



Workers'
Compensation
Board

BETTER FOR WORKERS

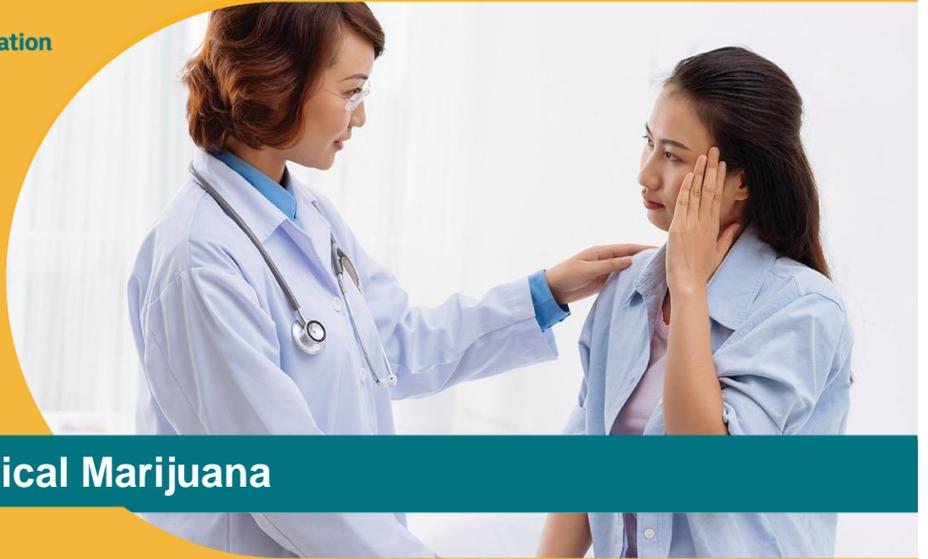
BETTER FOR BUSINESS

ELAIN SOBOL BERGER & DAVID WERTHEIM

WCB.NY.GOV



Workers'
Compensation
Board



Medical Marijuana

BETTER FOR WORKERS

New York State Workers' Compensation Board

BETTER FOR BUSINESS

NYS Medical Marijuana Program

Background: Compassionate Care Act

- In July 2014, Governor Andrew M. Cuomo and the New York State Legislature enacted the Compassionate Care Act to comprehensively regulate the manufacture, sale and use of medical marijuana.
- The program ensures that medical marijuana is available for treatment of certified patients with serious conditions and is dispensed and administered in a manner that protects public health and safety

Federal Law

- As a Schedule I drug under the Controlled Substances Act of 1970 (21 U.S.C. 801), marijuana may not be prescribed, administered, or dispensed, and it is illegal to possess, use, purchase, sell or cultivate.
- Drug Enforcement Agency (DEA) designates marijuana as a Schedule I controlled substance with:
 - “No currently accepted medical use.”
 - A lack of accepted safety for use under medical supervision, and a high potential for abuse.

Federal Law

- The US Attorney General (AG) may by rule transfer a drug or other substances between schedules of the Controlled Substance Act (CSA).
- The AG has delegated this responsibility to the Acting Administrator of the DEA.
 - Several drugs containing marijuana products have been approved and transferred to other Schedules under the CSA.
 - All other marijuana products are Schedule I.

Federal Law

The Rohrabacher-Blumenauer Amendment (formerly, the Rohrabacher-Farr Amendment)

- Prohibits the DOJ from using federal funds to interfere with state medical marijuana programs and from prosecuting medical marijuana businesses that are compliant with state law.
- New York is explicitly listed as one of the states with a legalized medical marijuana program.

Federal Law

“Cole Memo” (former authority)

- Provided that in jurisdictions with strong and effective regulatory systems governing legalized marijuana usage, which do not threaten federal priorities related to medical marijuana.
- The federal government will rely on state and local officials to enforce laws, and the DOJ will not prosecute cases stemming from conduct that is permitted under the state’s marijuana legalization program.

