.

(a) Approved medical marihuana products shall not be vaporized in a public place. In no event shall approved medical marihuana products be consumed through vaporization in any location in which smoking is prohibited under section thirteen hundred ninety-nine of the public health law, including

(1) places of employment;

(2) bars;

(3) food service establishments, except as provided in subdivision six of section thirteen hundred ninety-nine-q of the public health law;

(4) enclosed indoor areas open to the public containing a swimming pool;

(5) public means of mass transportation, including subways, underground subway stations, and when occupied by passengers, buses, vans, taxicabs and limousines;

(6) ticketing, boarding and waiting areas in public transportation terminals;

(7) youth centers and facilities for detention as defined in sections five hundred twenty-seven-a and five hundred three of the executive law;

(8) any facility that provides child care services as defined in section four hundred ten-p of the social services law, provided that such services provided in a private home are excluded from this subdivision when children enrolled in such day care are not present;

(9) child day care centers as defined in section three hundred ninety of the social services law and child day care centers licensed by the city of New York;

(10) group homes for children as defined in section three hundred seventy-one of the social services law;

(11) public institutions for children as defined in section three hundred seventy-one of the social services law;

(12) residential treatment facilities for children and youth as defined in section 1.03 of the mental hygiene law;

(13) all public and private colleges, universities and other educational and vocational institutions, including dormitories, residence halls, and other group residential facilities that are owned or operated by such colleges, universities and other educational and vocational institutions;

(14) general hospitals and residential health care facilities as defined in article twenty-eight of the public health law, and other health care facilities licensed by the state in which persons reside; provided, however, that the provisions of this subdivision shall not prohibit vaporization by patients in separate enclosed rooms of hospitals, residential health care facilities, and adult care facilities established or certified under title two of article seven of the social services law, community mental health residences established under section 41.44 of the mental hygiene law, or facilities where day treatment programs are provided, which are designated as smoking rooms for patients of such facilities or programs;

(15) commercial establishments used for the purpose of carrying on or exercising any trade, profession, vocation or charitable activity;

(16) indoor arenas;

(17) zoos;

(18) bingo facilities

(b) Vaporization of approved medical marihuana products shall not be permitted and no person shall vaporize an approved medical marihuana product within one hundred feet of the entrances, exits or outdoor areas of any public or private elementary or secondary schools; however, that the provisions of this subdivision shall not apply to vaporization in a residence, or within real property boundary lines of such residential real property.

(c) Consumption of approved medical marihuana product shall not be permitted in any motor vehicle, either public or private, that is located upon public highways, private roads open to motor vehicle traffic, parking area of a shopping center or any parking lot, as defined in section 129 of the Vehicle and Traffic Law.

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Wednesday, April 15, 2015
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Section 1004.19 - Reporting requirements for registered practitioners, certified patients and designated caregivers

1004.19 Reporting requirements for registered practitioners, certified patients and designated caregivers.

(a) A practitioner shall report to the department, in a manner determined by the department, the death of a certified patient or change in status of a serious condition involving a certified patient for whom the practitioner has issued a certification if such change may affect the patient’s continued eligibility for certification for use of approved medical marihuana product. A practitioner shall report such death or change of status not more than five (5) business days after the practitioner becomes aware of such fact.

(b) If a practitioner re-issues a patient’s certification to terminate the certification on an earlier date, then the registry identification card shall expire on such earlier date and shall be promptly returned to the department by the certified patient or designated caregiver.

(c) a practitioner shall report patient adverse events to the department, in a manner determined by the department, not more than five business days after the practitioner becomes aware of such adverse event, except that serious adverse events shall be reported not more than one business day after the practitioner becomes aware of such adverse event.

(d) A certified patient or designated caregiver, who has been issued a registry identification card, shall notify the department of any change in the information provided to the department not later than ten (10) business days after such change. A certified patient or designated caregiver shall report changes that include, but are not limited to, a change in the certified patient's name, address, contact information, medical status. A certified patient or designated caregiver shall report such changes on a form, and in a manner, determined by the department. Should a certified patient cease to have the serious condition noted on his or her certification, the certified patient or designated caregiver shall notify the department of such within 10 days and the certified patient's and designated caregiver's registry identification cards shall be considered void and shall be returned promptly to the department.

(e) If a certified patient's or designated caregiver's appearance has substantially changed such that the photograph submitted to the department does not accurately resemble such certified patient or designated caregiver, such person shall submit, in a timely manner, an updated photograph that meets the requirements set forth by the department.

(f) If a certified patient has a designated caregiver, that designated caregiver may notify the department of any changes on behalf of the certified patient using the same forms and process prescribed for certified patients.

(g) If a certified patient or designated caregiver notifies the department of any change that results in information on the registry identification card being inaccurate or the photograph needing to be replaced, the certified patient or designated caregiver shall obtain a replacement registry identification card. The department shall thereafter issue the certified patient or designated caregiver a new registry identification card. Upon receipt of a new registry identification card, the certified patient or designated caregiver shall destroy in a non-recoverable manner the registry identification card that was replaced.

(h) If a certified patient or designated caregiver becomes aware of the loss, theft or destruction of the registry identification card of such certified patient or designated caregiver, the certified patient or designated caregiver shall notify the department, on a form and in a manner prescribed by the department, not later than ten days of becoming aware of the loss, theft or destruction. The department shall inactivate the initial registry identification card upon receiving such notice and issue a replacement registry identification card upon receiving the applicable fee provided the applicant continues to satisfy the requirements of section thirty-three hundred sixty-one of the public health law and section 1004.3 of this part. Prior to issuance of the first replacement registry identification card, a certified patient or designated caregiver shall submit to the department a fee of $25, transmitted in a fashion as determined by the department. For each subsequent replacement registry identification card a certified patient or designated caregiver shall submit to the department a fee of $50, transmitted in a fashion as determined by the department.

(i) If a certified patient wishes to change or terminate his or her designated caregiver, the certified patient shall notify the department, in a manner determined by the department, and shall notify his or her designated caregiver as soon as practicable.

(1) The department shall issue a notification, in a format determined by the department, to the designated caregiver and the certified patient that the designated caregiver's registration card is invalid.

(2) In the event that the designated caregiver has no other active certified patients, the designated caregiver's registration card must be returned to the department within 10 business days.

(3) In the event that the certified patient has selected another designated caregiver, the proposed designated caregiver must register with the department as defined in section 1004.4 of this part.

(j) If a designated caregiver wishes to terminate his or her relationship with a certified patient, the designated caregiver shall notify the department, in a manner determined by the department, and shall notify the certified patient, as soon as practicable.

(1) the department shall issue a notification, in a format determined by the department, to the certified patient and the designated caregiver that the designated caregiver has terminated his or her relationship with the certified patient.

(2) in the event that the designated caregiver has no other active certified patients, the designated caregiver's registration card must be returned to the department within ten business days.

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Section 1004.20 - Proper disposal of medical marihuana products by certified patients or designated caregivers

1004.20 Proper disposal of medical marihuana products by certified patients or designated caregivers

(a) A certified patient or designated caregiver shall dispose of all approved medical marihuana product in the certified patient's or designated caregiver's possession no later than ten calendar days after the expiration of the patient's certification, if such certification is not renewed, or sooner should the patient no longer wish to possess medical marihuana.

(b) A certified patient or designated caregiver shall complete disposal of approved medical marihuana products by one of the following methods:

(1) rendering the approved medical marihuana product non-recoverable beyond reclamation in accordance with the Department of Environmental Conservation's guidance; or;

(2) returning the approved medical marihuana product to the dispensing facility from which it was purchased or any dispensing facility associated with the registered organization which manufactured the approved medical marihuana product, to the extent that the registered organization accepts product returns.

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Wednesday, December 27, 2017
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Section 1004.21 - General Prohibitions

1004.21 General Prohibitions.

(a) No person, except for a certified patient or designated caregiver, or an approved laboratorian shall open or break the seal placed on an approved medical marihuana product packaged by a registered organization and provided to the certified patient.

(b) No person associated with a registered organization shall enter into any agreement with a registered practitioner or health care facility concerning the provision of services or equipment that may adversely affect any person's freedom to choose the dispensing facility at which the certified patient or designated caregiver will purchase approved medical marihuana products.

(c) No approved medical marihuana product shall be sold, dispensed or distributed via a delivery service without prior written approval to the registered organization by the department, except that a designated caregiver may deliver the approved medical marihuana product to the designated caregiver's certified patient.

(d) No employee of a registered organization shall counsel a certified patient or designated caregiver on the use, administration of, and the risks associated with approved medical marihuana products, unless the employee is a physician, nurse practitioner, physician assistant or pharmacist with an active New York State license who has completed a four hour course pursuant to section 1004.1 of this part, or the employee is under the direct supervision of, and in consultation with, such physician, nurse practitioner, physician assistant, or the pharmacist on-site in the dispensing facility.

(e) No certified patient or designated caregiver shall be in possession of approved medical marihuana products without having in his or her possession his or her registry identification card. The certified patient or designated caregiver, upon request by the department or law enforcement, shall present such card to verify that the certified patient or designated caregiver is authorized to possess approved medical marihuana products.

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Section 1004.22 - Practitioner prohibitions

1004.22 Practitioner prohibitions

(a) A practitioner that is registered with the department shall not:

(1) directly or indirectly accept, solicit, or receive any item of value from a registered organization;

(2) offer a discount or any other item of value to a certified patient based on the patient's agreement or decision to use a particular practitioner, registered organization, brand or specific form of approved medical marihuana product produced by a registered organization;

(3) examine a qualifying patient for purposes of diagnosing a debilitating medical condition at any location owned or operated by a registered organization, or where medical marihuana products or related products necessary for the approved forms of administration of medical marihuana are acquired, distributed, dispensed, manufactured, sold, or produced; or

(4) directly or indirectly benefit from a patient obtaining a written certification. Such prohibition shall not prohibit a practitioner from charging an appropriate fee for the patient visit.

(b) A practitioner that issues written certifications, and such practitioner's co-worker, employee, spouse, parent, child, or sibling shall not have a direct or indirect financial interest in a registered organization or any other entity that may benefit from a certified patient's or designated caregiver's acquisition, purchase or use of approved medical marihuana products, including any formal or informal agreement whereby a registered organization provides compensation if the practitioner issues a written certification for a certified patient or steers a certified patient to a specific dispensing facility.

(c) A practitioner shall not issue a certification for himself/herself or for the practitioner's family members, employees or co-workers.

(d) A practitioner shall not receive or provide product samples containing marihuana.

(e) A practitioner shall not be a designated caregiver for any patients that he or she has certified under section 1004.2 of this Part. However, this shall not prohibit a facility, or a division, department, component, floor or other unit from being a designated caregiver pursuant to section 1004.4 of this Part.

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Statutory Authority:
Public Health Law, Section 3369-a

Section 1004.23 - Designated Caregiver Prohibitions and Protections

1004.23 Designated Caregiver Prohibitions and Protections

(a) An individual shall not serve as a designated caregiver for more than five certified patients at any given time.

(b) A designated caregiver may only obtain payment from the certified patient to be used for the cost of the approved medical marihuana product purchased for the certified patient in the actual amount charged by the registered organization; provided, however, that a designated caregiver may charge the certified patient for reasonable costs incurred in the transportation, delivery, storage and administration of approved medical marihuana products.

(c) Designated caregivers, including employees of facilities registered as designated caregivers and acting within their scope of employment, shall not be subject to arrest, prosecution, or penalty in any manner, or denied any right or privilege, including but not limited to civil penalty or disciplinary action by a business or occupational or professional licensing board or bureau, solely for an action or conduct in accordance with this Part.

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Statutory Authority:
Public Health Law, Section 3369-a

Section 1004.24 - Registered organizations; disposal of medical marihuana

1004.24 Registered organizations; disposal of medical marihuana

(a) The disposal of medical marihuana shall mean that the medical marihuana has been rendered unrecoverable and beyond reclamation.

(b) Registered organizations shall dispose of any medical marihuana that is outdated, damaged, deteriorated, contaminated or otherwise deemed not appropriate for manufacturing or dispensing, or any plant-based waste created as a by-product of the manufacturing processes. Registered organizations shall:

(1) obtain department approval of disposal methods; and

(2) dispose of liquid and chemical waste in accordance with applicable federal, state and local laws and regulations.

(c) registered organizations shall maintain records of disposal, which shall include:

(1) the type of plant material being disposed, if the material is a by-product of the manufacturing process;

(2) the brand and form of approved medical marihuana product being disposed, if a finished product;

(3) the weight of the disposed material, the number of plants, or in the case of a finished product, the quantity of the disposed product; and

(4) the signatures of at least two registered organization staff members who witnessed the disposal.

(d) All records of disposal shall be retained for at least five years and be made available for inspection by the department.

Effective Date:
Wednesday, December 27, 2017

STATE OF NEW YORK

6579--A

2019-2020 Regular Sessions

IN SENATE

June 16, 2019

Introduced by Sens. BAILEY, MYRIE -- read twice and ordered printed, and when printed to be committed to the Committee on Rules -- committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee

AN ACT to amend the penal law and the criminal procedure law, in relation to vacating records for certain proceedings; and to amend the public health law, in relation to the definition of smoking

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

Section 1. Section 221.05 of the penal law, as added by chapter 360 of the laws of 1977, is amended to read as follows:

§ 221.05 Unlawful possession of marihuana **in the second degree**.

A person is guilty of unlawful possession of marihuana **in the second degree** when he knowingly and unlawfully possesses marihuana.

Unlawful possession of marihuana **in the second degree** is a violation punishable only by a fine of not more than [~~one hundred~~] **fifty** dollars. [~~However, where the defendant has previously been convicted of an offense defined in this article or article 220 of this chapter, committed within the three years immediately preceding such violation, it shall be punishable (a) only by a fine of not more than two hundred dollars, if the defendant was previously convicted of one such offense committed during such period, and (b) by a fine of not more than two hundred fifty dollars or a term of imprisonment not in excess of fifteen days or both, if the defendant was previously convicted of two such offenses committed during such period.~~]

§ 2. Section 221.10 of the penal law, as amended by chapter 265 of the laws of 1979 and subdivision 2 as amended by chapter 75 of the laws of 1995, is amended to read as follows:

§ 221.10 [~~Criminal~~] **Unlawful** possession of marihuana in the [~~fifth~~] **first** degree.

A person is guilty of [~~criminal~~] **unlawful** possession of marihuana in the [~~fifth~~] **first** degree when he knowingly and unlawfully possesses[~~:~~

~~1. marihuana in a public place, as defined in section 240.00 of this chapter, and such marihuana is burning or open to public view; or~~

EXPLANATION--Matter in ***italics*** (underscored) is new; matter in brackets [-] is old law to be omitted.

LBD13421-04-9

~~2.~~] one or more preparations, compounds, mixtures or substances containing marihuana and the preparations, compounds, mixtures or substances are of an aggregate weight of more than [~~twenty-five grams~~] **one ounce**.

[~~Criminal~~] **Unlawful** possession of marihuana in the [~~fifth~~] **first** degree is a [~~class B misdemeanor~~] **violation punishable only by a fine of not more than two hundred dollars**.

§ 3. Subparagraph (ii) of paragraph (i) and paragraph (j) of subdivision 1 of section 440.10 of the criminal procedure law, subparagraph (ii) of paragraph (i) as amended by section 3 of part OO of chapter 55 of the laws of 2019, paragraph (j) as amended by section 2 of part MMM of chapter 59 of the laws of 2019, are amended and a new paragraph (k) is added to read as follows:

(ii) official documentation of the defendant's status as a victim of trafficking, compelling prostitution or trafficking in persons at the time of the offense from a federal, state or local government agency shall create a presumption that the defendant's participation in the offense was a result of having been a victim of sex trafficking, compelling prostitution or trafficking in persons, but shall not be required for granting a motion under this paragraph; [~~or~~]

(j) The judgment is a conviction for a class A or unclassified misdemeanor entered prior to the effective date of this paragraph and satisfies the ground prescribed in paragraph (h) of this subdivision. There shall be a rebuttable presumption that a conviction by plea to such an offense was not knowing, voluntary and intelligent, based on ongoing collateral consequences, including potential or actual immigration consequences, and there shall be a rebuttable presumption that a conviction by verdict constitutes cruel and unusual punishment under section five of article one of the state constitution based on such consequences[~~.~~]**; or**

(k) The judgment occurred prior to the effective date of this paragraph and is a conviction for an offense as defined by section 221.05 or 221.10 of the penal law as in effect prior to the effective date of this paragraph in which case the court shall grant the motion.

§ 4. Subdivision 6 of section 440.10 of the criminal procedure law, as added by chapter 332 of the laws of 2010, is amended to read as follows:

6. If the court grants a motion under paragraph (i) **or paragraph (k)** of subdivision one of this section, it must vacate the judgment and dismiss the accusatory instrument, and may take such additional action as is appropriate in the circumstances.

