




# Medical Marijuana in New York to Manage Chronic Pain

Grace Forde, M.D.  
Director of Neurological Services  
North American Partners In Pain Management



○ “Marijuana in its natural form is one of the safest therapeutically active substances known to man, By any measure of rational analysis marijuana can be safely used within a supervised routine of medical care. ... It would be unreasonable, arbitrary and capricious for DEA to continue to stand between those sufferers and the benefits of this substance in light of the evidence in this record.”

○ ---DEA Chief Administrative Law Judge Francis L. Young, Ruling in the matter of Marijuana Rescheduling Petition, September 6, 1988



# Adverse Effects

- No risk of lethal overdose, end-organ damage or labs to follow.
- Cannabis hyperemesis syndrome.
- “few...develop dependence...Risk factors...similar to ... other forms of substance abuse...antisocial personality and conduct disorders...”
- Impaired coordination and balance

# Adverse Effects (Cont.)

- “distinctive...withdrawal syndrome...identified...mild and short-lived...restlessness, irritability, mild agitation, insomnia, sleep EEG disturbance, nausea, and cramping”
- Review of 31 clinical studies of medical cannabinoids:
  - 96.6% of adverse events reported were not serious
  - “164 serious adverse events”—“no evidence of a higher incidence of serious adverse events...compared with control [drugs]”\* .

○ \*Wang T, Collet J, Shapiro S, Ware MA. Adverse effects of medical cannabinoids: a systematic review. *Canadian Medical Association Journal* 2008; 178(13):1669-1678.



# Common Misconceptions

- No evidence-based studies demonstrating that chronic cannabis use can cause or exacerbate schizophrenia.



# Relative Contraindications

- Rare hypersensitivity to THC or allergies to any inert materials in formulations
- Patients with infection requiring Th1 immunity activity for inhibition (e.g., Legionella)
- Personal or family history of psychosis



## Relative Contraindications (Cont.)

- Recent research has found that people with a specific variant of AKT1 gene which codes for an enzyme that affects dopaminergic signaling in the striatum are at increased risk of developing psychosis.
- The striatum is an area of the brain that becomes activated and flooded with dopamine when certain stimuli are present.



## Relative Contraindications (Cont.)

- Another study found an increased risk of psychosis among adults who had used marijuana in adolescence and also carried a specific variant of the gene for catechol-O-methyltransferase (COMT), an enzyme that degrades neurotransmitters such as dopamine and norepinephrine .





# Drug Interactions: Dronabinol Insert

In studies...MARINOL Capsules has [sic] been co-administered with a variety of medications

(e.g., cytotoxic agents, anti-infective agents, sedatives, or opioid analgesics)

without resulting in any clinically significant drug/drug interactions ...cannabinoids may interact with other medications through both metabolic and pharmacodynamic mechanisms. Dronabinol is highly protein bound to plasma proteins, and therefore, might displace other protein bound drugs. Although ...not ...confirmed in vivo...



# Clinically Useful Drug Interactions

- When THC co-administered with CBD, as can occur with the usage of some strains of herbal cannabinoid medicines and certain cannabinoid-based extractions
  - anxiogenic, dysphoric, and possibly short-term memory interrupting effects of THC are mitigated
- Evidence suggests cannabinoid drugs can enhance the analgesic activity of co-administered opioids
  - Opioid dose reductions

<b>Drug</b>	<b>Interaction with THC</b>
<b>SSRIs</b>	<b>THC can increase the effect of fluoxetine.</b>
<b>TCAs</b>	<b>THC can increase the side effects of amitriptyline (i.e. tachycardia, hypertension and sedation).</b>
<b>NSAIDs</b>	<b>Indomethacin and acetylsalicylic acid (aspirin) reduce the effects of THC.</b>
<b>Barbiturates</b>	<b>These increase the depressive effects of THC and also increase tachycardia associated with THC consumption.</b>
<b>BZDPs</b>	<b>These drugs can increase depression of the nervous system and also of the respiratory system.</b>
<b>β-Blockers</b>	<b>These reduce tachycardia associated with THC.</b>
<b>ETOH</b>	<b>This can increase nervous system deterioration.</b>
<b>Opioids</b>	<b>Increased sedation and analgesia.</b>
<b>Theophylline</b>	<b>Cannabinoids increase theophylline catabolism. A dosage increase is thus required in such cases.</b>
<b>Anticholinergics</b>	<b>Atropine and scopolamine can increase tachycardia produced by THC.</b>
<b>Disulfiram</b>	<b>THC interacts with disulfiram, causing a very unpleasant reaction in the patient. The combination of both substances should therefore be avoided.</b>