Federal Law

Memo issued by former AG Sessions in January 2018 (current authority)

- Rescinded the Cole Memo and three other memos related to exercising prosecutorial discretion around medical marijuana, and
- Directed federal law enforcement “to use previously established prosecutorial principles that provide them all the necessary tools to disrupt criminal organizations, tackle the growing drug crisis, and thwart violent crime across our country.”

New York Law: “Serious Condition”

Title V-A in Article 33 of the Public Health Law (PHL)

- Public Health Law § 3360(7)(a) (i) and (ii) provides the definition of a “serious condition” for which MM may be recommended by a certified provider.
- 10 NYCRR 1004.2: DOH emergency regulation, currently in effect.

New York Law: “Serious Condition”

Public Health Law § 3360(7)(a): Two Prongs Marijuana may be prescribed pursuant to:

- PHL §3360(7)(a)(i): for a **severe debilitating or life-threatening condition**, and
- PHL §3360(7)(a)(ii): a condition or symptom that is **clinically associated with or is a complication of the severe debilitating or life-threatening condition**.

“Severe Debilitating or Life-Threatening Conditions”

Current conditions under PHL 3360(7)(a)(i):

- Cancer
- Positive status for human immunodeficiency virus (HIV) or acquired immune deficiency syndrome (AIDS)
- Amyotrophic lateral sclerosis (ALS)
- Parkinson's disease

“Severe Debilitating or Life-Threatening Conditions” (cont’d)

- Multiple sclerosis
- Damage to the nervous tissue of the spinal cord with objective neurological indication of intractable spasticity
- Epilepsy
- Inflammatory bowel disease
- Neuropathies

“Severe Debilitating or Life-Threatening Conditions” (cont’d)

- Huntington’s disease
- Post-Traumatic Stress Disorder (PTSD)
- **Pain that degrades health and functional capability** where the use of medical marijuana is an alternative to opioid use, substance use disorder, or as added by the commissioner...*

*Regulation 1004.2(a)(8)(xiii), expands upon the statutory definition of pain that “*degrades health and functional capability*”

“Pain That Degrades Health and Functional Capability” (1004.2(a)(8)(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.

“Pain That Degrades Health and Functional Capability” (1004.2(a)(8)(xiii))

Any severe debilitating pain that the practitioner determines degrades health and functional capability (cont'd)

- Where the use of medical marijuana is an alternative to opioid use,
- Provided that the precise underlying condition is expressly stated on the patient's certification

Associated Conditions

Current associated conditions pursuant to PHL 3360(7)(a) and 10 NYCRR 1004.2:

- Cachexia or wasting syndrome;
- Severe or chronic pain resulting in substantial limitation of function;
- Severe nausea;
- Seizures;

Associated Conditions (cont'd)

- Severe or persistent muscle spasms;
- Post-Traumatic Stress Disorder;
- Opioid Use Disorder;
- Or such other conditions, symptoms or complications as added by commissioner of DOH.

Routes of Administration

Approved Routes of Administration

- Metered liquid or oil preparations
- Solid and semisolid preparations (e.g., capsules, chewable and effervescent tablets, lozenges)
- Metered ground plant preparations
- Topical forms and transdermal patches

Routes of Administration

Prohibited Routes of Administration

- The Compassionate Care Act expressly prohibits smoking as a form of MM. *(In keeping with New York's longstanding commitment to eliminate all smoking)*, as well as edibles.

New York State: Workers' Compensation Law §13

- WCL § 13(a) provides that “[t]he employer shall be liable for the payment of the expenses of medical, dental, surgical, optometric or other attendance or treatment, nurse and hospital service, [and] medicine ... for such period as the nature of the injury or the process of recovery may require.”

New York State: Workers' Compensation Law

- Beginning with Matter of WDF (2018 NY Wrk Comp G1403803), decided February 16, 2018, the Board has opened the door to permitting treatment with medical marijuana when a variance is requested (if the Medical Treatment Guidelines apply to the injury or condition) and requiring carriers to reimburse workers' compensation claimants for such treatment.