§ 5. Paragraph (k) of subdivision 3 of section 160.50 of the criminal procedure law, as added by chapter 835 of the laws of 1977 and as relettered by chapter 192 of the laws of 1980, is amended to read as follows:

(k) [~~(i)~~] The accusatory instrument alleged a violation of [~~article two hundred twenty or section 240.36 of the penal law, prior to the taking effect of article two hundred twenty-one of the penal law, or a violation of article two hundred twenty-one of the penal law; (ii) the sole controlled substance involved is marijuana; (iii) the conviction was only for a violation or violations; and (iv) at least three years have passed since the offense occurred.~~]**:**

(i) article two hundred twenty or section 240.36 of the penal law prior to the effective date of article two hundred twenty-one of the penal law, and the sole controlled substance involved was marihuana and the conviction was only for a violation or violations; or

(ii) section 221.05 or 221.10 of the penal law prior to the effective date of the chapter of laws of two thousand nineteen that amended this section; or

(iii) section 221.05 or 221.10 of the penal law.

No defendant shall be required or permitted to waive eligibility for sealing pursuant to this paragraph as part of a plea of guilty, sentence or any agreement related to a conviction for a violation of section 221.05 or section 221.10 of the penal law and any such waiver shall be deemed void and wholly unenforceable.

§ 6. Section 1.20 of the criminal procedure law is amended by adding a new subdivision 45 to read as follows:

45. "Expunge" means, where an arrest and any enforcement activity connected with that arrest, including prosecution and any disposition in any New York state court, is deemed a nullity and the accused is restored, in contemplation of the law, to the status such individual occupied before the arrest, prosecution and/or disposition; that records of such arrest, prosecution and/or disposition shall be marked as expunged or shall be destroyed as set forth in section 160.50 of this chapter. Neither the arrest nor prosecution and/or disposition, if any, of a matter deemed a nullity shall operate as a disqualification of any person so accused to pursue or engage in any lawful activity, occupation, profession or calling. Except where specifically required or permitted by statute or upon specific authorization of a superior court, no such person shall be required to divulge information pertaining to the arrest, prosecution and/or disposition of such a matter.

§ 7. Section 160.50 of the criminal procedure law is amended by adding a new subdivision 5 to read as follows:

5. (a) Expungement of certain marihuana-related records. Where an accusatory instrument alleged an offense described in paragraph (k) of subdivision three of this section, such count or counts of the accusatory instrument in such criminal action or proceeding shall, on the effective date of this paragraph, in accordance with the provisions of this paragraph, be vacated and dismissed, and all records of such count or counts and, in the absence of any other valid count or counts, all records of such action or proceeding shall be expunged, as described in subdivision forty-five of section 1.20 of this chapter, and the matter shall be considered terminated in favor of the accused and deemed a nullity, having been rendered by this paragraph legally invalid.

(b) Duties of certain state officials and law enforcement agencies. Commencing upon the effective date of this paragraph:

(i) the chief administrator of the courts shall promptly notify the commissioner of the division of criminal justice services and the heads of all appropriate police departments and other law enforcement agencies of all counts that have been vacated and dismissed pursuant to paragraph (a) of this subdivision and that, in the absence of any other valid count or counts, all records of such action or proceeding shall be expunged and the matter shall be considered terminated in favor of the accused and deemed a nullity, having been rendered legally invalid. Upon receipt of notification of such vacatur, dismissal and expungement, all records relating to such count or counts, or the criminal action or proceeding, as the case may be, shall be marked as expunged by conspicuously indicating on the face of the record and on each page or at the beginning of the digitized file of the record that the record has been designated as expunged. Upon the written request of the individual whose case has been expunged or their designated agent, such records shall be destroyed. Such records and papers shall not be made available to any

person, except the individual whose case has been expunged or such person's designated agent; and

(ii) where automatic vacatur, dismissal, and expungement, including record destruction if requested, is required by this subdivision but any record of the court system in this state has not yet been updated to reflect same (A) notwithstanding any other provision of law except as provided in paragraph (d) of subdivision one of this section and paragraph (e) of subdivision four of section eight hundred thirty-seven of the executive law: (1) when the division of criminal justice services conducts a search of its criminal history records, maintained pursuant to subdivision six of section eight hundred thirty-seven of the executive law, and returns a report thereon, all references to a conviction for an offense described in paragraph (k) of subdivision three of this section shall be excluded from such report; and (2) the chief administrator of the courts shall develop and promulgate rules as may be necessary to ensure that no written or electronic report of a criminal history record search conducted by the office of court administration contains information relating to a conviction for an offense described in paragraph (k) of subdivision three of this section; and (B) where court records relevant to such matter cannot be located or have been destroyed, and a person or the person's attorney presents to an appropriate court employee a fingerprint record of the New York state division of criminal justice services, or a copy of a court disposition record or other relevant court record, which indicates that a criminal action or proceeding against such person was terminated by conviction of an offense described in paragraph (k) of subdivision three of this section, then promptly, and in any event within thirty days after such notice to such court employee, the chief administrator of the courts or his or her designee shall assure that such vacatur, dismissal, and expungement, including record destruction if requested, have been completed in accordance with subparagraph (i) of this paragraph.

(c) Vacatur, dismissal and expungement as set forth in this subdivision is without prejudice to any person or such person's attorney seeking further relief pursuant to article four hundred forty of this chapter or any other law. Nothing in this section is intended or shall be interpreted to diminish or abrogate any right or remedy otherwise available to any person.

(d) The office of court administration, in conjunction with the division of criminal justice services, shall develop an affirmative information campaign and widely disseminate to the public, through its website, public service announcements and other means, in multiple languages and through multiple outlets, information concerning the expungement, vacatur and resentencing of marihuana convictions established by the chapter of the laws of two thousand nineteen that added this paragraph, including, but not limited to, the automatic expungement of certain past convictions, the means by which an individual may file a motion for vacatur, dismissal and expungement of certain past convictions, and the impact of such changes on such person's criminal history records.

§ 8. Subdivision 8 of section 1399-n of the public health law, as amended by chapter 13 of the laws of 2003, is amended to read as follows:

8. "Smoking" means the burning of a lighted cigar, cigarette, pipe or any other matter or substance which contains tobacco or marihuana as defined in section thirty-three hundred two of this chapter.

§ 9. This act shall take effect on the thirtieth day after it shall have become a law.

NEW YORK STATE OF OPPORTUNITY. Department of Health

ANDREW M. CUOMO
Governor

HOWARD A. ZUCKER, M.D., J.D.
Commissioner

SALLY DRESLIN, M.S., R.N.
Executive Deputy Commissioner

Novel Coronavirus (COVID-19) Guidance for Registered Organizations

Several registered organizations have reached out to the Department for guidance regarding Novel Coronavirus (COVID-19). The Department recognizes that registered patients may have severe debilitating or life-threatening conditions and are often immunocompromised and would like to share the following direction:

1. **Registered Organizations are considered essential businesses**
    - In the event non-essential businesses are forced to shut-down due to COVID-19, Registered Organizations in the Medical Marijuana Program will be considered essential and allowed to remain open because they are considered medical providers.
2. **Dispensing Modification requests**
    - The Department has received multiple requests from ROs to dispense medical marijuana products at the door of the dispensing facility to limit potential exposure to RO staff and other patients. ROs may dispense from the doors of the dispensing facilities provided that you maintain compliance with all current laws, rules and regulations including but not limited to dispensing on camera, checking the PMP as required and validating registry ID cards.
3. **Home Delivery**
    - **To help facilitate social distancing, the Department directs that <u>until April 16, 2020</u>, registered organizations who have been approved to deliver medical marijuana products to the homes of registered patients and designated caregivers may expand delivery services statewide without seeking the Department's prior written approval.**
    - Registered Organizations approved for home delivery should encourage patients to utilize this service whenever possible.
        - When conducting deliveries, it is recommended that the RO's drivers follow the guidance below:
            - Wear masks and gloves while making deliveries
            - Hand sanitize or wash their hands after each delivery
            - Encourage patients to use their own pens when requiring a signature for the product
            - If not, all pens should be sanitized before changing hands (whether it be between a RO personnel or between personnel/consumer).
            - Additionally, ROs may confirm receipt of the delivered medications by the registered patient or caregiver through a phone call, text or email, in lieu of getting a signature. Such confirmation should be documented and retrievable upon audit.
4. **Schedule appointments whenever possible**
    - Provided that your registered organization is equipped to do so, please encourage patients to schedule an appointment before coming into a dispensing facility to avoid overcrowding.

5. **Have a plan in place if staff become ill.**
    - Postpone large meetings and gatherings
    - Encourage staff to stay home if they are feeling sick or have a sick individual in their home
    - If a member of your staff tests positive or may have been exposed to COVID-19, please refer to the following link on the DOH website: https://health.ny.gov/diseases/communicable/coronavirus/docs/guidance_for_employers.pdf
6. **Supply chain issues**
    - Notify the Department as soon as possible of any existing and/or anticipated disruptions to your organization's supply chain and ability to manufacture medical marijuana products.
7. **Sanitation**
    - Increase and continue the use of general sanitation across all registered facilities:
        - All registered facilities should continue to perform routine cleaning and sanitizing of all areas including high contact surfaces such as counters, telephones, computer mice and keyboards, light switches, handrails and doorknobs
        - Regular cleaning and laundering of uniforms and other linens
        - Frequent waste removal
        - Increased handwashing with soap and water for a minimum of 20 seconds
        - When soap and water are not available, use an alcohol-based hand sanitizer that contains at least 70% alcohol
        - Cover coughs and sneezes with tissues or elbow
        - Dispose of soiled tissues immediately
8. **Post cleaning guidance.**
    - Please reference the attached *COVID-19 General Building Cleaning Guidance* and post the information in a conspicuous location on the premises of each manufacturing and dispensing facility.

For additional information, please see the Department's webpage: https://health.ny.gov/diseases/communicable/coronavirus/ and the CDC's Novel Coronavirus webpage: https://www.cdc.gov/coronavirus/2019-ncov/.

Pursuant to the authority vested in the Commissioner of Health by section 3369-a of the Public Health Law (PHL), section 1004.11 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) is hereby amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Subdivision (n) of section 1004.11 is amended to read as follows:

* * *

(n) No synthetic marihuana additives nor any cannabinoid preparation not produced by a registered organization in an approved manufacturing facility shall be used in the production of any medical marihuana product[.]; provided, however, that a registered organization may use hemp, or extracts derived from hemp, grown and processed under the authority of the New York State Department of Agriculture and Markets in the manufacturing of medical marihuana products.

Regulatory Impact Statement

Statutory Authority:

The Commissioner of Health is authorized pursuant to section 3369-a of the Public Health Law (PHL) to promulgate rules and regulations necessary to effectuate the provisions of Title V-A of Article 33 of the PHL.

Legislative Objectives:

The legislative objective of Title V-A is to comprehensively regulate the manufacture, sale and use of medical marihuana, by striking a balance between potentially relieving the pain and suffering of those individuals with serious conditions, as defined in section 3360(7) of the Public Health Law, and protecting the public against risks to its health and safety.

Needs and Benefits:

Regulatory amendments to subdivision (n) of section 1004.11 are necessary to allow registered organizations the ability to use extracts derived from hemp, such as cannabinoids and terpenes, as additives to the registered organization's approved medical marihuana products. This use is limited to hemp and extracts derived from hemp, and only when grown and produced under the authority of the New York State Department of Agriculture and Markets. Allowing registered organizations to use hemp and its derivatives will help to reduce registered organizations' manufacturing costs, thereby reducing costs to patients.

Costs:

Costs to the Regulated Entity:

The regulatory amendments do not impose additional costs to regulated entities. Registered organizations will likely benefit from a reduction in manufacturing costs as a result of the allowance of hemp and extracts derived from hemp.

Costs to Local Government:

The regulatory amendments do not require local governments to perform any additional tasks; therefore, it is not anticipated to have an adverse fiscal impact.

Costs to the Department of Health:

With the availability of hemp and hemp extracts, additional effort will be required to review product proposals, test new medical marihuana products, and monitor compliance as the Department continues to balance the need to make medical marihuana products available at lower costs while protecting public health and safety. Any additional workload will be handled within existing resources.

Local Government Mandates:

These amendments do not impose any new programs, services, duties or responsibilities on local government.

Paperwork:

The regulatory amendments do not impose any new recordkeeping or paperwork requirements.

Duplication:

No relevant rules or legal requirements of the Federal and State governments duplicate, overlap or conflict with these regulations.

Alternatives:

An alternative to the regulatory amendments would be to not make any changes to the regulation. However, this alternative was not adopted since the regulatory amendments will help to lower registered organizations' manufacturing costs, ultimately resulting in lower-cost medical marihuana products for patients, without compromising patient safety.

Federal Standards:

Federal requirements do not include provisions for a medical marihuana program.

Compliance Schedule:

There is no compliance schedule imposed by these amendments, which shall be effective upon publication of a Notice of Adoption in the New York State Register.

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Statement in Lieu of Regulatory Flexibility Analysis

No regulatory flexibility analysis is required pursuant to section 202-b(3)(a) of the State Administrative Procedure Act. The amendment does not impose an adverse economic impact on small businesses or local governments, and it does not impose reporting, record keeping or other compliance requirements on small businesses or local governments.

Statement in Lieu of Rural Area Flexibility Analysis

A Rural Area Flexibility Analysis for these amendments is not being submitted because the amendments will not impose any adverse impact or significant reporting, record keeping or other compliance requirements on public or private entities in rural areas. There are no other compliance costs imposed on public or private entities in rural areas as a result of the amendments.

Statement in Lieu of Job Impact Statement

No job impact statement is required pursuant to section 201-a(2)(a) of the State Administrative Procedure Act. It is apparent, from the nature of the amendment, that it will not have an adverse impact on jobs and employment opportunities.

STATE OF NEW YORK

6184--A

2019-2020 Regular Sessions

IN SENATE

May 21, 2019

Introduced by Sens. METZGER, MAY, SKOUFIS -- read twice and ordered printed, and when printed to be committed to the Committee on Agriculture -- committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee

AN ACT to amend the agriculture and markets law, in relation to the growth of industrial hemp and the regulation of hemp extract; and to repeal certain provisions of such law relating thereto

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

Section 1. Subdivision 1 of section 505 of the agriculture and markets law, as added by chapter 524 of the laws of 2014, is amended to read as follows:

1. "Industrial hemp" means the plant Cannabis sativa L. and any part of such plant**, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers**, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.

§ 2. Section 506 of the agriculture and markets law, as amended by section 1 of part OO of chapter 58 of the laws of 2017, is amended to read as follows:

§ 506. Growth, sale, distribution, transportation and processing of industrial hemp and products derived from such hemp permitted. [~~Notwithstanding any provision of law to the contrary, industrial~~] **1. Industrial** hemp and products derived from such hemp are agricultural products which may be grown, produced [~~and~~]**,** possessed [~~in the state, and~~]**,** sold, distributed, transported [~~or~~] **and/or** processed [~~either~~] in [~~or out of~~] state [~~as part of agricultural pilot programs pursuant to authorization under federal law and the provisions of this article~~] **pursuant to authorization under federal law and/or the provisions of this article**.

[~~Notwithstanding any provision of law to the contrary restricting the growing or cultivating, sale, distribution, transportation or processing~~

EXPLANATION--Matter in ***italics*** (underscored) is new; matter in brackets [-] is old law to be omitted.

LBD11646-10-9

~~of industrial hemp and products derived from such hemp, and subject to authorization under federal law, the~~]

2. The commissioner may authorize the growing or cultivating of industrial hemp as part of agricultural pilot programs conducted by the department and/or an institution of higher education to study the growth and cultivation, sale, distribution, transportation and processing of such hemp and products derived from such hemp provided that the sites and programs used for growing or cultivating industrial hemp are certified by, and registered with, the department.

3. The industrial hemp used for research pursuant to this section shall be sourced from authorized New York state industrial hemp producers. The research partner may obtain an exemption for only grain or fiber from this requirement upon a satisfactory showing to the department that a suitable variety of industrial hemp for the research project is not grown in New York and/or the use of New York sourced hemp is not practicable for the project. Hemp for extracts can only be sourced from authorized New York state industrial hemp producers.

4. Nothing in this section shall limit the jurisdiction of the department under any other article of this chapter.

§ 3. Section 507 of the agriculture and markets law is REPEALED and a new section 507 is added to read as follows:

§ 507. Licensing; fees. 1. No person shall grow, process, produce, distribute and/or sell industrial hemp or products derived from industrial hemp in the state unless (a) licensed biennially by the commissioner or (b) authorized by the commissioner as part of an agricultural research pilot program established under this article.

2. Application for a license to grow industrial hemp shall be made upon a form prescribed by the commissioner, accompanied by a per-acre license fee and a non-refundable application fee of five hundred dollars.

3. The applicant shall furnish evidence of his or her good character, experience and competency, that the applicant has adequate facilities, equipment, process controls, testing capability and security to grow hemp.

4. Growers who intend to cultivate hemp for cannabinoids shall be required to obtain licensure from the department pursuant to article twenty-nine-A of this chapter.

5. A renewal application shall be submitted to the commissioner at least sixty days prior to the commencement of the next license period.

§ 4. Section 508 of the agriculture and markets law is REPEALED and a new section 508 is added to read as follows:

§ 508. Compliance action plan. If the commissioner determines, after notice and an opportunity for hearing, that a licensee has negligently violated a provision of and/or a regulation promulgated pursuant to this article, that licensee shall be required to comply with a corrective action plan established by the commissioner to correct the violation by a reasonable date and to periodically report to the commissioner with respect to the licensee's compliance with this article for a period of no less than the next two calendar years following the commencement date of the compliance action plan. The provisions of this section shall not be applicable to research partners conducting hemp research pursuant to a research partner agreement, the terms of which shall control.