# Is cannabis associated with respiratory depression?

○ **No**

- Cannabinoid receptor expression is low in the brainstem accounting for the lack of respiratory depression and the absence risk of respiratory arrest with the use of cannabis and cannabinoid products.



# Cannabinoids and Opioids

# Cannabinoid–Opioid Interaction in Chronic Pain

DI Abrams<sup>1</sup>, P Couey<sup>1</sup>, SB Shade<sup>2</sup>, ME Kelly<sup>1</sup> and NL Benowitz<sup>3</sup>

Cannabinoids and opioids share several pharmacologic properties and may act synergistically. The potential pharmacokinetics and the safety of the combination in humans are unknown. We therefore undertook a study to answer these questions. Twenty-one individuals with chronic pain, on a regimen of twice-daily doses of sustained-release morphine or oxycodone were enrolled in the study and admitted for a 5-day inpatient stay. Participants were asked to inhale vaporized cannabis in the evening of day 1, three times a day on days 2–4, and in the morning of day 5. Blood sampling was performed at 12-h intervals on days 1 and 5. The extent of chronic pain was also assessed daily. Pharmacokinetic investigations revealed no significant change in the area under the plasma concentration–time curves for either morphine or oxycodone after exposure to cannabis. Pain was significantly decreased (average 27%, 95% confidence interval (CI) 9, 46) after the addition of vaporized cannabis. We therefore concluded that vaporized cannabis augments the analgesic effects of opioids without significantly altering plasma opioid levels. The combination may allow for opioid treatment at lower doses with fewer side effects.