New York State: Workers' Compensation Law

- The Board's authority in Matter of WDF and its progeny is principally based on the Public Health Law and WCL § 13
- Matter of Kellner Bros. Inc. (2018 Wrk Comp 80316448)
 - Not the seminal MM case, but the case with the best developed arguments for and against MM

Matter of Kellner Bros. Inc 2018 Wrk Comp 80316448

Facts:

- Carrier files an RFA-2OP with the Board seeking opioid weaning consistent with the Non-Acute Pain Medical Treatment Guidelines based on IME report.
- Claimant was directed to produce up-to-date medical including a report from his physician as to whether alternatives to opioids were available.

Matter of Kellner Bros. Inc 2018 Wrk Comp 80316448

Facts:

- Treating physician indicated that patient was being weaned off his opioids and was finding MM “very helpful.”
- Subsequent IME report indicates that the claimant has “significantly tapered” his opioid use as a result of using a combination of MM and morphine sulfate.

Matter of Kellner Bros. Inc 2018 Wrk Comp 80316448

Facts:

- At the August 17, 2017, hearing, the claimant’s counsel indicates that the treating physician appears on the DOH registry and requests that the claimant be reimbursed for the costs of his MM certification.
- The carrier objected that MM is illegal under Federal Law and is not an authorized form of treatment because it is not FDA approved.

Matter of Kellner Bros. Inc 2018 Wrk Comp 80316448

Facts:

- The WCLJ found “ that MM is appropriate medication and medically necessary” and accordingly authorized the MM treatment and directed the carrier to reimburse the claimant for out-of-pocket expenses regarding MM.

Matter of Kellner Bros. Inc 2018 Wrk Comp 80316448

Facts: Carrier appeal

- **Federal Pre-emption:** Violation of federal CSA.
- **Violation of PHL 3368 (2):** “Nothing in (Title 5A of the PHL) shall be construed to require an insurer or health plan to provide coverage for MM.”
- **Conflicts with MTGs** because the treating provider did not request a variance to treat with MM.

Matter of Kellner Bros. Inc 2018 Wrk Comp 80316448

Board Panel Decision:

- The claimant was prescribed medical marijuana to treat chronic pain for an established neck injury. Therefore, the claimant's treating medical provider was required to adhere to the Board's Non-Acute Pain Medical Treatment Guidelines, which do not authorize treatment with medical marijuana. The provider should have sought a variance.
- WCLJ decision rescinded.

MM Compensability

Board Panel decisions not only set precedent for permitting treatment with MM utilizing a variance, but also set forth four requirements for determining whether MM is reimbursable.

NYS Workers' Compensation Payments for MM

For a claimant to be reimbursed for MM:

- The certification must have been written by a medical provider registered with the DOH to prescribe MM,
- Who is also Board authorized,
- For an established site of injury or condition,
- For a use authorized under Public Health Law (PHL) §3360(7), and
- In accordance with the Medical Treatment Guidelines (MTGs), where applicable.

NYS Workers' Compensation: Payments for MM

As marijuana remains a controlled substance under federal law, carriers cannot implicate the federal banking system when paying for MM.

Two options for MM payment:

- Reimbursement to the claimant, or
- Permit payment to the dispensary when carrier/SIE does not have funds in/or associated with the federal banking system

Board determination: Reimbursement to the claimant

NYS Workers' Compensation: Payments for MM

- If a variance is approved, payment for MM should be made by reimbursement to the claimant as a medical and travel (M&T) reimbursement.
- Authority for this stems from WCL §13(a) for “other attendance and treatment.”
- PHL §3368(2) exempts health insurers, but workers' compensation falls under ‘basic insurance’ not health.
- Thus, M & T is proper mechanism for the dispensed, variance approved, MM.

Payment to Providers

WCL § 13(a) also provides authority to compel employers/carriers to pay for all medical visits.

- A physician should use an appropriate E&M code to reflect the assessment and plan that includes the certification of the patient and prescription for MM.
- A variance is not to be used for billing for medical visits nor for the completion of the patient certificate for MM

Variance Request for MM

Medical Marijuana is not addressed in the Medical Treatment Guidelines and a **variance is required that supports compliance with both:**

- The NYS Department of Health's criteria for the use of Medical Marijuana, and
- The Medical Treatment Guideline variance criteria.