§ 5. Section 509 of the agriculture and markets law is REPEALED and a new section 509 is added to read as follows:

§ 509. Granting, suspending or revoking licenses. The commissioner may decline to grant a new license, may decline to renew a license, may

suspend or revoke a license already granted after due notice and opportunity for hearing whenever he or she finds that:

1. any statement contained in an application for an applicant or licensee is or was false or misleading;

2. the applicant or licensee does not have good character, the required experience and/or competency, adequate facilities, equipment, process controls, testing capability and/or security to produce hemp or products derived from hemp;

3. the applicant or licensee has failed or refused to produce any records or provide any information demanded by the commissioner reasonably related to the administration and enforcement of this article; or

4. the applicant or licensee, or any officer, director, partner, holder of ten percent of the voting stock, or any other person exercising any position of management or control has failed to comply with any of the provisions of this article or rules and regulations promulgated pursuant thereto.

§ 6. Section 510 of the agriculture and markets law is REPEALED and a new section 510 is added to read as follows:

§ 510. Regulations. The commissioner may develop regulations consistent with the provisions of this article for the growing and cultivation, sale, distribution, and transportation of industrial hemp grown in the state, including:

1. the authorization or licensing of any person who may: acquire or possess industrial hemp plants or seeds; grow or cultivate industrial hemp plants; and/or sell, purchase, distribute, or transport such industrial hemp plants, plant parts, or seeds;

2. maintaining relevant information regarding land on which industrial hemp is produced within the state, including the legal description of the land, for a period of not less than three calendar years;

3. the procedure for testing of industrial hemp produced in the state for delta-9-tetrahydrocannabinol levels, using a representative non-decarboxylated sample of flowers and leaves from the whole plant or other similarly reliable methods;

4. the procedure for effective disposal of industrial hemp plants or products derived from hemp that are produced in violation of this article;

5. a procedure for conducting at least a random sample of industrial hemp producers to verify that hemp is not produced in violation of this article;

6. any required security measures; and

7. such other and further regulation as the commissioner deems appropriate or necessary.

§ 7. Section 511 of the agriculture and markets law is REPEALED and a new section 511 is added to read as follows:

§ 511. Prohibitions. Except as authorized by state law, and regulations promulgated thereunder, the growth, cultivation, processing, sale, and/or distribution of industrial hemp is prohibited.

§ 8. Section 512 of the agriculture and markets law is REPEALED and a new section 512 is added to read as follows:

§ 512. Industrial hemp data collection and best farming practices. The commissioner shall have the power to collect and publish data and research concerning, among other things, the growth, cultivation, production and processing methods of industrial hemp and products derived from industrial hemp and work with the New York state college of agriculture and life science at Cornell pursuant to section fifty-seven hundred twelve of the education law and the Cornell cooperative exten-

sion pursuant to section two hundred twenty-four of the county law to promote best farming practices for industrial hemp which are compatible with state water quality and other environmental objectives.

§ 9. Sections 513 and 514 of the agriculture and markets law are REPEALED and two new sections 513 and 514 are added to read as follows:

§ 513. Access to criminal history information through the division of criminal justice services. In connection with the administration of this article, the commissioner is authorized to request, receive and review criminal history information through the division of criminal justice services (division) with respect to any person seeking a license or authorization to undertake a hemp pilot project. At the commissioner's request, each researcher, principal and/or officer of the applicant shall submit to the department his or her fingerprints in such form and in such manner as specified by the division, for the purpose of conducting a criminal history search and returning a report thereon in accordance with the procedures and requirements established by the division pursuant to the provisions of article thirty-five of the executive law, which shall include the payment of the prescribed processing fees for the cost of the division's full search and retain procedures and a national criminal history record check. The commissioner, or his or her designee, shall submit such fingerprints and the processing fee to the division. The division shall forward to the commissioner a report with respect to the applicant's previous criminal history, if any, or a statement that the applicant has no previous criminal history according to its files. Fingerprints submitted to the division of criminal justice services pursuant to this section may also be submitted to the federal bureau of investigation for a national criminal history record check. If additional copies of fingerprints are required, the applicant shall furnish them upon request.

§ 514. Aids to enforcement. 1. The commissioner shall have full access to all premises, buildings, factories, farms, vehicles, cars, boats, airplanes, vessels, containers, packages, barrels, boxes, and/or cans for the purpose of enforcing the provisions of this article. The commissioner may, at such locations, examine industrial hemp and hemp products and may open any package and/or container reasonably believed to contain industrial hemp or hemp products, to determine whether such industrial hemp or hemp products follow applicable law or regulation.

2. A search warrant shall be issued by any court to which application is made therefor, whenever it shall be made to appear to such court that a licensee has: refused to permit any industrial hemp to be inspected or samples taken therefrom; refused to permit access to any premises, or place where licensed activities are conducted; and/or refused or prevented access thereto by any inspector of the department and that such inspector has reasonable grounds to believe that such person has any industrial hemp in his or her possession, or under his or her control and/or is in violation of the provisions or regulations of this article. In such a case, a warrant shall be issued in the name of the people, directed to a police officer, commanding him or her to: (a) search any place of business, factory, building, premises, or farm where licensed activities have occurred and any vehicle, boat, vessel, container, package, barrel, box, tub or can, containing, or believed to contain industrial hemp in the possession or under the control of any person who shall refuse to allow access to such hemp for inspection or sampling, (b) permit the inspection and sampling of any industrial hemp found in the execution of the warrant, as the officer applying for the search warrant shall designate when the same is found, by an inspector

or a department official authorized by the commissioner or by this chapter, and/or (c) permit access to any place where access is refused or prevented, and to allow and enable a department inspector or other department official to conduct an inspection of the place. The provisions of article six hundred ninety of the criminal procedure law shall apply to such warrant as far as applicable thereto. The officer to whom the warrant is delivered shall make a return in writing of his or her proceedings thereunto to the court which issued the same.

3. The commissioner may quarantine industrial hemp when he or she has reason to believe that such commodity does not meet the definition thereof, set forth in subdivision one of section five hundred five of this article, or is otherwise in violation of or does not meet a standard set forth in, applicable law or regulation. The quarantine may by the issuance of an order directing the owner or custodian of industrial hemp not to distribute, dispose of, or move that commodity without the written permission of the commissioner. The commissioner may also quarantine a product by placing a tag or other appropriate marking thereon or adjacent thereto that provides and requires that such product must not be distributed, disposed of, or moved without his or her written permission, or may quarantine a product by otherwise informing the owner or custodian thereof that such condition must be complied with.

4. The commissioner may seize industrial hemp by taking physical possession of industrial hemp when he or she has substantial evidence to believe that such commodity does not meet the definition thereof, set forth in subdivision one of section five hundred five of this article, or is otherwise in violation of, or does not meet a standard set forth in, applicable law or regulation.

5. Subsequent to quarantining or seizing industrial hemp, as authorized in subdivisions three and four of this section, the commissioner shall promptly give the owner or custodian thereof an opportunity to be heard to show cause why such industrial hemp should not be ordered destroyed. The commissioner shall, thereafter, consider all the relevant evidence and information presented and shall make a determination whether such industrial hemp should be ordered to be destroyed; that determination may be reviewed as provided for in article seventy-eight of the civil practice law and rules.

§ 10. The agriculture and markets law is amended by adding a new article 29-A to read as follows:

ARTICLE 29-A

REGULATION OF HEMP EXTRACT

Section 520. Definitions.
521. Rulemaking authority.
522. Cannabinoid related hemp extract licensing.
523. Cannabinoid grower licenses.
524. Cannabinoid manufacturer license.
525. Cannabinoid extractor license.
526. Cannabinoid license applications.
527. Information to be requested in applications for licenses.
528. Fees.
529. Selection criteria.
530. Limitations of licensure; duration.
531. License renewal.
532. Form of license.
533. Amendments to license and duty to update information submitted for licensing.
534. Record keeping and tracking.

535. Inspections and ongoing requirements.
536. Packaging and labeling of hemp extract.
537. Provisions governing the growing, manufacturing and extracting of hemp extract.
538. Laboratory testing.
539. Advertising.
540. Research.
541. Regulations.
542. Cannabinoid permit.
543. New York hemp product.
544. Penalties and violations of this article.
545. Hemp workgroup.
546. Prohibitions.
547. Severability.

§ 520. Definitions. Wherever used in this article unless otherwise expressly stated or unless the context or subject matter requires a different meaning, the following terms shall have the representative meanings hereinafter set forth or indicated:

1. "Applicant" means a for-profit entity or not-for-profit corporation and includes board members who submit an application to become a licensee.

2. "Hemp extract" means any product made or derived from industrial hemp, including the seeds thereof and all derivatives whether growing or not, with a delta-9-tetrahydrocannabinol concentration of not more than an amount of the plant Cannabis sativa L. and any part of such plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9-tetrahydrocannabinol concentration of not more than an amount determined by the department in regulation, used or intended for human or animal consumption or use for its cannabinoid content, as determined by the commissioner in regulation. Hemp extract excludes industrial hemp used or intended exclusively for an industrial purpose and those food and/or food ingredients that are generally recognized as safe by the department, and shall not be regulated as hemp extract within the meaning of this article.

3. "Cannabinoid grower" means a person licensed by the department, and in compliance with article twenty-nine of this chapter, to acquire, possess, cultivate, and sell hemp extract for its cannabinoid content.

4. "Cannabinoid manufacturer" means a person licensed by the department to acquire, possess, and manufacture hemp extract from licensed cannabinoid growers or cannabinoid extractors for the manufacture and sale of hemp extract products marketed for cannabinoid content and used or intended for human or animal consumption or use.

5. "Cannabinoid extractor" means a person licensed by the department to acquire, possess, extract and manufacture hemp extract from licensed cannabinoid growers for the manufacture and sale of hemp extract products marketed for cannabinoid content and used or intended for human or animal consumption or use.

6. "License" means a license issued pursuant to this article.

7. "Industrial hemp" means the plant Cannabis sativa L. and any part of such plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9-tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.

§ 521. Rulemaking authority. 1. The department shall perform such acts, prescribe such forms and propose such rules, regulations and

orders as it may deem necessary or proper to fully effectuate the provisions of this article.

2. The department shall have the power to promulgate any and all necessary rules and regulations governing the production, processing, transportation, distribution, and sale of hemp extract, including but not limited to the licensing of cannabinoid growers, manufacturers, extractors and retailers, including, but not limited to:

(a) prescribing forms and establishing application, reinstatement, and renewal fees;

(b) the qualifications and selection criteria for licensing, or permitting;

(c) limitations on the number of licenses to be awarded;

(d) the books and records to be created and maintained by licensees, and permittees, including the reports to be made thereon to the department, and inspection of any and all books and records maintained by any licensee, or permittee, and on the premises of any licensee or permittee;

(e) methods of producing, processing, and packaging hemp extract; conditions of sanitation, and standards of ingredients, quality, and identity of hemp extract products cultivated, processed, packaged, or sold by licensees; and

(f) hearing procedures and additional causes for cancellation, revocation, and/or civil penalties against any person licensed, or permitted by the department.

3. The department, in consultation with the department of environmental conservation and the New York state energy research and development agency, shall promulgate necessary rules and regulations governing the safe production of hemp extract, including environmental and energy standards.

§ 522. Cannabinoid related hemp extract licensing. 1. Persons growing, processing, extracting, and/or manufacturing hemp extract or producing hemp extract products distributed, sold or marketed for cannabinoid content and used or intended for human or animal consumption or use, shall be required to obtain the following license or licenses from the department, depending upon the operation:

(a) cannabinoid grower license;

(b) cannabinoid manufacturer license;

(c) cannabinoid extractor license.

2. Notwithstanding subdivision one of this section, those persons growing, processing or manufacturing food or food ingredients from industrial hemp pursuant to article twenty-nine of this chapter, which food or food ingredients are generally recognized as safe, shall be subject to regulation and/or licensing by the department.

§ 523. Cannabinoid grower licenses. 1. A cannabinoid grower's license authorizes the acquisition, possession, cultivation and sale of hemp extract grown or used for its cannabinoid content on the licensed premises of the grower.

2. A person holding a cannabinoid grower's license shall not sell hemp extract products marketed, distributed or sold for its cannabinoid content and intended for human consumption or use without also being licensed as a manufacturer or extractor pursuant to this article or otherwise permitted pursuant to section five hundred forty-two of this article.

3. Persons growing industrial hemp pursuant to article twenty-nine of this chapter are not authorized to and shall not sell hemp extract for human or animal consumption or use, other than as food or a food ingre-

dient that has been generally recognized as safe in accordance with the department or determined by the state to be safe for human consumption as food or a food ingredient without also being licensed as a manufacturer or extractor pursuant to this article or otherwise permitted pursuant to section five hundred forty-two of this article.

4. A person authorized under article twenty-nine of this chapter as an industrial hemp grower shall apply for a cannabinoid grower license provided it can demonstrate to the department that its cultivation of industrial hemp meets all the requirements for hemp extract cultivated under a cannabinoid grower license.

§ 524. Cannabinoid manufacturer license. 1. A cannabinoid manufacturer license authorizes the licensee's acquisition, possession, and manufacture of hemp extract from a licensed cannabinoid grower or cannabinoid extractor for the processing of hemp extract or the production of hemp extract products marketed, distributed or sold for cannabinoid content and used or intended for human or animal consumption or use.

2. Notwithstanding subdivision one of this section, nothing shall prevent a cannabinoid manufacturer from manufacturing industrial hemp products not used or intended for human or animal consumption or use.

§ 525. Cannabinoid extractor license. 1. A cannabinoid extractor license authorizes the licensee's acquisition, possession, extraction and manufacture of hemp extract from a licensed cannabinoid grower for the processing of hemp extract or the production of hemp extract products marketed, distributed or sold for cannabinoid content and used or intended for human or animal consumption or use.

2. No cannabinoid extractor licensee shall engage in any other business on the licensed premises; except that nothing contained in this article shall prevent a cannabinoid extractor licensee from also being licensed as a cannabinoid grower on the same premises.

3. Notwithstanding subdivisions one and two of this section, nothing shall prevent a cannabinoid extractor from manufacturing industrial hemp products not used or intended for human or animal consumption or use.

4. A person authorized under article twenty-nine of this chapter as an industrial hemp processor shall qualify for a cannabinoid extractor license provided it can demonstrate to the department that its extraction of industrial hemp meets all the requirements for hemp extract under a cannabinoid extractor license.

§ 526. Cannabinoid license applications. 1. Persons shall apply for a cannabinoid grower license, cannabinoid manufacturer license and/or a cannabinoid extractor license by submitting an application upon a form supplied by the department, providing all the requested information, verified by the applicant or an authorized representative of the applicant.

2. A separate license shall be required for each facility at which growing, manufacturing and/or extracting is conducted.

3. Each applicant shall remit with its application the fee for each requested license.

§ 527. Information to be requested in applications for licenses. 1. The department shall have the authority to prescribe the manner and form in which an application must be submitted to the department for licensure under this article.

2. The commissioner is authorized to adopt regulations, including by emergency rule, establishing information which must be included on an application for licensure under this article. Such information may include, but is not limited to: information about the applicant's identity, including racial and ethnic diversity; information about prior use

of farmland; ownership and investment information, including the corporate structure; evidence of good moral character, including the submission of fingerprints by the applicant to the division of criminal justice services; information about the premises to be licensed; financial statements; and any other information prescribed in regulation.

3. All license applications shall be signed by the applicant (if an individual), by a managing partner (if a limited liability corporation), by an officer (if a corporation), or by all partners (if a partnership). Each person signing such application shall verify it as true under the penalties of perjury.

4. All license or permit applications shall be accompanied by a check, draft or other forms of payment as the department may require or authorize in the amount required by this article for such license or permit.

5. If there be any change, after the filing of the application or the granting of a license, in any of the facts required to be set forth in such application, a supplemental statement giving notice of such change, cost and source of money involved in the change, duly verified, shall be filed with the department within ten days after such change. Failure to do so shall, if willful and deliberate, be cause for revocation of the license.

6. In giving any notice, or taking any action in reference to a licensee of a licensed premises, the department may rely upon the information furnished in such application and in any supplemental statement connected therewith, and such information may be presumed to be correct, and shall be binding upon a licensee or licensed premises as if correct. All information required to be furnished in such application or supplemental statements shall be deemed material in any prosecution for perjury, any proceeding to revoke, cancel or suspend any license, and in the department's determination to approve or deny the license.

7. The department may, in its discretion, waive the submission of any category of information described in this section for any category of license or permit, provided that it shall not be permitted to waive the requirement for submission of any such category of information solely for an individual applicant or applicants.

§ 528. Fees. The department shall have the authority to charge licensees a biennial license fee. Such fee may be based on the amount of hemp extract to be grown, processed, manufactured or extracted by the licensee, the gross annual receipts of the licensee for the previous license period, or any other factors deemed appropriate by the department.