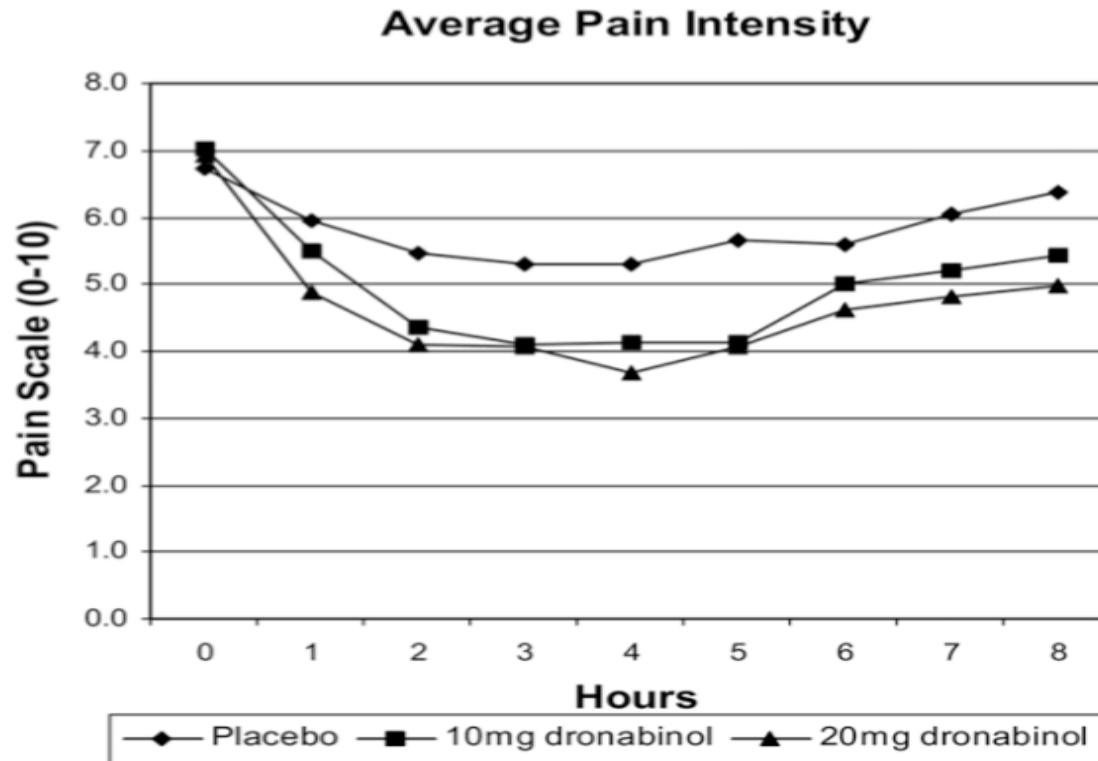
**Table 1** Participant characteristics

	Morphine group	Oxycodone group
<i>n</i>	10	11
Women	4	6
Caucasian	8	9
Mean age (range)	42.9 (33–55)	47.1 (28–61)
Mean opioid dose (mg) (range)	62 Twice daily (10–200)	53 Twice daily (10–120)
Mean pain score day 1 (95% CI)	34.8 (29.4, 40.1)	43.8 (38.6, 49.1)

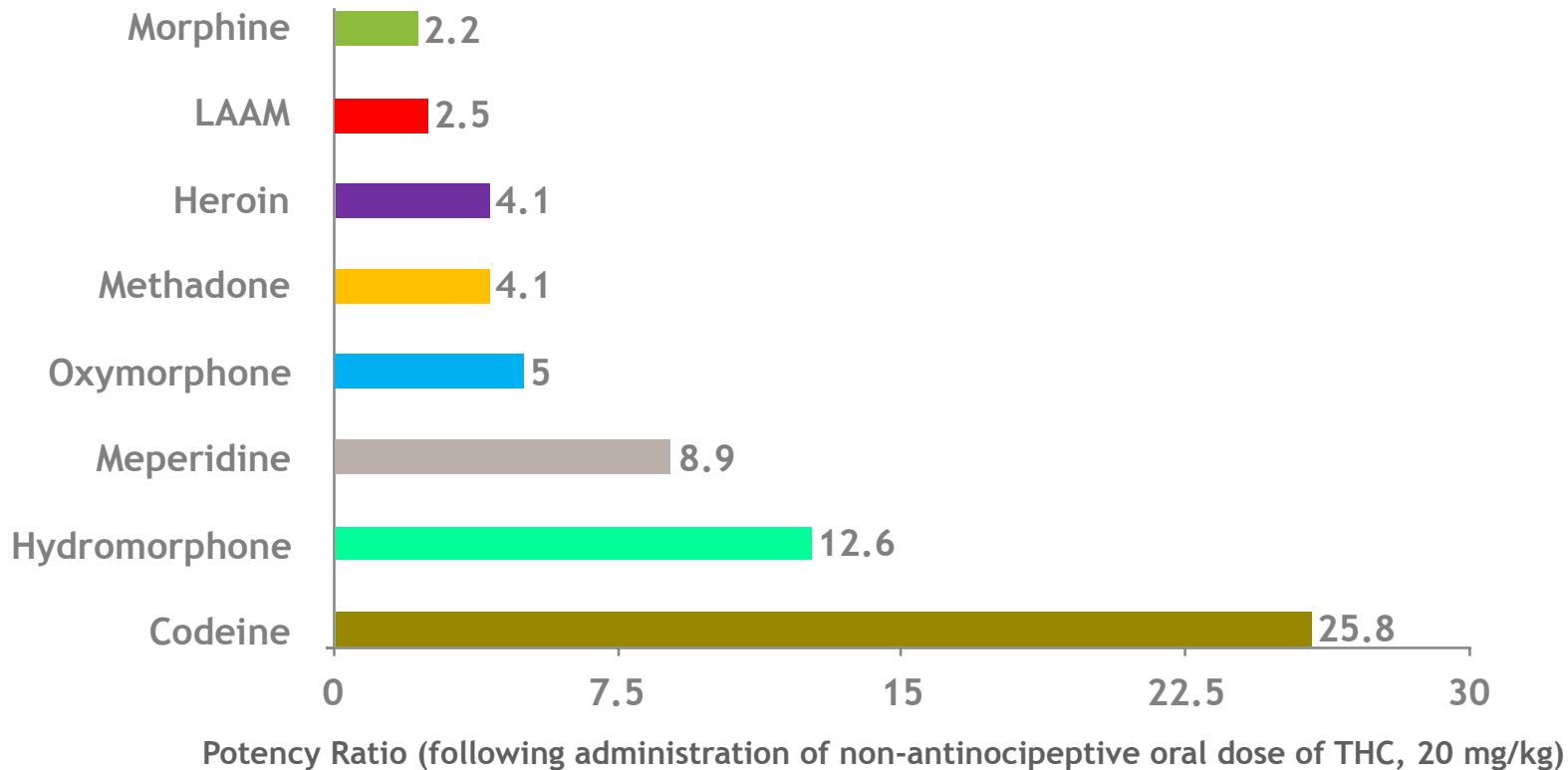
CI, confidence interval.

# Effects of THC in Patients on Opioids

Significant reduction in pain intensity in patients administered cannabinoids while on stable doses of opioids




# Opioid Sparing Effects of THC




\*Data from animal studies , mouse tail-flick test for antinociception; LAAM, levo-  $\alpha$ -acetylmethadol






## Evidence suggesting that Medicinal Marijuana has a positive effect on Opioid use in the treatment of chronic pain

- Could “Pot” help solve the US opioid epidemic?
  - <http://www.sciencemag.org/news/2016/11/could-pot-help-solve-us-opioid-epidemic>
- National Institute on Drug Abuse: “Is marijuana safe and effective as medicine?”
  - Existing studies cumulatively suggest that medical marijuana products may have a role in reducing the use of opioids needed to control pain.
    - The opioid crisis in America’s workforce
      - <http://www.castlighthealth.com/typ/the-opioid-crisis/>




## Evidence suggesting that Medicinal Marijuana has a positive effect on Opioid use in the treatment of chronic pain

- Do medical marijuana laws reduce addiction and deaths related to pain killers?
  - States permitting medical marijuana dispensaries experience a relative decrease in both opioid addictions and opioid overdose deaths compared to states that do not.
    - <http://www.nber.org/papers/w21345>
- Medical marijuana legalization is associated with reductions of 23% in hospitalizations due to opioid dependence and 13% due to overdose.
  - <http://www.ncbi.nlm.nih.gov/pubmed/28259087>




## Evidence suggesting that Medicinal Marijuana has a positive effect on Opioid use in the treatment of chronic pain

- Cannabis as a substitute for prescription drugs - a cross-sectional study
  - 46% of 2,774 cannabis users reported using it as a substitute for prescription drugs, the most common being opioids (35.8%)
    - Corroon, Mischley, Sexton, J of Pain Research, Mar 2017
- 93% of patients prefer cannabis over opioids for managing pain.
  - Jacinta Bowler 30 Jun 2017
    - <http://www.sciencealert.com>



Evidence suggesting that Medicinal Marijuana has a positive effect on Opioid use in the treatment of chronic pain

- A study of 83 chronic pain patients in New Mexico medical cannabis program found that 34% quit prescription pharmaceuticals after 10 months.
- A survey of 1,513 New England dispensary members reported 76.7% reduced use of opiates after starting medical cannabis
  - <https://ncbi.nlm.nih.gov/pubmed/28372506>



## Evidence suggesting that Medicinal Marijuana has a positive effect on Opioid use in the treatment of chronic pain

- A survey of 244 chronic pain patients found medical cannabis use associated with a 64% decrease in opioid use, decreased number and side effects of medications, and an improved quality of life.
- Boehnke, Litinas, Clauw, J Pain June 2016
  - <http://www.ncbi.nlm.nih.gov/pubmed/27001005>



## How does cannabis use affect sleep in patients suffering from neuropathic pain

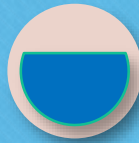
- Randomized controlled trial of smoked cannabis for neuropathic pain
- N=23
- Results
  - Participants receiving cannabis with tetrahydrocannabinol (THC) level of 9.4% reported improved ability to fall asleep and improved quality of sleep compared to the group receiving placebo.