§ 529. Selection criteria. 1. An applicant shall furnish evidence:

(a) its ability to effectively maintain a delta-9-tetrahydrocannabinol concentration that does not exceed a percentage of delta-9-tetrahydrocannabinol cannabis set by the commissioner on a dry weight basis of combined leaves and flowers of the plant of the genus cannabis, or per volume or weight of cannabis product;

(b) its ability to comply with all applicable state laws and regulations;

(c) that the applicant is ready, willing and able to properly carry on the activities for which a license is sought; and

(d) that the applicant is in possession of or has the right to use land, buildings and equipment sufficient to properly carry on the activity described in the application.

2. The department, in considering whether to grant the license application, shall consider whether:

(a) it is in the public interest that such license be granted, taking into consideration whether the number of licenses will be adequate or excessive to reasonably serve demand;

(b) the applicant and its managing officers are of good moral character and do not have an ownership or controlling interest in more licenses or permits than allowed by this chapter;

(c) preference shall be given to applicants that are currently farming in the state and are eligible or currently receiving an agricultural assessment pursuant to article twenty-five-AA of this chapter; and

(d) the applicant satisfies any other conditions as determined by the department.

3. If the commissioner is not satisfied that the applicant should be issued a license, the commissioner shall notify the applicant in writing of the specific reason or reasons for denial.

4. The commissioner shall have authority and sole discretion to determine the number of licenses issued pursuant to this article.

§ 530. Limitations of licensure; duration. 1. No license pursuant to this article may be issued to a person under the age of eighteen years.

2. The department shall have the authority to limit, by canopy, plant count or other means, the amount of hemp extract allowed to be cultivated, processed, extracted or sold by a licensee.

3. All licenses under this article shall expire two years after the date of issue and be subject to any rules or limitations prescribed by the commissioner in regulation.

§ 531. License renewal. 1. Each license, issued pursuant to this article, may be renewed upon application therefor by the licensee and the payment of the fee for such license as prescribed by this article.

2. In the case of applications for renewals, the department may dispense with the requirements of such statements as it deems unnecessary in view of those contained in the application made for the original license, but in any event the submission of photographs of the licensed premises shall be dispensed with, provided the applicant for such renewal shall file a statement with the department to the effect that there has been no alteration of such premises since the original license was issued.

3. The department may make such rules as may be necessary, not inconsistent with this chapter, regarding applications for renewals of licenses and permits and the time for making the same.

4. The department shall provide an application for renewal of a license issued under this article not less than ninety days prior to the expiration of the current license.

5. The department may only issue a renewal license upon receipt of the prescribed renewal application and renewal fee from a licensee if, in addition to the criteria in section five hundred twenty-seven of this article, the licensee's license is not under suspension and has not been revoked.

6. The department shall have the authority to charge applicants for licensure under this article a non-refundable application fee. Such fee may be based on the type of licensure sought, cultivation and/or production volume, or any other factors deemed reasonable and appropriate by the department to achieve the policy and purpose of this chapter.

§ 532. Form of license. Licenses issued pursuant to this article shall specify:

1. the name and address of the licensee;

2. the activities permitted by the license;

3. the land, buildings and facilities that may be used for the licensed activities of the licensee;

4. a unique license number issued by the department to the licensee; and

5. such other information as the commissioner shall deem necessary to assure compliance with this chapter.

§ 533. Amendments to license and duty to update information submitted for licensing. 1. Upon application of a licensee to the department, a license may be amended to allow the licensee to relocate within the state, to add or delete licensed activities or facilities, or to amend the ownership or organizational structure of the entity that is the licensee. The fee for such amendment shall be two hundred fifty dollars.

2. In the event that any of the information provided by the applicant changes either while the application is pending or after the license is granted, within ten days of any such change, the applicant or licensee shall submit to the department a verified statement setting forth the change in circumstances of facts set forth in the application. Failure to do so shall, if willful and deliberate, be cause for revocation of the license.

3. A license shall become void by a change in ownership, substantial corporate change or location without prior written approval of the commissioner. The commissioner may promulgate regulations allowing for certain types of changes in ownership without the need for prior written approval.

4. For purposes of this section, "substantial corporate change" shall mean:

(a) for a corporation, a change of eighty percent or more of the officers and/or directors, or a transfer of eighty percent or more of stock of such corporation, or an existing stockholder obtaining eighty percent or more of the stock of such corporation; and

(b) for a limited liability company, a change of eighty percent or more of the managing members of the company, or a transfer of eighty percent or more of ownership interest in said company, or an existing member obtaining a cumulative of eighty percent or more of the ownership interest in said company.

§ 534. Record keeping and tracking. 1. The commissioner shall, by regulation, require each licensee pursuant to this article to adopt and maintain security, tracking, record keeping, record retention and surveillance systems, relating to all hemp extract at every stage of acquiring, possession, manufacture, transport, sale, or delivery, or distribution by the licensee, subject to regulations of the commissioner.

2. Every licensee shall keep and maintain upon the licensed premises, adequate books and records of all transactions involving the licensee and sale of its products, which shall include all information required by rules promulgated by the department.

3. Each sale shall be recorded separately on a numbered invoice, which shall have printed thereon the number, the name of the licensee, the address of the licensed premises, and the current license number.

4. Such books, records and invoices shall be kept for a period of five years and shall be available for inspection by any authorized representative of the department.

§ 535. Inspections and ongoing requirements. All licensees shall be subject to reasonable inspection by the department, in consultation with the department of health, and a person who holds a license must make himself or herself, or an agent thereof, available and present for any

inspection required by the department. The department shall make reasonable accommodations so that ordinary business is not interrupted and safety and security procedures are not compromised by the inspection.

§ 536. Packaging and labeling of hemp extract. 1. The department, in consultation with the department of health, is hereby authorized to promulgate rules and regulations governing the packaging and labeling of hemp extract products, sold or possessed for sale in New York state.

2. Such regulations shall include, but not be limited to, requiring labels warning consumers of any potential impact on human health resulting from the consumption of hemp extract products that shall be affixed to those products when sold, if such labels are deemed warranted by the department. No label may state that hemp extract can treat, cure or prevent any disease without approval pursuant to federal law.

3. Such rules and regulations shall establish a QR code which may be used in conjunction with similar technology for labels and establish methods and procedures for determining, among other things, serving sizes for hemp extract products, active cannabinoid concentration per serving size, number of servings per container, and the growing region, state or country of origin if not from the United States. Such regulations shall also require a supplement fact panel that incorporates data regarding serving sizes and potency thereof.

4. The packaging, sale, or possession by any licensee of any hemp product intended for human or animal consumption or use not labeled or offered in conformity with rules and regulations promulgated in accordance with this section shall be grounds for the imposition of a fine, and/or the suspension, revocation or cancellation of a license.

§ 537. Provisions governing the growing, manufacturing and extracting of hemp extract. 1. No licensed cannabinoid grower, manufacturer or extractor shall sell, or agree to sell or deliver in the state any hemp extract products, as the case may be, except in sealed containers containing quantities in accordance with size standards pursuant to rules adopted by the department. Such containers shall have affixed thereto such labels as may be required by the rules of the department.

2. Licensed cannabinoid growers shall be prohibited from using pesticides.

3. All hemp extract products shall be extracted and manufactured in accordance with good manufacturing processes, pursuant to Part 111 or 117 of Title 21 of the Code of Federal Regulations as may be modified and decided upon by the commissioner in regulation.

4. Within thirty days of the effective date of this article, the department shall approve the manufacture, distribution, and sale of beverages containing no more than twenty milligrams of cannabidiol per twelve ounce beverage. The hemp extract used in such beverages shall be grown, extracted and manufactured in the state of New York. The department shall issue guidance on the label, warning, point of sale, and advertising for such beverages.

5. Terpenes derived from the hemp plant are generally recognized as safe.

§ 538. Laboratory testing. 1. Every cannabinoid manufacturer and cannabinoid extractor shall contract with an independent laboratory to test the hemp extract products produced by the licensed manufacturer or extractor. The commissioner, in consultation with the commissioner of health, shall approve the laboratory and require that the laboratory report testing results in a manner determined by the commissioner. The commissioner is authorized to issue regulations requiring the laboratory to perform certain tests and services.

2. Cannabinoid manufacturers and cannabinoid extractors shall make laboratory test reports available to persons holding a cannabinoid permit pursuant to section five hundred forty-two of this article for all cannabis products manufactured by the licensee.

3. On-site laboratory testing by licensees is permissible; however, such testing shall not be certified by the department and does not exempt the licensee from the requirements of quality assurance testing at a testing laboratory pursuant to this section.

§ 539. Advertising. The department shall promulgate rules and regulations governing the advertising of hemp extract and any other related products or services as determined by the commissioner.

§ 540. Research. 1. The department shall promote research and development through public-private partnerships to bring new hemp extract and industrial hemp derived products to market within the state.

2. The commissioner may develop and carry out research programs which may include programs at the New York state college of agriculture and life sciences, pursuant to section fifty-seven hundred twelve of the education law and/or New York state university research institutions relating to industrial hemp and hemp extract.

§ 541. Regulations. The commissioner shall make regulations to implement this article.

§ 542. Cannabinoid permit. The department is hereby authorized to issue cannabinoid permits to retailers, wholesalers, and distributors authorizing them to sell cannabis products derived from hemp extract. The commissioner shall have the authority to set fees for such permit, to establish the period during which such permit is authorized, and to make rules and regulations, including emergency regulations, to implement this section.

§ 543. New York hemp product. The commissioner may establish and adopt official grades and standards for hemp extract and hemp extract products as he or she may deem advisable, which are produced for sale in this state and, from time to time, may amend or modify such grades and standards.

§ 544. Penalties and violations of this article. Notwithstanding the provision of any law to the contrary, the failure to comply with the requirements of this article, the rules and regulations promulgated thereunder, may be punishable by a fine of not more than one thousand dollars for a first violation; not more than five thousand dollars for a second violation; and not more than ten thousand dollars for a third violation and each subsequent violation thereafter.

§ 545. Hemp workgroup. The commissioner shall appoint a New York state industrial hemp and hemp extract workgroup, composed of researchers, producers, processors, manufacturers and trade associations, to make recommendations for the industrial hemp and hemp extract programs, state and federal policies and policy initiatives, and opportunities for the promotion and marketing of industrial hemp and hemp extract as consistent with federal and state laws, rules and regulations, which workgroup shall continue for such time as the commissioner deems appropriate.

§ 546. Prohibitions. Except as authorized in this article, the manufacturing of hemp extract for human or animal consumption and the distribution and/or sale thereof is prohibited in this state unless the manufacturer is licensed under this article. Hemp extract and products derived therefrom for human and animal consumption produced outside the state shall not be distributed or sold in this state unless they meet all standards and requirements established for such product manufactured

in the state under this article and its rules and regulations as determined by the department.

§ 547. Severability. If any provision of this article or the application thereof to any person or circumstances is held invalid, such invalidity shall not affect other provisions or applications of the article which can be given effect without the invalid provision or application, and to this end the provisions of this article are declared to be severable.

§ 11. This act shall take effect on the ninetieth day after it shall have become a law.

Industrial Hemp Agricultural Research Pilot Program
Program Guidance
For Period: January 1, 2020 – October 31, 2020

The 2018 Farm Bill significantly changed federal regulation of the growing of industrial hemp in the U.S. Foremost among those changes, industrial hemp is removed from the federal list of controlled substances, defining hemp as "the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis."

In addition, the U.S. Department of Agriculture (USDA) has now established a national licensing system for hemp and adopted federal regulations for hemp licensing. Each state has the option to obtain primary regulatory authority for industrial hemp in that state, pursuant to a USDA-approved plan. The USDA's Interim Final Rule, adopted November 1, 2019, can be found at https://www.ams.usda.gov/rules-regulations/hemp.

In that New York State has not yet submitted a plan to USDA, the pathway to grow industrial hemp in New York State remains through participation in New York's Industrial Hemp Agricultural Research Pilot Program, authorized under the provisions of the 2014 Farm Bill and administered by the Department of Agriculture and Markets. In 2020, anyone planning to grow industrial hemp for any purpose in New York must obtain an authorization as a Research Partner before they can undertake their project. The pilot program will terminate on November 1, 2020, pursuant to federal law. Prior to that time, the Department will advise research partners how they will be transitioned to the new licensing programs.

INDUSTRIAL HEMP AGRICULTURAL RESEARCH PILOT PROGRAM

For the period of January 1 ,2020 – October 31, 2020, industrial hemp and products derived from such hemp may be grown, produced and possessed in the state only as part of the Pilot Program. Research Partners approved by the Department may undertake research projects to study the growth and cultivation, sale, distribution, transportation and processing of such hemp and products derived from such hemp. Until a new licensing program is established, no other growing or processing of industrial hemp in New York State is permitted.[1]

[1] Agriculture and Markets Law, Section 506

APPLICATIONS: PROCESS

Those seeking to grow and cultivate hemp in the Program must apply. If the application is approved, the applicant must execute a Research Partner Agreement, which, among other things, describes the authorized scope of work, establishes the standards for the work, and sets forth the respective duties and obligations of the parties. The steps to applying:

1. The Department reviews the application and notifies the applicant of the decision.
2. The Department will send approved applicants a Research Partner Agreement to be signed and notarized by the applicant.
3. The applicant will return the signed and notarized Research Partner Agreement to the Department.
4. Upon receipt of the signed Research Partner Agreement, the Department will issue and mail to the Research Partner (formerly the applicant) an official Industrial Hemp Research Partner Authorization and the fully executed Research Partner Agreement.

An applicant is not authorized to grow or cultivate industrial hemp until it has received the official Industrial Hemp Research Partner Authorization document from the Department.

APPLICATIONS: ELIGIBILITY

Each application and renewal application must include the following:

- A description and map of each location where industrial hemp will be cultivated, by physical address and by GPS co-ordinates, visually depicting the buildings, structures, and improvements on the premises and identifying their use, and describing the relevant activities conducted at the location
- A detailed research plan and summary of the issues and matters that the applicant intends to study in conjunction with growing or cultivating of industrial hemp
- A marketing plan
- A seed/propagule acquisition plan
- Statement of relevant experience of the individual responsible for the research project
- A nonrefundable $500 application fee.

An authorization to conduct research in this Department pilot program is not a right. The decision to grant such an authorization is at the sole discretion of the Department based upon, among other things, its needs or interests, the evaluation of the proposed project,

and the qualifications and experience of the applicant. Disqualifying factors may include but are not limited to:

- An incorrect or incomplete application
- Poor research design
- Lack of experience or qualification to undertake the proposed project
- Recent drug-related felony convictions of researchers
- Proposing to use a growing or processing location already registered by an existing Research Partner
- Inability of the Department to adequately supervise or regulate the proposed project
- The proposed undertaking of medical research
- The proposed processing of food in such a way to concentrate CBD content.

APPLICATIONS: AMENDMENTS

Research Partners can submit requests to amend their original application by submitting an Amendment Form. Amendments may include, among other things, adding additional acreage, change of location of grow sites, and changes to the scope of work contained in the research plan set forth in the initial application. All requests to amend are subject to review and approval by the Department. Amendments to an existing Research Partner's scope of work are not subject to the $500 application fee.

Compliance with prior years' program reporting requirements, if applicable, is a condition to the granting of an amendment.

ACQUISITION OF SEEDS AND PLANTS

Purchasing seed: Seed procurement is the responsibility of the Research Partner. Research Partners who plan to obtain seed through an international import should check with the seed supplier to determine what documentation is required for such a transaction.

Selling seed: Viable industrial hemp seed shall not be sold to any individual or entity not authorized as a Research Partner.

Purchasing hemp plants: Industrial hemp plants may be procured only by Research Partners and they may be purchased only from a registered nursery grower who is an authorized Research Partner (in New York State or in another state with a pilot program). All interstate shipments of hemp plants must be from a plant grower licensed in the state of origin or be accompanied by a phytosanitary certificate.

Compliance with seed laws: Be aware of plant variety protection (PVP) laws and regulations and be certain that the seed procured is in compliance with PVP and all other applicable New York State seed laws and regulations. More information on New York's seed laws may be found at https://agriculture.ny.gov/regulations-article-9-inspection-and-sale-seeds-sections-ssss-136-142.

INSPECTIONS

The registered locations of a Research Partner are subject to inspection by the Commissioner and by his or her authorized agents, employees, or officers, pursuant to Agriculture and Markets Law Section 20, as often and to the extent necessary to ensure compliance with the respective Research Partner Agreement and State and Federal laws relating to the possession, sale, or cultivation of industrial hemp. The Commissioner may authorize agents, employees, or officers of the New York State Department of Health and law enforcement to accompany him or her during an inspection of the registered locations of a Research Partner.

The Research Partner shall inspect the registered locations as often as necessary to ensure compliance with the requirements of the Program.

SAMPLING

Growers must submit a Harvest Report Form (https://agriculture.ny.gov/plant-industry/harvest-report-form) at least 20 days prior to the expected harvest date. Following receipt of the form, a Horticultural Inspector will contact the grower to set up a date, time, and location for inspection.

The Horticulture Inspector will arrive on site to take a pre-harvest sample, ideally within 14 days of harvest. He or she will verify that the locations and descriptions of the industrial hemp fields are consistent with what was reported on the original application and on any addendum to the original application.

The Horticulture Inspector will collect the samples and send to the Department laboratory for testing.

TESTING FOR THC

During the 2020 growing season regulatory samples taken by the department will measure for and report delta-9 THC and delta-9 THC acid separately. Results of both tests will be listed on the report, but the department will only take action on delta-9 THC sample results. Growers should be aware that many other industrial hemp states and the USDA measure and act on total THC (delta-9 THC plus delta-9 THC acid) sample results.

Regulatory testing conducted by the Department is conducted at a single point in time on a small number of plants in hemp fields. The results provide information with respect only to the sampled plants at the time of sampling. Regulatory testing results provide no certification or assurance that the hemp harvested and sold by that grower meets the legal limit for THC.

The results of any regulatory testing for THC levels are intended solely for the Department's management of the research program and its determination of compliance with program requirements.

CBD PRODUCTS: REQUIRED TESTING

Research Partners making any CBD product intended for human or animal consumption or absorption into the body must ensure that their CBD products are free from chemical, physical, and biological contamination. The analytical tests typically used to detect for chemical, physical and biological contamination include for example: cannabinoid profile (THC and CBD), solvents, pesticides, heavy metals, bacteria and molds. Please refer to the New York State Medical Marijuana program (10 NYCRR Part 1004.14) or accredited third parties[2] for further guidance on how to perform such analytical tests and the frequency at which they are performed.

The Department does not approve nor maintain a listing of acceptable laboratories that can detect for chemical, physical and biological contamination in CBD products. However, the Department will accept any tests performed by private laboratories accredited by the ISO/IEC 17025:2005,2017 standard. To find out if your private laboratory holds this accreditation ask them to send you a copy of their ISO/IEC 17025 certificate.

CBD PRODUCTS: PROCESS AUDITS

In accordance with the Department's CBD Processor Research Partner Agreement, any facility manufacturing CBD products intended for human or animal consumption or absorption into the body shall be audited prior to sale or distribution of product to verify compliance with the relevant federal standard. Such audits must be conducted by a qualified, independent third party. The results of such a third-party audit shall be submitted to the Department prior to sale or distribution of the product. The third-party audit must provide evidence that the CBD processor is complying with the following requirements:

[2] To be considered qualified by the Department, a third-party auditor must be accredited by the American National Standards Institute, the ANSI National American Board, or the International Standards Organization (ISO) in the field of dietary supplement manufacturing. Examples of accredited third-party auditors in the field of dietary supplement manufacturing include the U.S. Pharmacopeia Convention, the Underwriters Laboratories Registrar, and NSF International.

- A CBD product developed and/or produced under a Research Partner Agreement, to the extent it is or will be a component of a dietary supplement,[3] must be manufactured, tested and labeled in accordance with this agreement and FDA law and regulations concerning dietary supplements, including, without limitation, 21 CFR 111.403(L) and 21 CFR 101.
- A CBD or other cannabinoid product developed and/or produced under a Research Partner Agreement, to the extent it introduces cannabinoids into or onto the body through topical application or other method for purposes other than as a dietary supplement, must be manufactured and labeled in accordance with 21 CFR 111 and 21 CFR 201 and complies with the provisions set forth in the Research Partner Agreement.

Applicants should be aware that the U.S. FDA has taken the position that CBD products are not dietary supplements. Applicants should understand the different regulatory approaches of the FDA and the State, and they should seek competent professional guidance with respect to the risk of engaging in the processing of CBD and the manufacture of CBD products under all applicable law. All Research Partners must make their own independent determination with respect to the legal obligations and requirements under federal and state law with respect to any product it produces.

SALE OF DRIED FLOWER

Industrial hemp flower that is marketed in New York as a food item, a food ingredient, or a food additive is being sold in violation of state law. This is true whether the seller is in the Research Pilot Program or not.

Growers may freely market and sell hemp and parts of the hemp plant (i.e. leaves, stalks, seeds) only to individuals or entities that use or process the hemp for purposes other than its cannabinoid content. Growers can sell hemp or parts of the hemp plant for use as fiber, construction materials, or in three forms as food (hulled seed, protein seed powder, and seed oil).

However: hemp and parts of the hemp plant that are sold *for its cannabinoid content* may be sold in New York State only to processors authorized as Research Partners in this program. The Research Partner Agreements do not bar out of state sales, but the research partner should be aware of any applicable federal or state law that govern such transactions before engaging in interstate commerce.

[3] A Dietary Supplement is any product a product intended to supplement the diet, containing a vitamin, mineral, herb, botanical, amino acid, and/or dietary substance used to supplement a person's diet by increasing the total dietary intake and as further specified in § 201(ff) of the Food Drug and Cosmetic Act.

Processors in the Research Pilot Program are not authorized to sell hemp flower in New York State as a final product for human consumption except to authorized processor or in dietary supplement form. Such final product must meet the processing, packaging, labeling and other standards set out in the Research Partner Agreement. Note that the dried flower needs significant additional processing in order to meet dietary supplement standards. Selling product out-of-state is not prohibited by the program, but processors are advised to understand the laws of the state they sell into.

This Program imposes no restrictions on sales of hemp plants or parts of hemp plants to be processed into cosmetic products such as lotions, creams, balms, soaps, etc. However, all other federal and state laws concerning the manufacture and sale of cosmetics must be adhered to.

No products intended for vaping or other forms of inhalation are permitted in this Research Pilot Program.

CHANGE OF OWNERSHIP

The terms of the Research Partner Agreement forbid the assignment or transfer of the Authorization. The Department will allow changes of ownership of the authorization holder upon request by the original applicant and upon a showing that the new shareholders or members meet the Department's review standards (e.g., new individuals must pass the same background check as the original individuals), that there is ongoing research and that the scope of the research remains the same and with a sufficient degree of continuity by those previously involved in the research. These evaluations are made on a case-by-case basis, upon application to the Department.

OTHER CONSIDERATIONS

- All Research Partners are required to file an annual report summarizing the results of their research pilot project and presenting any data collected in the course of that research. Annual reports are due on the anniversary of the project start date. Failure to file annual reports in a timely manner is grounds for revocation of permit.
- Losses sustained due to violation(s) of state or federal law, weather or any other condition during the research are the responsibility of the Research Partner. Applicants who are unable to bear the potential loss of assets and production costs of participating in the Industrial Hemp Agricultural Research Pilot Program should not apply to become Research Partners.
- The New York State Department of Environmental Conservation Pesticide Program has updated the NYSPAD database to add a designation for hemp. To find out what pesticides may currently be used on hemp crops, go to

http://www.dec.ny.gov/nyspad and select PRODUCTS SEARCH. Click on ADVANCED SEARCH. Within the Use/Type box, use the dropdown menu in the PESTICIDE USE box to select HEMP (INDUSTRIAL). Then click search to see the list of products that may be used in hemp production. The list will be updated periodically.

- The Department reserves to right to make determinations regarding the appropriateness of proposed growing and/or processing locations. Applicants must have an ownership or lease interest in the growing/processing location.
- Shared processing facilities must be registered to only one entity.
- Growing of industrial hemp in residential settings or as an ornamental is not allowed.

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GLOSSARY OF TERMS

Authorization: the final document issued upon approval of an Industrial Hemp Research Pilot Program application and the execution of the Research Partner Agreement, which allows the Research Partner to participate in the Program.

CBD (Cannabidiol): an extracted chemical component of the Cannabis sativa plant that is commonly used in wellness products.

Fiber, Grain or other Industrial Use: industrial hemp grown, processed and/or used for purposes other than the consumption or absorption of cannabinoids into the body.

Growing of Industrial Hemp: the planting and cultivation of Cannabis sativa with a THC content of not more than 0.3 percent, up to and including the harvesting and drying of the crop. Growing of industrial hemp does not include any processing steps beyond harvesting and drying.

Harvest Report: the document filed within 20 days of the anticipated date of harvesting an industrial hemp crop. Filing the Harvest Report starts the process of scheduling a time for a NYS Horticulture Inspector to visit the grow site to take samples of the industrial hemp plants that will then be sent to the Department for THC testing. The Harvest Report form can be found at https://agriculture.ny.gov/plant-industry/harvest-report-form.

Research Partner: a person or entity that has been authorized by the Department to grow and/or process industrial hemp as part of the NYS Industrial Hemp Agricultural Research Pilot Program.

Research Partner Agreement: the agreement that sets forth the terms and conditions for the research pilot, including, among other things, the scope of work, permitted activities, and obligations of a Research Partner in the Department's Program. Sample Research Partner Agreements are available for review on the Department's website at https://agriculture.ny.gov/industrial-hemp.

Scope of Work: the information provided in the application or approved amendments to participate in the Industrial Hemp Agricultural Research Pilot Program as a Research Partner.

For assistance with questions regarding the NYS Industrial Hemp Research Pilot Program, please call (877) 249-6841 or send an email to IndustrialHempNYS@agriculture.ny.gov.

Changes to New York's Industrial Hemp Agricultural Research Pilot Program FAQ

On October 31, 2019, the USDA released details on the new federal licensing program. Visit here for details.

On December 9, 2019, Governor Andrew M. Cuomo signed A7680a/S6184a, creating a state hemp licensing program for hemp growers and processors. Visit here for more information.

These two actions will change the landscape for growers and processors in New York State. Here's what you need to know:

1. **What does this mean for NY hemp growers? Do either of these changes affect my hemp grower license?**

   The new state legislation does not immediately affect the Department's current growers of hemp.

   The federal program lays out the terms of the new federal hemp licensing program that will replace the current federal research pilot program. These changes do not take full effect until November 1, 2020.

   Research Partners with current, valid authorizations to grow hemp do not need to take any additional action to remain in the Research Pilot Program. Their authorizations are still valid through October 31, 2020.

   New growers who would like to join the Research Program and growers whose authorizations expire prior to October 31, 2020, will be able to apply in early 2020 for authorization to grow industrial hemp in the 2020 growing season.

2. **Does this mean that your policy on CBD in food has changed?**

   No. The bill does not change the State's policy on CBD in food. The State does not currently allow the addition of CBD to food and beverages. The State allows the manufacture and sale of CBD as a dietary supplement, which ensures that it meets strict requirements for manufacturing, labeling and advertising for increased consumer awareness and protection.

3. **Can I start selling CBD water? The law signed allows 20 milligrams of CBD to be added to beverages.**

No, it remains illegal to sell foods and beverages with CBD added. The State law signed does not take effect for 90 days. The Governor and the legislature have agreed on legislative changes, which include removing that provision, to be enacted before March 9, 2020.

4. **How can I get a license to sell products with CBD or other hemp extracts?**

   A licensing program will be established in 2020 to allow the manufacture and sale of dietary supplement products with CBD or other hemp extracts. Until then, producers outside the Research Program are not able to manufacture dietary supplements containing CBD.

5. **Will New York State be joining the federal program?**

   The Department has concerns about several provisions of the USDA's Interim Final Rule and how they would affect our growers. Our priority is to support our growers and the hemp industry in New York State. We are in conversation with the USDA and with other states to help us determine the best course to keep our hemp industry growing. We expect to submit comments to the USDA on this Interim Final Rule.

   The Department encourages the industry to share their thoughts or concerns about the Interim Final Rule by submitting comments here. Comments will be accepted until December 30, 2019.

DEPARTMENT-CONDUCTED RESEARCH PARTNER AGREEMENT

INDUSTRIAL HEMP GROWERS

This Department-Conducted Research Partner Agreement for Industrial Hemp Growers ("Research Agreement"), dated _____between the State of New York, acting by and through the New York State Department of Agriculture and Markets, or another agency, department or authority of New York State subsequently designated by the State (the "Department") and _____(the "Research Partner").

WHEREAS, pursuant to Title 7 U.S.C. § 5940 and New York State Agriculture and Markets Law § 505, et seq., the Commissioner of the New York State Department of Agriculture and Markets has been granted the authority to approve sites for the study of the growth and cultivation, sale, distribution, transportation and processing of hemp and products derived from such hemp as part of an agricultural pilot program conducted by the Department; and

WHEREAS, the Department has decided to undertake an agricultural research pilot program with respect to industrial hemp as provided for in 7 U.S.C § 5940 (the "Research Pilot Program"); and

WHEREAS, pursuant to Agriculture and Markets Law § 506, et seq., the Department has the authority to partner with individuals, businesses and institutions of higher education in connection with its Research Pilot Program;

WHEREAS, the Research Partner has submitted an application to engage in research with respect to growth and cultivation of industrial hemp;

NOW THEREFORE, in consideration of the mutual covenants, terms and conditions set forth herein, the parties do hereby agree as follows:

SCOPE OF RESEARCH

1. The Research Partner shall act as a researcher in connection with the Research Pilot Program.

2. The Research Partner's authority to study industrial hemp in the manner set forth on its "Application to become a Research Partner in the Department's Industrial Hemp Research Pilot Program" (attached as Exhibit 1, and herein referred to as the "Scope of Work") shall commence upon the execution of this agreement by both parties and shall continue unless suspended or terminated, as set forth below.

3. The Research Partner's authority to research industrial hemp is limited to the research set forth in the Scope of Work and the Research Partner shall strictly adhere to the Scope of Work, except as otherwise authorized pursuant to

Paragraph 4, herein. The Department will monitor the Research Partner's compliance with the research focus, scope, locations and size as set forth in the Scope of Work and shall have the right to monitor compliance by, among other things, having the right to: access the registered premises, engage in periodic, unannounced inspections, conduct sampling and regulatory testing, inspect the books and records of the Research Partner, and to promptly receive information reasonably requested of the Research Partner with respect to the research project and/or its operations.

4. The Research Partner shall obtain prior written approval from the Department before implementing any modifications to the Scope of Work, including without limitation any modification of the research focus, scope, locations or size described in the Scope of Work and any changes to any site at which the research is being conducted (including additional addresses, changes or additions to any field, greenhouse, building and/or GPS coordinate).

5. Should the Research Partner seek to conduct additional industrial hemp research separate and distinct from that which is described in the Scope of Work, the Research Partner shall make new application for such other research pilot and must be approved by the Department prior to conducting the proposed research. Should the Research Partner decide to process industrial hemp beyond minimal processing for an agricultural product and intend to process hemp for its cannabinoid content, the Research Partner shall submit a separate application to become a research partner engaged in the processing of industrial hemp.

PARTIES CONDUCTING RESEARCH

6. At all times during the term of this Research Agreement, and with respect to the obligations surviving the expiration, suspension or termination of the Research Agreement as set forth in Paragraph 50 herein, the Research Partner shall remain responsible for the performance under this Research Agreement. If requested by the Department, the Research Partner shall present evidence of its continuing legal authority to do business in New York State, integrity, experience, satisfactory performance, ability and/or organizational and financial capacity to perform the Scope of Work.

7. The Research Partner shall disclose any felony or drug-related misdemeanor conviction within the last ten years and, upon the Department's request, agree to provide fingerprints and all necessary consents for the Department to obtain a criminal background check on the Research Partner, if an individual. In the event the Research Partner is not an individual, the Research Partner shall identify (a) the individual(s) in control of the Research Partner; and (b) whether such individuals have been convicted of any felony or drug-related misdemeanor within the last ten years. The Research Partner, upon the Department's request, shall provide

fingerprints and deliver all necessary consents for the Department to obtain a criminal background check on the individuals listed on Exhibit 2. The felony or drug-related misdemeanor conviction of the Research Partner or any of the individuals listed on Exhibit 2 and may result in the suspension or termination of the Research Agreement. During the term of this Research Agreement, in the event there is a change to the information provided under this paragraph, the Research Partner shall update that information within ten days of its occurrence.

8. The Research Partner shall: (a) provide a list of other persons (including all subcontractors, agents, independent contractors) who will provide material assistance of any kind to the Research Partner's research described in the Scope of Work; and (b) upon the Department's request, provide fingerprints and obtain all necessary consents for background checks for any such persons. During the term of this Research Agreement, in the event there is a change to the information provided under this paragraph, the Research Partner shall update that information within ten days of its occurrence.

9. The Research Partner shall notify the Department of any felony or drug-related misdemeanor conviction rendered against or plea of guilty entered by any individual performing services in connection with the Scope of Work during the term of this Research Agreement, within ten days of its occurrence. Such conviction may result in the disqualification of that person or entity from continued performance of the Scope of Work and/or may result in the suspension or termination of the Research Agreement.

10. The Research Partner's engagement of any subcontractor to perform any work described in the Scope of Work shall be approved in advance by the Department. The Research Partner shall require any subcontractor to provide information requested by the Department to determine whether the proposed subcontractor is a responsible service provider.

11. The Research Partner, notwithstanding any subcontracting, shall remain responsible and liable for all work performed by a subcontractor or under any subcontract with respect to the Scope of Work.

12. Upon execution of a subcontract, the Research Partner shall provide detailed subcontract information, and/or a copy of the subcontract, within fifteen (15) calendar days after execution. In the event the Research Partner chooses to provide only detailed subcontract information, upon the Department's request, the Research Partner shall provide copies of all contracts or subcontracts relating to the work described in the Scope of Work.

13. The Department, during the course of the pilot, retains the discretion to, among other things: (a) determine what persons, entities, and sites may continue to

participate in the Research Pilot Program; and (b) de-certify and de-register a site used to grow, cultivate or process industrial hemp at any time, following an opportunity to be heard.

14. It is understood and agreed that the legal status of the Research Partner, its employees, agents, partners, or subcontractors is that of an independent contractor and in no manner, shall they be deemed employees or agents of the State of New York and, therefore, are not entitled to any of the benefits associated with such employment or designation.