# Compassionate Care Act



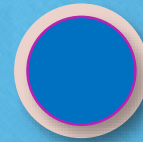
## PATIENT CERTIFICATION

Registered Practitioner issues certification to patient with serious condition and clinically associated condition.



## PATIENT REGISTRATION

Patient registers with NYSDOH and receives a registry ID card. Any designated caregivers must also register.



## PRODUCT DISPENSING

Certified patient/ designated caregiver presents card to registered org's dispensing facility for product.



# Definition of Serious Condition

Patients with one of the following severe debilitating or life-threatening conditions:

- Cancer
- HIV positive status or AIDS
- Amyotrophic Lateral Sclerosis (ALS)
- Parkinson's Disease
- Multiple Sclerosis
- Spinal cord damage with objective indication of intractable spasticity
- Epilepsy
- Inflammatory Bowel Disease
- Neuropathies
- Huntington's Disease





# Definition of Serious Condition

Patients with one of the following severe debilitating or life-threatening conditions:

- Chronic Pain (Effective March 22, 2017)
  - 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;

**AND**



# Definition of Serious Condition

The condition is clinically associated with:

- cachexia,
- severe or chronic pain,
- severe nausea,
- seizures, or
- severe or persistent muscle spasms.

The Commissioner of Health may add other serious conditions.

# Practitioner Registration Prerequisites

- Qualified to treat patients with one or more of the serious conditions in the Compassionate Care Act;
- Have completed a department-approved course on the medical use of marijuana;



# Practitioner Registration Prerequisites (Cont.)

- Licensed, in good standing as a physician and practicing medicine, as defined in article 131 of the Education Law, in New York State, **or**
- be 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 with the program (Effective 3/15/2017).





## Practitioner Registration

- Following successful completion of the course, a practitioner can log in to the Health Commerce System and access the Medical Marijuana Data Management System to register.
- Physician assistants must email an authorization form along with the information above. The authorization form can be found on the Medical Marijuana Program's website or by using the following link:  
<https://www.health.ny.gov/forms/doh-5246.pdf>



# Practitioner Registration

- When the practitioner completes the registration process in MMDMS, the practitioner must make a consent option:
  - Consent to be listed on the NYSDOH Medical Marijuana Program website;
  - Consent to be listed in the MMDMS, available only to practitioners with HCS access; or
  - Do not consent to being listed.

# Patient Certification

- NYSDOH implemented an electronic patient certification system called the Medical Marijuana Data Management System (MMDMS).
- The instructions for using MMDMS are posted on the NYSDOH Medical Marijuana Program website.  
[https://www.health.ny.gov/regulations/medical\\_marijuana/practitioner/docs/patient\\_certification\\_instructions.pdf](https://www.health.ny.gov/regulations/medical_marijuana/practitioner/docs/patient_certification_instructions.pdf)



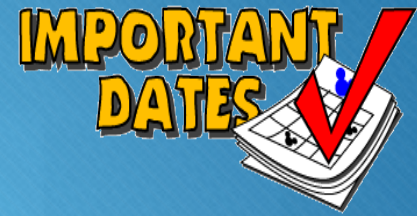


# Patient Certification

- Practitioner name, address, phone number, and e-mail (auto-populate with the information contained in the HCS business contact profile);
- License & DEA registration numbers (auto-populate);
- Patient name, DOB, address (NOT a PO Box), phone number and email address if available;
- Patient's severe debilitating or life-threatening condition(s) and the condition or symptom clinically associated with, or a complication of the severe debilitating or life-threatening condition.



# Patient Certification - Expiration



- Certifications expire **up to one year** after the date issued (do not confuse the certification expiration date with dosing recommendation end date!);
- If the patient is terminally ill, and a New York State resident, the certification shall not expire until the patient's death or the practitioner revokes the certification.
  - Terminally Ill, in Public Health Law 3360(13), 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.