REPORTS, PUBLICATION AND INTELLECTUAL PROPERTY

15. The Research Partner shall file an annual report summarizing the results of the research described in the Scope of Work and share any data related to the growth, cultivation, sale, distribution, transportation and minimal processing of hemp and products derived from hemp during the course of that research, including, without limitation the dates of harvest of each variety planted, the amount of each variety harvested, and the disposition and/or use of the industrial hemp crop and the economic viability of the project. Annual reports shall be submitted to the Department on each anniversary of the issuance date set forth on the Research Partner's certification of authorization so long as the Research Partner Agreement is in force.

16. The State shall have a perpetual royalty-free, non-exclusive and irrevocable right to reproduce, publish or otherwise use, and to authorize others to use, data and materials required to be reported to the Department with respect to the Research Partner's agricultural research pilot or the results and accomplishments achieved.

17. All rights and title to intellectual property created, invented or discovered exclusively by the Research Partner in connection with the Research Pilot Program shall vest in the Research Partner. All rights and title to intellectual property created, invented or discovered exclusively by one or more New York State employees without the use of the Research Partner's resources shall vest in New York State. All rights and title to intellectual property created, invented or discovered jointly by one or more employees of the Research Partner and one or more employees of New York State with the use of Research Partner resources shall be jointly owned by the Research Partner and New York State.

CONFIDENTIALITY

18. Any data or records marked as confidential may be used or maintained only for the limited purposes of the Research Pilot Program. The parties agree that (a) the Department's obligation under this section may be limited by the requirements of the Freedom of Information Law or other applicable provisions of State and federal law and (b) the parties shall comply with the provisions of the New York State Information Security Breach and Notification Act (General Business Law § 899-aa; State Technology Law § 208).

19. The Research Partner consents to: (a) the Department providing information to law enforcement agencies about the industrial hemp research activities taking place at the agricultural pilot program sites; (b) entry onto all premises where hemp plants, product or materials are located by the Department, with or without cause, with or without advance notice, for inspection, sampling, testing or any other purpose relating to the research being conducted.

RISKS OF INDUSTRIAL HEMP RESEARCH

20. Pursuant to Title 7 U.S.C. § 5940 and New York State Agriculture and Markets Law § 505, et seq., the Department has been granted the authority and has decided to undertake an agricultural research pilot program with respect to industrial hemp as provided for under Federal and state law. The Research Partner acknowledges that absent participation in the Department's Research Pilot Program, the conduct of the research described herein might constitute a violation of both federal and state law.

21. The Research Partner is aware that: the federal and state regulatory environment surrounding industrial hemp is in transition; certain aspects of the law relating to industrial hemp are subject to differing interpretations; and the possession of industrial hemp outside the terms of this Research Agreement or the Scope of Work may constitute a violation of state and/or federal law.

22. The Research Partner is aware of the adoption of The Agriculture Improvement Act of 2018 (the "2018 Farm Bill"), which act contains provisions that materially change the federal and state legal and regulatory approach to industrial hemp.

23. Section 7605(b) of the 2018 Farm Bill provides for the repeal of 7 U.S.C. § 5940 (Legitimacy of Industrial Hemp Research) one year after the date on which the Secretary of Agriculture establishes a plan under § 297C of the Agriculture Marketing Act of 1946. At or prior to that time, the Research Pilot Program will be terminated, and the Research Partner, should it intend to engage in the research set forth in the Scope of Work or such other activities with respect to industrial

hemp, shall be required to qualify for and obtain all state and/or federal licenses required for its operation.

24. The Research Partner acknowledges that the state of the law with respect to industrial hemp is in flux at both the federal and state level, and that the Department expressly reserves the right, at its sole discretion, to eliminate, modify and/or add requirements concerning the research project or end the research pilot program, upon 60-day written notice.

25. The Research Partner is aware that there is currently proposed legislation, the adoption of which would require licensing by the State, may impose additional requirements or restrictions with respect to the Scope of Work and/or the Research Partner's operation and impose, additional fees and may authorize broader activities with respect to industrial hemp than permitted under the Research Partner Agreement

26. The Research Partner has made and shall continue to make its own independent determination with respect to its legal obligations under federal and state law with respect to any product it produces under this Research Agreement, and nothing in this Research Agreement shall be construed as the Department's position or determination as to how any product produced hereunder should be categorized and/or regulated under federal law.

27. The Research Partner represents that it is aware of the federal and state statutes governing the proposed research project, including the applicable guidance.

28. The Research Partner represents that it is aware of its obligation to comply with all current and future local, state, and federal laws and regulations applicable to, among other things, the growth, cultivation and processing of on-farm agricultural products.

29. The Research Partner acknowledges the inherent risk associated with participation in a research program focusing on a new crop. By entering this Research Agreement and agreeing to perform the Scope of Work, the Research Partner assumes and bears sole responsibility for financial or other losses that may result from the Research Partner's choice to participate as a researcher under the Research Pilot Program to study industrial hemp.

30. The Research Partner represents that it has sought whatever legal or other advice it believes to be appropriate and is not relying upon the Department's approval of its research proposal or any other statement or conduct by the Department in connection with the Research Partner's evaluation of any legal or other risk to which the Research Partner may be exposed in undertaking the project.

31. The Research Partner acknowledges that: (a) the Research Partner is responsible for its research, product testing and product safety; (b) the Department's approval of the Research Partner's application does not constitute an endorsement, approval or warranty, express or implied, as to the safety of any product grown or sold pursuant to this Research Agreement; and (c) the Department expressly disclaims any warranty of merchantability or fitness for a particular purpose for any product grown or sold pursuant to this Research Agreement.

32. The Research Partner agrees that the Department is not responsible for reimbursing or compensating it for any actual loss and/or loss of anticipated profits resulting from the Research Partner's involvement with or participation in the Research Pilot Program.

GROWTH AND CULTIVATION STANDARDS

33. Prior to planting, the Research Partner shall provide the Department with a list of the industrial hemp varieties that will be planted by or on behalf of the Research Partner and the amount of seed to be planted for each variety.

34. A harvest report form shall be submitted to the Department at least 20 days prior to the expected harvest date. However, in the event that planting does not occur, or a crop fails, the Research Partner shall inform the Department of either these events as soon as possible.

35. The Research Partner shall prepare, maintain, and make available to the Department, upon request, a record that sets forth an accurate inventory of industrial hemp plants and seeds and shall reasonably ensure that the industrial hemp seed and/or plants that are possessed, grown, or cultivated meet the definition of industrial hemp.

36. The Research Partner is responsible for the routine testing of the industrial hemp it produces to ensure that the delta-9 THC content does not exceed 0.3 percent, on a dry weight basis.

37. The Research Partner shall immediately make available to the Department such records relating to sampled specimens having a concentration of more than 0.3 percent of delta-9 tetrahydrocannabinol on a dry weight basis, in a form and at a location satisfactory to the Department.

38. The Research Partner shall promptly dispose of all industrial hemp in its possession reasonably believed, based upon the results of regulatory or other sampling, to have a concentration of more than 0.3 percent of delta-9 tetrahydrocannabinol, on a dry weight basis.

39. The Research Partner consents to the forfeiture or destruction, without compensation, of hemp material found by the Department to have a measured delta-9 THC content of more than 0.3 percent on a dry weight basis. The Research Partner consents to the Department's sampling, testing and inspection, without compensation, of any hemp material identified by the Department at the location described in the Scope of Work for the purpose of verifying the THC content of the hemp material grown, cultivated and/or possessed by the Research Partner.

40. The Department shall have full access to all premises, buildings, factories, farms, vehicles, cars, boats, airplanes, vessels, containers, packages, barrels, boxes, and/or cans for the purpose of enforcing the provisions of this article. Department representatives may, at such locations, examine industrial hemp and hemp products and may open any package and/or container reasonably believed to contain industrial hemp or hemp products, to determine whether such industrial hemp or hemp products follow applicable law or regulation.

41. The Department may quarantine industrial hemp when it has reason to believe that such commodity does not meet the definition thereof, set forth in § 505(1) of the Agriculture and Markets Law, or is otherwise in violation of or does not meet a standard set forth in, applicable law, regulation or the Research Partner Agreement. The quarantine may be put into effect by: (1) delivering written notice directing the owner or custodian of industrial hemp not to distribute, dispose of, or move that commodity without the written permission of the Department or (2) by placing a tag or other appropriate marking on the product or commodity or adjacent thereto that provides and requires that such product must not be distributed, disposed of, or moved without the Department's written permission, or (3) by otherwise informing the owner or custodian thereof that such condition must be complied with, followed by written notice of the quarantine.

42. The Department may seize industrial hemp by taking physical possession of industrial hemp when it has substantial evidence to believe that that commodity does not meet the definition thereof, set forth in subdivision (1) of § 505 of Agriculture and Markets Law, or is otherwise in violation of, or does not meet a standard set forth in, applicable law, or this Research Partner Agreement.

43. Subsequent to quarantining or seizing industrial hemp, as authorized in subdivisions (2) and (3) of this section, the Department shall promptly give the owner or custodian thereof an opportunity to be heard to show cause why such industrial hemp should not be ordered destroyed. The Department shall, thereafter, consider all the relevant evidence and information presented and shall make a determination whether such industrial hemp should be ordered to be destroyed; that determination may be reviewed as provided for in article seventy-eight of the civil practice law and rules.

44. It is the responsibility of the Research Partner to ensure that any product grown and cultivated pursuant to this Research Agreement is safe.

45. The Research Partner is solely responsible for any statements made with respect to the product and its safety.

46. In addition to any testing required to ensure the industrial hemp is being grown and cultivated using good agricultural practices and is safe for human or animal consumption/use, the Research Partner shall obtain confirmation of any self-testing for, among other things, THC content from a laboratory that is acceptable to the Department to perform such testing.

47. Any testing required under the Research Partner Agreement is the responsibility of the Research Partner and shall be performed at a laboratory that is acceptable to the Department to perform such testing. The Research Partner shall deliver the results of all such testing to the Department within seven days of receipt.

SUSPENSION AND TERMINATION

48. The Department, in its sole discretion, reserves the right to suspend any or all activities under this Research Agreement if it discovers information and has reasonable cause to believe that the Research Partner has failed to abide by any of the terms of this Research Agreement, or if the Research Pilot Program is altered or terminated by legislative, judicial or executive action. In the event of such suspension, the Research Partner shall be given written notice outlining the particulars of such suspension. Upon issuance of such notice, the Research Partner shall comply with the terms of the suspension order. Activity under this Research Agreement may resume at such time as the Commissioner or his or her designee issues a written notice authorizing a resumption of performance under the Research Agreement.

49. This Agreement may be terminated by either party without cause upon ninety (90) days prior written notice. In no event shall any suspension or termination by the Department constitute or be deemed a breach of contract, and, therefore, no liability shall be incurred by or arise against the State, its officers or employees for actual losses, anticipated lost profits and/or any other damages.

50. When it is determined that the Research Partner has failed to abide by any of the terms of this Research Agreement, upon written notice and following a reasonable opportunity to be heard, the Commissioner or his or her designee may terminate this Research Agreement, without any payment or compensation due to any party.

LIABILITY

51. The Research Partner shall be fully liable for the actions of its employees, agents, partners, or subcontractors and shall fully defend, indemnify, and hold harmless the State, its officers, and employees from suits, actions, proceedings, claims, losses, damages, and costs of every name and description relating to any and all accidents, personal injury and damage to real or personal tangible property caused by any intentional act or negligence of the Research Partner, or its employees acting within the scope of their employment, agents, partners and/or subcontractors in connection with this Research Agreement, without limitation; provided, however, that the Research Partner shall not be obligated to indemnify the State, its officers, or employees for any claim, loss, damage, or cost arising from this Research Agreement to the extent caused by the negligent act, failure to act, gross negligence, or willful misconduct of the State, its officers, or employees.

52. The State shall not be liable for any consequential, indirect or special damages of any kind which may result directly or indirectly from this Research Agreement.

TAXES

53. In the performance of any work under the Research Agreement, the Research Partner will be responsible for all applicable federal, State, and local taxes and for all FICA contributions that the Research Partner may be required to make on its own behalf or on behalf of its employees, agents, partners, or subcontractor.

FORCE MAJEURE

54. Neither party hereto will be liable for losses, defaults, or damages under this Research Agreement that result from delays in performing, or inability to perform, all or any of the obligations or responsibilities imposed upon it pursuant to the terms and conditions of this agreement, due to or because of acts of God, a public enemy, acts of government, earthquakes, floods, strikes, civil strife, terrorism, fire or any other cause beyond the reasonable control of the party that was so delayed in performing or so unable to perform, provided that such party was not negligent and shall have used reasonable efforts to avoid and overcome such cause. Such party will resume full performance of such obligations and responsibilities promptly upon removal of any such cause. Notwithstanding the occurrence of any event described above, the Department's right of access to the Registered Premises shall not be denied.

ASSIGNMENT /CHANGE OF CONTROL

55. This Research Agreement is not assignable or transferrable by the Research Partner. Any change of control or ownership of the Research Partner or of the individuals doing research pursuant to this Research is subject to and permitted only upon the prior written approval of the Department, which approval may be granted or withheld, in the Department's sole discretion. The Department may assign, transfer and/or delegate the administration of this Research Partner Agreement to another agency, department or authority of the State of New York. The Department shall provide written notice of any assignment, transfer or delegation, at least 15 days prior to its effective date.

NOTICES

56. Any notice or communication by any party to the other required or permitted hereunder shall be in writing and shall be deemed duly served as of: (a) the date it is delivered by hand; (b) three business days after having been mailed by certified mail, postage prepaid, return receipt requested, or (c) the next business day after having been sent for delivery on the next business day, shipping prepaid, by a nationally recognized overnight courier, in each case to the receiving party at the address set forth on the signature page of this Research Agreement, or at such other address as a party may designate by written notice to the other party sent in the manner set forth herein.

SEVERABILITY

57. In the event that any one or more of the provisions of this Research Agreement shall for any reason be declared unenforceable under the laws or regulations in force, such provision will have no effect on the validity of the remainder of this agreement, which shall then be construed as if such unenforceable provision had never been written or was never contained in this Research Agreement.

SURVIVAL

58. The provisions of Section 15 (Publication/Publicity), Sections 16, 17(Intellectual Property), Sections 18, 19 (Confidentiality), Sections 51, 52 (Liability) and Section 53 (Taxes) of this Research Agreement shall survive its suspension or termination.

ENTIRE AGREEMENT

59. This Research Agreement and any referenced exhibits constitute the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior agreements and understandings of the parties, whether written or oral, with respect to the subject matter hereof. No statement, promise,

condition, understanding, inducement or representation, oral or written, express or implied that is not contained herein shall be binding or valid. This Research Agreement may not be changed, modified or altered in any manner except by an instrument in writing executed by the Department and the Research Partner.

IN WITNESS WHEREOF, the parties hereto have executed this Research Agreement as of the day and year first written above, and the persons signing this agreement represent and warrant that they are duly authorized to sign on behalf of the respective parties.

THE STATE OF NEW YORK,
acting by and through the Commissioner of
the Department of Agriculture and Markets

By: _____
Name:
Title:
Date:

RESEARCH PARTNER SIGNATURE BLOCK

By: _____
Name:
Title:
Date:

ACKNOWLEDGEMENT FOR CORPORATIONS OR OTHER ENTITIES

STATE OF NEW YORK)
ss.:
COUNTY OF _____)

On the ____ day of _____, 20__, before me personally appeared _____, to me known, who being by me duly sworn, did depose and say that he/she resides at _____, and is the _____ of the Research Partner described herein, which executed the foregoing Research Agreement; and that he/she signed his/her name with authorization of the Research Partner.

Notary _____

ACKNOWLEDGEMENT FOR INDIVIDUALS

STATE OF NEW YORK)
ss.:
COUNTY OF _____)

On the ____ day of _____, 20__, before me personally appeared _____, to me known, who being by me duly sworn, did depose and say that he/she resides at _____, and is the Research Partner described herein, who executed the foregoing Research Agreement.

Notary _____

INSIGHT

Second Time's a Charm? Governor Cuomo Introduces New Legislation to Regulate Adult-Use Cannabis in New York State

January 24, 2020
Author: Neil M. Willner

To help close New York's $6 billion budget gap, Governor Andrew Cuomo introduced legislation that would legalize adult-use cannabis within the state as part of his proposed budget for fiscal year 2021, anticipating that tax revenue could bring in hundreds of millions of dollars over the next several years. Since the New York State Legislature must approve the budget by April, New York could see adult-use cannabis become a reality within the next few months.

The revamped Cannabis Regulation and Taxation Act (CRTA) includes new social justice initiatives to help those communities disproportionally affected by the drug war, allows for on-site cannabis consumption, and creates a three-tiered licensing scheme similar to New York's Alcoholic Beverage Control Law. The Act would create a centralized Office of Cannabis Management to oversee the state's medical marijuana program, adult-use program and hemp program. Led by an executive director, the Office of Cannabis Management also would include a "cannabis control board" comprising five board members appointed by the governor. Among a slew of delegated tasks, the board would be charged with approving social and economic equity plans, approving the type and number of licenses, creating new licenses and promulgating rules for the cannabis regime.

The executive director would have the authority to limit the number, scope and availability of licenses and permits to be issued for cannabis-related activities. In addition, the executive director would be required to appoint a deputy director for health and safety and a deputy director for social and economic equity.

Adult-Use Cannabis
In legalizing recreational cannabis for adults 21 years of age and older, CRTA creates six license categories:

- Cultivator license
- Processor license
- Cooperative license
- Distributor license
- Retail dispensary license
- On-site consumption license.

Like New York's Alcoholic Beverage Control Law, CRTA prohibits vertical integration, banning overlapping ownership interest across multiple license categories. For example, persons or entities holding a cultivator license are prohibited from holding a retail dispensary license and cannot have any direct or indirect interest in one.

Cultivator licensees are permitted to plant, grow, clone, harvest, dry, cure, grade and trim adult-use cannabis. Licensees also can obtain one processor's license and one distributor's

Attorneys
Neil M. Willner

Services
Cannabis Law

Insurance Regulatory & Compliance

Insurance & Reinsurance Coverage

Medical Malpractice & Health Care

Offices
White Plains

license.

Processor licensees are permitted to blend, extract, infuse, package, label, brand and sell cannabis products to licensed distributors.

Distributor licensees are permitted to distribute and sell cannabis from a licensed processor, microbusiness cultivator or adult-use cooperative to a licensed dispensary. Distributors are expressly permitted to charge fees for distributing cannabis based on the volume of cannabis distributed.

Retail dispensary licensees are permitted to sell cannabis on their licensed premises to retail consumers. Licensees can have up to three retail locations.

Retail dispensary licensees also can have **an on-site consumption license**, provided that they notify the municipality in which the on-site consumption site resides. The provisions governing on-site consumption licenses are noticeably vague and, unlike prior versions of the legislation, there are no restrictions regarding the amount of cannabis, or form factors of cannabis, consumers can purchase. The vague provisions that inevitably will be circumscribed by regulators could open the door for a new and burgeoning market sector.

The legislation also requires the Office of Cannabis Management to create an economic equity plan that actively promotes racial, ethnic and gender diversity in the adult-use cannabis industry. The plan must (1) prioritize applicants who qualify as a minority, a women-owned business, a social equity applicant or a disadvantaged farmer and (2) positively impact areas that have been harmed through disproportionate enforcement of the war on drugs.

In addition to adult-use licenses, CRTA establishes various "special-use" permits for ancillary businesses. These permits include:

- Nursery permit to produce clones, immature plants and seeds
- Solicitor's and broker's permit to solicit cannabis orders and broker transactions for commissions
- Delivery permit to authorized cannabis dispensary licensees or third parties to deliver cannabis directly to consumers
- Caterer's permit to authorize the service of cannabis products at a function or event in a hotel, restaurant, club or ballroom.

Licensees also are expected to abide by strict packaging, labeling and advertising restrictions. CRTA sets forth various requirements that the Office of Cannabis Management must include in its regulations applicable to protect consumers and the general public.

Like last year's legislation, counties or cities can opt out of the adult-use plan. However, they must have 100,000 or more residents and adopt a local law or ordinance by a majority vote of the governing body.

The 10 Registered Organizations (ROs) that currently have medical marijuana licenses will not be grandfathered automatically into the adult-use program. CRTA gives the executive director authority to grant some or all of the ROs the ability to cultivate, process, distribute and sell adult-use cannabis products without abiding by the restrictions that prohibit overlapping ownership interests across tiers. The Office of Cannabis Management will have the authority to hold a competitive bidding process to determine which ROs will be entitled to this exemption. Alternatively, ROs can apply for any adult-use cannabis license, but they will be subject to the ownership interest restrictions.

Medical Marijuana

CRTA leaves New York's existing medical marijuana regime largely intact, and includes only a handful of changes. Significantly, certified patients are permitted to grow their own cannabis at home for medical use. Moreover, the Office of Cannabis Management is authorized to license additional medical marijuana providers over and above the 10 currently operating in the state.

Under CRTA, hospitals, nursing homes and other care facilities can register as designated caregiver facilities, permitting the facilities to possess, deliver, transport or administer medical cannabis to certified patients under its care.

Finally, CRTA creates a "cannabis research license" that permits a licensee to produce, process, and purchase and possess cannabis for clinical studies and to research the efficacy

and safety of using cannabis as part of medical treatment.

Cannabinoid Hemp and Hemp Extract

The proposed hemp legislation is nearly identical to the hemp bill signed into law by Governor Cuomo in late 2019, and creates a cannabinoid hemp processor license to process cannabinoid hemp used for human consumption. CRTA also creates a cannabinoid hemp retailer license, requiring retailers who sell hemp for human consumption to consumers to be registered and licensed with the state.

The legislation permits the Office of Cannabis Management to promulgate packaging and labeling regulations, requiring processors to include information such as serving sizes and dosages, active cannabinoid concentration per serving size, and the growing region, state or country of origin of the hemp.

Unlike prior versions of hemp legislation, there is no prohibition against adding cannabinoids to foods or beverages.

As CRTA moves through the state legislature, Wilson Elser's Cannabis Law practice team will keep a close watch.

INSIGHT

Designating Access to Cannabis an Essential Service amid COVID-19 Pandemic

March 20, 2020

Authors: Ian A. Stewart, Ruben Espinosa, Neil M. Willner, Dean A. Rocco

NOTE: The response by governmental entities to Covid-19 is rapidly developing and subject to change at any time without notice. The information within this report is current only through March 19, 2020.

Many states and municipalities are considering whether businesses that provide access to cannabis should be designated an "essential service" in the face of the COVID-19 pandemic. Essential services are those services and functions that are necessary, even during a pandemic, to maintain the health and welfare of the public. States and municipalities have different priorities for what constitutes an essential service, but most include essential infrastructure, transportation services, grocery stores, hardware stores, laundry services, banks, health care operations and pharmacies.

Access to cannabis used for medical purposes varies greatly state to state. In medical cannabis states, registered medical cannabis patients have little or no choice but to obtain their medicine through licensed dispensaries. In adult-use states such as California and Colorado, many who use cannabis for medical purposes obtain it through adult-use retail stores and delivery services. Regardless of the distribution model, a strong argument can be made that access to cannabis through retail stores and delivery services should be included as an essential service and remain available to the public during the crisis.

In addition to the angst of medical patients who fear losing access to their medicine, many cannabis businesses know that lengthy shelter-in-place orders and other mandatory closures pose an existential threat to the industry, which is overwhelmingly composed of small businesses that are already faced with expensive compliance costs, high taxes and razor thin profit margins.

Within the past few days, several states and municipalities have responded publicly by identifying cannabis operations as essential businesses that may remain open. Others have modified their policies regarding delivery services. Following is a breakdown of select jurisdictions that have responded to the current crisis.

California

On March 19, 2020, an **emergency order** was issued by Governor Gavin Newsom ordering all 40 million California residents to stay at home and not work, except for essential services, which are defined in the order as the 16 critical infrastructure sectors identified by the Cybersecurity and Infrastructure Security Agency (CISA). Although cannabis is not identified specifically within the CISA list, the order identifies certain services as essential, including food, prescriptions and health care.

In support of the governor's order, the California State Public Health Officer and the California Department of Public Health have released a list of essential critical infrastructure workers. Cannabis retailers are listed as part of the essential workforce under the category of workers

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in other medical facilities. In addition, “workers supporting cannabis retail and dietary supplement retail” are listed as essential workforce within the food and agriculture sector.

California’s Bureau of Cannabis Control has sent a notice clarifying that “because cannabis is an essential medicine for many residents, licensees may continue to operate at this time so long as their operations comply with local rules and regulations.” Cannabis businesses must implement social distancing measures.

In addition to the state order, multiple cities and counties within California have issued orders that explicitly include cannabis as an essential service. These include Los Angeles, San Francisco, Palm Springs, Orange County and Los Angeles County.

Colorado

On March 16, 2020, Governor Polis ordered the closure of all Colorado restaurants and bars to in-person dining. The state has not yet issued guidance that may impact marijuana businesses, though Governor Polis has indicated that Colorado will treat cannabis dispensaries the same as other pharmacies. Notably, both Summit and Gunnison counties issued their own, more restrictive closure ordinances, but both permitted marijuana dispensaries to remain open, along with banks, grocery stores, pharmacies and certain other services.

Florida

On March 16, 2020, **Emergency Order 20-002** was enacted to temporarily allow qualified physicians to use telemedicine to recertify medicinal cannabis certifications for qualified patients. Unless extended, the Emergency Order will be in effect for only 30 days, and qualified physicians may not use telemedicine to certify any patients after April 15, 2020.

At this time, it is unclear whether there is a pending statewide decision to shut down nonessential businesses. The City of Miami Beach has shut down nonessential businesses, which excludes pharmacies, grocery stores, convenience stores, private offices, banks, hotels, hospitals, medical service providers, medical supply stores**,** hardware stores, gasoline service stations and automotive supply/repair centers. While state dispensaries are not specifically identified, it is likely they are excluded based on these terms.

Illinois

On March 16, 2020, the Illinois Department of Financial and Professional Regulation issued guidance to help stop the rapid spread of COVID-19. That guidance specifically recognizes that “medical cannabis patients may be particularly vulnerable to COVID-19 due to preexisting conditions.” In light of this, the state granted an emergency variance to allow cannabis dispensaries to service medical cannabis patients and designated caregivers outside “limited access areas” until March 30, 2020, provided the dispensaries follow these specific protocols:

- The exchange of cash and product must take place on the dispensary’s property or on a public walkway or at the curb of the street adjacent to the dispensary. No delivery is permitted.
- The patient or caregiver’s card must be scanned prior to purchase and the purchase must be tracked in the state traceability system.
- Cash must be taken into the dispensary after each transaction.
- Security must be present for outdoor exchanges.

The variance does not apply to adult-use purchases.

The guidance further calls for dispensaries to ensure patients, caregivers and purchasers remain more than six (6) feet from other patrons while in line and within the dispensaries.

The guidance also includes sanitary practices, requiring dispensaries to remain vigilant in their observance. This includes allowing agents to wash their hands frequently throughout the day and to provide an ample supply of hand soap. All surfaces that patients are required to touch must be disinfected at least every 30 minutes. Dispensaries also are urged to post their sanitation protocols and inform patients and caregivers of the measures being taken. Department inspectors will be watching cameras daily to ensure compliance with regular laws and this new guidance.

The **guidance document** can be found on the website of the Illinois Department of Financial and Professional Regulation.

Massachusetts

The Cannabis Control Commission has not issued any guidance on marijuana sales during the COVID-19 pandemic. The Commission's staff is working remotely, and allowing doctors to renew medical marijuana certifications over the phone and by video so long as the patient was seen in person within the past year. The Commission also is encouraging medical dispensaries to expand medical delivery while recreational delivery is still coming online. While there are reports of adult-use customers trying to stockpile marijuana, the Commission has allowed the dispensaries to decide how to manage customers on their own. In compliance with social distancing, some dispensaries are requiring that customers place orders before arriving at the dispensary. Patient groups are advocating that cannabis businesses be designated "essential."

Michigan

On March 16, 2020, the Marijuana Regulation Agency of Michigan (MRA) published an **advisory bulletin** modifying its home delivery policy for both medicinal and adult-use businesses. The MRA has publicly encouraged home delivery services and has temporarily allowed curbside pickup. The MRA also allows home delivery for patients and customers whose current residential addresses do not match the addresses on their state-issued identification cards. The MRA requires that each marijuana establishment first seek approval for their delivery procedure. A 24- to 48-hour time frame has been announced for its approval process.

Nevada

On March 17, 2020, Governor Steve Sisolak issued guidance for a 30-day shutdown of Nevada businesses and social life. Cannabis dispensaries are permitted to remain open if employees and customers strictly comply with social distancing protocols. Nevada's social distancing guidelines require that dispensaries ensure that each person stays six (6) feet distant from others. The Nevada Health Response Center also is encouraging consumers to use delivery services and not congregate in stores.

New York

On March 19, 2020, Governor Cuomo issued an Executive Order requiring all businesses to use telecommuting or work from home procedures to the maximum extent possible, with the exception of essential businesses. On March 17, 2020, the New York State Department of Health **issued guidance** identifying registered organizations in the state's medical marijuana program as essential businesses during the COVID-19 pandemic. (Notably, New York does not yet have an adult-use commercial cannabis program.)

In the event that nonessential businesses are forced to shut down, the Department has granted permission for registered organizations in the state's medical marijuana program to remain open since they are considered medical providers. The Department acknowledges that "many registered medical marijuana patients may have severe debilitating or life-threatening conditions and are immunocompromised." As a result, the Department has announced modifications to its dispensing and home delivery policies.

Regarding dispensing, registered organizations are allowed to dispense medical marijuana products at their dispensary doors to limit potential exposure to their staff and other patients. In doing so, each dispensary still must comply with all current laws, rules and regulations.

Regarding home delivery, the Department directs that until April 16, 2020, registered organizations approved to deliver medical marijuana products to the homes of patients and caregivers are permitted to expand their delivery services without seeking the Department's prior written approval. However, it is recommended that drivers:

- Wear masks and gloves while making deliveries
- Sanitize their hands after each delivery
- Encourage patients to use their own pens when a signature is required.

Registered organizations are allowed to confirm receipt of the delivered medical marijuana products by the patient or caregiver through a phone call, text or email in lieu of obtaining a signature so long as the confirmation is documented and retrievable upon audit.

Oregon

On March 16, 2020, Governor Kate Brown issued **an order** allowing businesses, including

recreational and medical marijuana dispensaries, to remain open at their own discretion. Businesses are required to implement strong social distancing measures and close temporarily until a reliable policy is in place.

Pennsylvania

While the Department of Health has strongly encouraged bars and restaurants to close, medical marijuana dispensaries have been permitted to remain open. (Notably, Pennsylvania does not yet have an adult-use commercial cannabis program.) A health department spokesperson recently told the *Philadelphia Inquirer* that "medical marijuana dispensaries are considered pharmacies and therefore considered essential businesses." Although home delivery is prohibited in Pennsylvania, the Department of Health has announced that it is "considering options to assist patients during the COVID-19 response."

Washington

On March 17, 2020, the Liquor and Cannabis Board issued guidance in response to the COVID-19 pandemic. Following Governor Jay Inslee's proclamation shutting down restaurants, bars, coffee shops or a slew of other public venues where people congregate, Director Rick Garza sent an **email bulletin** to industry members explaining marijuana retailers are not required to close. The guidance echoed take-out requirements for restaurants and curbside pickup variances permitted to alcohol licensees and temporarily allows "cannabis retailers to sell to qualifying patients or their designated providers outside of their business but within the licensed property line." This essentially permits curbside pickup for marijuana patients. Restrictions, however, prohibit drive-through windows. Moreover, qualified patients and designated providers must be valid medical marijuana cardholders and registered with the state's Department of Health.

Conclusion

The cannabis industry has faced other crises. Most recently, the industry vigorously responded to and successfully weathered the vape crisis during the fall of 2019. The COVID-19 pandemic, however, presents a more immediate and potentially existential threat to a wide cross-section of cannabis businesses. Developments occur rapidly and we expect additional jurisdictions to make decisions on medical cannabis as an essential service within the coming days.

The Wilson Elser Cannabis Law practice is monitoring these developments closely. Additional information can be found at **www.wilsonelser.com/cannabis**.

INSIGHT

FDA Report Brings Hope for CBD Dietary Supplements

March 17, 2020

Authors: Ian A. Stewart, Neil M. Willner

In response to a recent directive from Congress, the U.S. Food and Drug Administration (FDA) has released a report that describes "the agency's progress toward obtaining and analyzing data to help determine a policy of enforcement discretion and the process in which CBD meeting the definition of hemp will be evaluated for use in products." The report outlines a variety of actions taken or being considered by the FDA to advance the potential regulatory pathways for CBD.

Reiterating many of its long-standing positions, the FDA stood firm and expressed its primary concern for consumer safety and lack of scientific data on CBD products. The report maintains the FDA's hands-off approach to CBD in cosmetics and does little to advance the agency's stance on CBD in human and animal drugs and foods. But, for perhaps the first time, the FDA signaled a policy shift and potential regulatory pathway for CBD in dietary supplements.

Recognizing its authority to create an exemption through rulemaking that would allow CBD products to be sold as dietary supplements, the FDA will continue evaluating the differences between full-spectrum and broad-spectrum products compared with isolate products. This shift hints at a regulatory pathway that the industry has suspected for some time.

Safety Concerns Remain the Priority

The FDA continues to highlight its concern over the potential safety risks of using CBD, including risks associated with liver injury, drug interactions, drowsiness that may affect driving, and potential male reproductive toxicity. Also of concern are the long-term effects of using CBD, cumulative exposure and use by vulnerable populations such as children, the elderly and women who are pregnant or lactating.

Essential questions include: What happens if you use CBD daily for sustained periods of time? What level of intake triggers the known risks associated with CBD? How do different methods of exposure affect intake, such as oral consumption, topical use or vaping? What is the effect of CBD on the developing brain?