Practitioner Information: Johnson, MMDMS, 43 NEW SCOTLAND AVENUE, ALBANY, NY, 12208. Patient Information: SA..., 1 SAMPLE ST, ALBANY, NY, 12210. Dosing Recommendations: 1. Product: No Preference, Form/Administration Method: /Inhalation, THC/CBD Ratio: High:Low, Concentration: High THC Low CBD. 2. Product: No Preference, Form/Administration Method: [redacted], THC/CBD Ratio: Low:High, Concentration: Low THC High CBD. Patient Certification Issue Date: 03/09/2016, Patient Certification Expiration Date: None.

As the practitioner named above, I attest to the following:

- I am a licensed practitioner currently in good standing in New York State, and possess an active Drug Enforcement Administration registration;
I am currently registered with the New York State Department of Health to issue this certification;
I am caring for this patient in relation to the serious and associated conditions listed above;
By training and/or experience, I am qualified to treat the serious condition(s) listed above;
In my professional opinion and based on my review of past treatments, the patient named above is likely to receive therapeutic or palliative benefit from the primary or adjunctive treatment with medical marijuana for the serious condition(s) listed above;
I have explained the potential risks and benefits of the use of medical marijuana to the above-named qualifying patient and/or the qualifying patient's parent or legal guardian, if applicable, and have documented in the patient's medical record that such explanation has been provided; and
The above-named qualifying patient and/or the qualifying patient's parent or legal guardian, if applicable, have provided informed consent.

Practitioner Signature: Johnson MMDMS Date: 03/09/2016

FALSE STATEMENTS MADE HEREIN ARE PUNISHABLE AS A CLASS A MISDEMEANOR PURSUANT TO PENAL LAW § 210.45. ISSUANCE OF A CERTIFICATION WHEN (i) THE RECIPIENT HAS NO MEDICAL NEED FOR IT, OR (ii) IT IS FOR A PURPOSE OTHER THAN THOSE DEFINED IN PHL § 3360 (7) IS PUNISHABLE AS A CLASS E FELONY PURSUANT TO PENAL LAW § 179.10.

This certification, containing the practitioner's handwritten signature, must be provided to the patient and a copy of this signed certification must be included in the patient's medical record. To register, patients will need to login to https://my.ny.gov/, click the "Health Applications" icon, and then click the "Medical Marijuana Data Management System" link. Patients who do not have a NY.gov account will need to visit https://my.ny.gov/ and click on the "Don't have an Account?" button to create a personal NY.gov ID first.

# Patient Certification – Attestation

As the practitioner named above, I attest to the following:

- I am a licensed practitioner currently in good standing in New York State, and possess an active Drug Enforcement Administration registration;
- I am currently registered with the New York State Department of Health to issue this certification;
- I am caring for this patient in relation to the serious and associated conditions listed above;
- By training and/or experience, I am qualified to treat the serious condition(s) listed above;
- In my professional opinion and based on my review of past treatments, the patient named above is likely to receive therapeutic or palliative benefit from the primary or adjunctive treatment with medical marijuana for the serious condition(s) listed above;
- I have explained the potential risks and benefits of the use of medical marijuana to the above-named qualifying patient and/or the qualifying patient's parent or legal guardian, if applicable, and have documented in the patient's medical record that such explanation has been provided; and
- The above-named qualifying patient and/or the qualifying patient's parent or legal guardian, if applicable, have provided informed consent.

**Practitioner Signature:** \_\_\_\_\_ **Date:** 12/31/2015

Sample Doctor

**FALSE STATEMENTS MADE HEREIN ARE PUNISHABLE AS A CLASS A MISDEMEANOR PURSUANT TO PENAL LAW § 210.45. ISSUANCE OF A CERTIFICATION WHEN (i) THE RECIPIENT HAS NO MEDICAL NEED FOR IT, OR (ii) IT IS FOR A PURPOSE OTHER THAN THOSE DEFINED IN PHL § 3360 (7) IS PUNISHABLE AS A CLASS E FELONY PURSUANT TO PENAL LAW § 179.10.**