The FDA's Position on CBD in Drugs, Food and Cosmetics Remains Unchanged

The FDA has not changed – and almost certainly will not change – its position with respect to the use of CBD as a drug. Under the Food, Drug and Cosmetics Act's drug exclusion rule, once a substance that was never in the food supply is (1) an active ingredient of an approved drug product or (2) an active ingredient of a product in clinical trials that have been made public, a food or supplement containing that substance cannot be shipped in interstate commerce.

The FDA has cited Epidiolex® as an example of a clinical investigation regarding CBD that has been made public. Epidiolex was approved by the FDA in June 2018 for treatment of childhood seizures associated with two rare forms of epilepsy. The Agency has therefore concluded that CBD products are in fact drugs and require FDA approval.

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The FDA again maintains a strong position that CBD cannot lawfully be added to human or animal food because "the data currently available to FDA raise safety concerns about the use of CBD in food." The report encourages the continued development and sharing of information with the FDA "regarding whether there are conditions under which CBD could safely be added to food."

The report does not materially change the FDA's position with respect to CBD in cosmetic products. The agency has stated previously that although certain cosmetic ingredients are prohibited or restricted by regulation, "currently that is not the case for any cannabis or cannabis-derived ingredients."

Nevertheless, the FDA warns that no ingredient − including cannabis-derived ingredients – can be used in a cosmetic if "it causes the product to be adulterated or misbranded." A cosmetic may be considered adulterated "if it bears or contains any poisonous or deleterious substance that may render it injurious to users under the conditions of use prescribed in the labeling."

The FDA also cautions that a product may be considered both a cosmetic and a drug − even if it affects the appearance − if it is "intended to affect the structure or function of the body, or to diagnose, cure, mitigate, treat or prevent disease."

The report states that the FDA is aware of only limited data on CBD when used topically. The FDA points to some animal studies that provide information on the skin permeability of CBD cream or gel, but notes that clinical evidence of safety is lacking. The agency has initiated a research study to evaluate CBD and THC levels in a sample of cosmetic products to assess sensitization and dermal penetration.

The FDA Anticipates Rulemaking for Allowing CBD in Dietary Supplements

Though CBD products cannot be marketed lawfully as dietary supplements, the FDA is considering using its authority to create an exemption through its rulemaking process. The report cautions that the FDA is considering how potential CBD rulemaking may impact the agency's ability to provide effective oversight not only for CBD products but also for other types of dietary supplements.

For example, the FDA lacks clear authority to require dietary supplement companies to disclose what products they are making and selling to consumers. There also is concern that expanding the FDA's responsibility to include a large number of new products will impact the agency's overall workload and the prioritization of CBD over other dietary supplements. The report nevertheless outlines several "additional next steps" that may facilitate this rulemaking, discussed below.

Vape Products

The FDA deftly sidesteps its lack of regulatory authority over CBD vape products. The report acknowledges that the FDA has no regulatory oversight over some products containing CBD that fall outside its jurisdiction "even to address potentially serious matters of public health and safety." The report identifies certain public health questions with vaping CBD, including toxicity concerns as well as the potential use by children and other vulnerable populations.

The FDA affirms that it will regulate CBD-containing vape products that meet the definition of "tobacco products," which cannot be marketed without FDA premarket authorization. Left unsaid in the report, however, is the fact that the vast majority of CBD vape products do not contain tobacco or nicotine, such that they are not currently regulated by the FDA. For these products, the report merely concludes that "more safety data and research are needed on this route of administration and potential applications for local and systemic effects."

Additional Next Steps

The FDA identifies several "additional next steps" relating to its enforcement policy, including the need for additional safety information, further engagement with other regulatory partners, evaluation of full-spectrum and broad-spectrum hemp extracts, new research and CBD product sampling.

Enforcement Policy

The report confirms that the "FDA has been actively monitoring the CBD market for violative products that pose the greatest risk to consumers." This includes products being marketed with unsubstantiated therapeutic claims, as well as products that put the public at risk in other ways, such as through contamination, incorrect statements about the amount of CBD and products marketed for use by vulnerable populations such as children.

With regard to possible changes to its enforcement policy, the report states that the "FDA is currently evaluating issuance of a risk-based enforcement policy that would provide greater transparency and clarity regarding factors FDA intends to take into account in prioritizing enforcement decisions."

Distinguishing Full-Spectrum and Broad-Spectrum Hemp Extracts from CBD Isolate Products
For the first time, the FDA has stated publicly that it intends to evaluate whether "full-spectrum" or "broad-spectrum" hemp extracts should be treated differently than other CBD products, including those that contain highly concentrated CBD isolate. See our recent article on this topic, "**Uncertainty Surrounds Legality of Different CBD Forms**."

The FDA report states:

Products that are being marketed with such terms can vary widely in their characteristics, but our understanding is that such terms generally are intended to convey that the product is not a CBD isolate, and that the products contain other substances extracted from the plants. At the same time, we are aware that many products currently marketed as "full-spectrum" or "broad-spectrum" hemp extracts may contain very high concentrations of CBD, and may be derived from varieties of the hemp plant that have been selected specifically for their high CBD content.

The FDA is actively seeking information regarding the manufacturing processes for full- and broad-spectrum hemp products and how they compare with CBD isolate products. "Such information will be critical to informing our evaluation of the regulatory status of such products."

Receipt of Safety Information; Further Collaboration, Research and Product Sampling
To facilitate receipt of additional product-specific information, the FDA is reopening indefinitely the docket established as part of its May 2019 public meeting in order to have a central publicly accessible place to receive new information.

The FDA also will collaborate with state and local regulators, other federal agencies and foreign regulatory counterparts to share information on cannabis-derived compounds, including CBD. In addition, the FDA continues to pursue additional research into CBD products, including studying CBD exposure during pregnancy and the use of CBD in cosmetic products, among other studies.

The report also explains that Congress has instructed the FDA to perform a sampling study of the current CBD marketplace "to determine the extent to which products are mislabeled or adulterated." The agency will report the results of its sampling study to Congress within 180 days. This inevitably recognizes the proliferation of CBD products in the marketplace and the extent to which bad actors could harm consumers. When the FDA last randomly sampled CBD products in 2015, just 2 of the 24 products sampled contained the amount of CBD claimed on the label.

The Takeaway

While the FDA is firmly entrenched in its position regarding CBD in foods and beverages, it has finally expressed a clear intent to create a viable regulatory pathway for CBD as a dietary supplement. The new report clearly indicates a desire by the agency to strike a balance between consumer demand and concerns over safety.

Whereas many have been frustrated by a perceived lack of action on the part of the FDA, this report lays out several concrete steps that may pave the way for CBD as a dietary supplement through FDA rulemaking. These steps include a focus on obtaining safety and use data on specific CBD products, completion of research studies already under way and conducting a sampling study on CBD products to help prevent product mislabeling and adulteration.

The FDA's report has been issued amid other signs that CBD policy is advancing in the United States and abroad. FDA's newly appointed commissioner, Stephen Hahn, acknowledged on February 26, 2020, that CBD products are here to stay. "People are using these products. We're not going to be able to say you can't use these products. It's a fool's game to try to even approach that."

Commissioner Hahn further recognized that "We have to be open to the fact that there might be some value in these products and certainly Americans think that's the case. But we want to get them information to help them make the right decisions."

New guidance on CBD products also has been issued in the United Kingdom by its Food Standards Agency (FSA). This guidance allows current CBD products to remain on the shelves but requires businesses to submit novel food authorization applications by March 31, 2021. After that date, only products for which the FSA has a valid application will be allowed to remain on the market. The guidance should facilitate the availability of regulated CBD products in the United Kingdom.

The World Health Organization (WHO) also recently weighed in on CBD products, emphasizing that CBD is not subject to control under the 1961 Single Convention because it "shows no potential for abuse or dependence and any ill-effects are minimal." In its January 31, 2020, report for the United Nations Commission on Narcotic Drugs, WHO stated that it was "aware that CBD products, such as foods, are being sold in many countries," and that "Member States can regulate its availability using their own national legislation."

Those who wish to see movement toward a regulatory pathway for CBD in the United States should take encouragement from the FDA's report to Congress. Given that the agency moves notoriously slowly in its regulation of drugs, food and supplements, there appears to be good progress made since public hearings were held by the FDA in May 2019. All eyes are now on the results of the FDA's CBD product sampling study, which is due to be reported to Congress by June 20, 2020.

This article appeared in the March 16, 2020, edition of *Law360*.

INSIGHT

The Empire State of Cannabis

July 9, 2019
Author: Neil M. Willner

Marijuana decriminalization is in, adult-use is out, a regulated hemp-derived CBD marketplace is in limbo, and NYC begins CBD ban.

For New York's cannabis industry, 2019 began with a bang and ended with a whimper. In January, Governor Cuomo announced that legalizing marijuana and creating a regulated adult-use marketplace was a top legislative priority. Indeed, Governor Cuomo included an omnibus marijuana bill as part of his proposed budget. Known as the "Cannabis Regulation and Taxation Act," the bill would have legalized recreational marijuana, overhauled the state's medical marijuana system and created new hemp regulations. Since the senate and assembly were both under democratic control, "green fever" swept across the state.

The anticipation quickly waned. Democrat leaders argued that Governor Cuomo's proposal lacked sufficient social justice components and failed to help those communities most affected by the war on drugs. As the April deadline neared for the budget's passage, it became increasingly clear that the Cannabis Regulation and Taxation Act would not make the final cut.

After the budget left recreational cannabis in the dust, new excitement mounted as negotiations continued in the Legislature to pass a stand-alone bill, the revitalized "Marijuana Regulation and Taxation Act," before the 2019 legislative session ended in mid-June.

Ultimately, the bill failed in a rollercoaster final week, and once the smoke cleared the Legislature passed a compromise marijuana decriminalization bill and a bill to regulate hemp extracts such as cannabidiol (CBD). While Governor Cuomo is expected to sign the decriminalization bill into law, he recently stated he is not yet sure if he will sign the new hemp legislation.

S 6579A – New York's Marijuana Decriminalization Legislation

Once signed into law, Senate Bill 6579A will decriminalize marijuana and automatically expunge low-level marijuana offenses. Under the new bill, possession of up to one ounce of marijuana will exact a $50 fine and will be considered a violation. Possession of one to two ounces of marijuana – currently a class B misdemeanor – would become a violation subject to a fine of up to $200 and no longer punishable by jail time.

To help address the racial disparities in the number of marijuana arrests in New York, S 6579A automatically expunges the records of those who were convicted of minor marijuana offenses. The bill explicitly states the expunged low-level marijuana convictions cannot "operate as a disqualification of a person to pursue or engage in any lawful activity, occupation, profession or calling."

S 6184A – Industrial Hemp and Hemp Extracts Regulations

Tucked away behind the chaos of the closing days of New York's legislative session was an overlooked but critically important bill passed by both houses in the Legislature. The bill will regulate New York's hemp program and hemp extracts, such as CBD. In addition, Senate Bill 6184A amends the Agricultural and Markets law and the

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existing hemp program, creating new licensing requirements and setting forth a regulatory framework for consumable CBD products. As noted, Governor Cuomo is unsure whether he will sign the bill into law, recently commenting that he needs more time for review.

The legislation would change the definition of "industrial hemp" to include "all derivatives, extracts, and cannabinoids" of industrial hemp. It will require that hemp used for extracts be sourced from authorized New York state industrial hemp producers.

The most significant change under S 6184A would be creating a new regulatory scheme for hemp extracts. The bill would create three new license categories for cannabinoid-related hemp extracts: (1) a cannabinoid grower license, (2) a cannabinoid manufacturer license and (3) a cannabinoid extractor license. The Department of Agriculture and Markets also would have the authority to issue permits to retailers, wholesalers and distributors to sell hemp extract products.

Addressing the dearth of formal standards in the industry, the bill puts consumer protection at the forefront, authorizing the Department of Agriculture and Markets to promulgate rules and regulations governing the packaging and labeling of hemp-extract products sold in New York state. At minimum, the regulations prohibit labels from stating hemp extracts can treat, cure or prevent disease, without prior approval from the federal government. The rules and regulations also would require a supplement fact panel as well as QR codes with testing data, cannabinoid per-serving data and number of servings per container. Also, hemp extract products must be manufactured in accordance with federal goods manufacturing processes.

In an attempt to protect New York growers, the bill would require all hemp extracts sold in the state to be from New York–licensed manufacturers. Out-of-state products would not be permitted to be sold in New York unless they meet all of New York's requirements.

While this bill is not yet law, New York is following the path of states such as Texas and Florida, which recently passed legislation regulating hemp extracts intended for human consumption. Existing manufacturers must take notice of the quickly evolving regulatory landscape and prepare for ramped-up regulation of CBD-infused products at the state level.

The New York City Ban on CBD in Food and Drink Effective July 1, 2019

The New York City Department of Health and Mental Hygiene (NYCDOH) began enforcing a ban it announced earlier this year on CBD in foods and drinks. The NYCDOH will start embargoing products in stores that violate the ban, and the products will have to be returned to the supplier or discarded. Starting October 1, 2019, the NYCDOH will begin issuing violations to foodservice establishments and retailers for offering food or drink containing CBD. Violations may be subject to finds, and for foodservice establishments, violation points may count toward the establishment's **letter grade**.

The ban also applies to packaged goods. In a July 1 tweet, the NYCDOH stated the "NYC Health Code prohibits adding CBD to food or drink, including in packaged food products."

NEW YORK STATE OF OPPORTUNITY. Department of Health

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Governor

HOWARD A. ZUCKER, M.D., J.D.
Commissioner

SALLY DRESLIN, M.S., R.N.
Executive Deputy Commissioner

Medical Marijuana Program
Practitioner Guidance for the use of Medical Marijuana to treat Opioid Use Disorder

Section 3360(7) of the Public Health Law (PHL) was amended on September 24, 2018 to add pain that degrades health and functional capability where the use of medical marijuana is an alternative to an opioid, and substance use disorder, as serious conditions for which patients may be certified to use medical marijuana. Amendments to the Medical Use of Marijuana regulations were made to address these amendments to PHL. The regulatory amendments also add opioid use disorder (OUD) as an associated condition. This document provides guidance to registered practitioners who may issue certifications for patients with OUD as the associated condition.

FDA approved medications for OUD including methadone, buprenorphine or long-acting naltrexone, with counseling and/or behavioral therapies if needed, continue to be the standard of care for OUD, as this approach has been proven to be clinically effective and lifesaving.

1. The Medical Use of Marijuana regulations, Title 10 of the of the New York Codes, Rules and Regulations (NYCRR) § 1004.2(a)(10)(i), require that the practitioner hold a federal Drug Addiction Treatment Act of 2000 (DATA 2000) waiver to be qualified to certify patients for treatment of substance use disorder or OUD with medical marijuana.

2. A registered practitioner must be caring for the patient in relation to the patient's OUD. "Caring for" is defined in PHL § 3360(2) as treating a patient, in the course of which the practitioner has completed a full assessment of the patient's medical history and current medical condition.

3. Registered practitioners should review the Diagnosis and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) criteria for the diagnosis of OUD to ensure an accurate diagnosis of the patient for OUD has been made and is documented in the patient's medical record prior to certifying the patient for medical marijuana.

4. Practitioners are strongly encouraged to consult with any other health care providers caring for the patient's OUD prior to initiating medical marijuana treatment, provided that the patient has consented. If the patient does not have a relationship with a behavioral health specialist, practitioners are encouraged to make a referral.

5. When considering medical marijuana for OUD, pursuant to 10 NYCRR § 1004.2(a)(11), practitioners must review past treatments and determine, in the practitioners' professional medical opinion, that the patient is likely to receive therapeutic or palliative benefit from medical marijuana.

6. When certifying patients, practitioners may make recommendations or limitations regarding the authorized brand, form, administration method, dosage and use of the approved medical marijuana product. Practitioners should consider which ratio of tetrahydrocannabinol (THC) and cannabidiol (CBD), two of the major active cannabinoids, would be appropriate for their patients. Products that are high in THC, high in CBD, or a balance of THC and CBD are available.

7. Pursuant to 10 NYCRR § 1004.2(a)(13), practitioners must discuss with patients the risks versus benefits of medical marijuana.

Medical Marijuana Program
Practitioner Guidance for the use of Medical Marijuana to treat Opioid Use Disorder

8. Practitioners should make an effort to determine patients' current and prior cannabis use in determining appropriate frequency and level of dosing, which may differ between patients who are experienced cannabis users and cannabis-naïve patients.

9. When issuing the certification for a patient to treat OUD, the practitioner should set a certification termination date no more than three months from the certification issue date, to ensure that the patient remains engaged in his or her treatment program.

10. Practitioners should design a treatment plan and document the patient's agreement to the plan. Provided that the patient has consented, the practitioner should communicate the patient's treatment plan with the patient's behavioral and non-behavioral health care providers, if applicable.

Additional Resources

https://www.health.ny.gov/diseases/aids/consumers/prevention/buprenorphine/docs/bupe_best_practices_2019.pdf

https://www.samhsa.gov/medication-assisted-treatment/treatment#medications-used-in-mat

https://www.oasas.ny.gov/

https://www.oasas.ny.gov/legal/documents/OASASFAQsMedicalMarijuana.pdf

https://combataddiction.ny.gov/get-information

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6135562/pdf/can.2018.0022.pdf

Questions?

Contact the Medical Marijuana Program at mmp@health.ny.gov or call 844-863-9312.