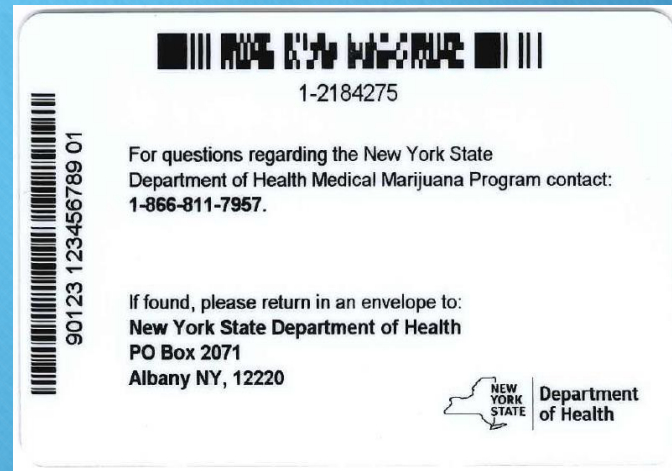
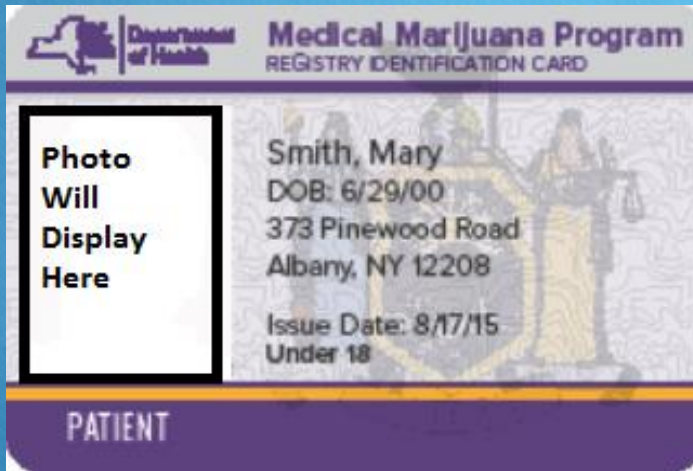
This certification, containing the practitioner's handwritten signature, must be provided to the patient and a copy of this signed certification must be included in the patient's medical record. The patient's parent, legal guardian, or other appropriate person over 21 years of age, is required to register on behalf of this patient as a proxy applicant. The proxy applicant will need to login to <https://my.ny.gov/>, click the "Health Applications" icon, and then click the "Medical Marijuana Data Management System" link to register this patient. Proxy applicants who do not have a NY.gov account will need to visit <https://my.ny.gov/> and click the "Don't have an Account?" button to create a personal NY.gov ID first.



## Incorporation of I-STOP

- Practitioners must consult the PMP Registry prior to issuing a certification to a patient for medical marijuana.
- Dispensing facilities must report data to the Prescription Monitoring Program (PMP) Registry and consult the PMP Registry prior to dispensing the approved medical marijuana product to the certified patient, or his or her designated caregiver.

# Sample ID Card





# Practitioner Reporting Requirements

- Death or change in status of a certified patient's serious condition if such change may affect the patient's continued eligibility for certification (not more than 5 business days after becoming aware of such facts).
- Patient adverse events (not more than 5 business days after becoming aware, except that serious adverse events shall be reported not more than 1 business day after becoming aware).
- Adverse event reporting via the Person Electronic Response Data System (PERDS) application on the HCS.



## Protections: PHL §3369(1)

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.



# Cost

- Cost varies among the different dispensaries, however, on average the cost is around \$200-\$400 a month depending on the quantity patient consumes.
- Not covered by insurance, nor can you use your HSA
- Cash and debit cards only at all dispensaries. No credit cards.
- Cannot deduct the cost as a medical expense



# Dispensaries

The 5 original registered organizations are listed below. To find the location of the dispensary near you you can check on the 5 different organizations web sites.

In alphabetical order:

- <http://col-careny.com/ny>
- <http://etainhealth.com/ny>
- <https://medmenstores.com/ny/>
- <http://www.pharmacannis.com/ny>
- <http://vireohealthny.com/ny>



# Dispensaries (Cont.)

- The following companies were recently awarded registrations (in alphabetical order):
  - Citiva Medical
  - Fiorello Pharmaceuticals
  - New York Canna
  - Pallia Tech NY
  - Valley Agriceuticals