Medical Treatment Guidelines And MM

Of note, General Guideline Principle A. 20 states:

- Medical treatment that is experimental/investigational and not approved for any purpose, application or indication by the FDA is not permitted under these Guidelines.

Question: Since MM is a Schedule I Drug, how can MM be considered a treatment option under the MTGs?

- FDA has approved three drugs containing synthetic marijuana products and one plant derived CBD drug.

Federally Approved Marijuana Products

Marinol: Active ingredient dronabinol, a synthetic THC that mimics natural THC. Moved from Schedule I→Schedule III in 1999

- 1985: Nausea and vomiting associated with cancer chemotherapy, not responsive to conventional anti-emetics
- 1992: Anorexia with weight loss in AIDS

Cesamet: Active ingredient nabilone, a synthetic cannabinoid similar to THC. Schedule II

- 1985: Nausea and vomiting associated with cancer chemotherapy

Syndros: Synthetic liquified dronabinol. Schedule II

- 2016: Same indications as Marinol

Federally Approved Marijuana Products

Epidiolex: First FDA approved drug derived from plant purified cannabidiol (CBD). Schedule V

- 2018: Difficult-to-control seizures in patients with rare Dravet and Lennox-Gastaut syndromes

Variance Request for MM

- The variance request must provide documentation that the physician is both **authorized** by the WCB to treat injured workers **and** is **registered** by the NYS Department of Health to certify patients for Medical Marijuana.
- There must be documentation by the provider that the patient has been certified for Medical Marijuana and a copy of the certificate for the Medical Marijuana Program must be provided with the variance request, and
- Medical Treatment Guideline criteria are met.

NYS WCB Authorized Providers

- For a physician to treat WC claimants, the physician must be authorized by the WCB per WCL § 13-b.

Physician/Practitioner Registration Criteria

Pursuant to 10 NYCRR §1004.1(a), medical practitioners seeking to issue certifications for their patients to receive medical marijuana (MM) products must meet the following criteria:

- Be qualified to **treat patients** with one or more of the serious conditions set forth in Public Health Law (PHL) §3360(7);
- Be licensed, in good standing as a physician and practicing medicine, as defined in Education Law Article 131;

Registration Criteria (cont'd)

- Have completed a two to four hour course approved by the Commissioner of Health; and
- Registered with the New York State Department of Health (DOH) Medical Marijuana Program.
- Once these four requirements have been satisfied, the provider may recommend MM to eligible patients.

Additional Practitioner Criteria

- To recommend MM as treatment for Substance Use Disorder (a Serious Condition), or Opioid Use Disorder (an Associated Condition), 1004.2(a)(10) requires that:

“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.”

Registration Criteria, NPs and PAs

Pursuant to 10 NYCRR §1004.1(a)(2), in addition to physicians, MM may be recommended by:

- Nurse Practitioners
- Physician Assistants under the supervision of a physician registered by DOH

Workers' Compensation: NPs and PAs

NPs and PAs:

- Currently NPs and PAs can not become WCB authorized and must be under the direct and personal supervision of a physician
- As of January 1, 2020
 - NPs may obtain WCB authorization
 - PAs may obtain WCB authorization with a supervising physician who is WCB authorized.

Variance

It is recognized there are legitimate reasons for exceptions to the Medical Treatment Guidelines:

- The variance process defines the criteria for exceptions to the MTGs, including treatment that is not addressed in the guidelines
- NYS DOH's [qualifying serious and associated conditions include conditions for which there are MTGs](#), including Mid and Low Back and Neck and Non-Acute Pain (NAP)
- However, MM is not addressed as a treatment option in these Guidelines, so a variance would be required

DOH MM Criteria And MTG Conditions

NYS DOH's MM qualifying serious and associated conditions that are covered by NYS MTGs include:

- Damage to the nervous tissue of the spinal cord with objective neurological indication of intractable spasticity
- Neuropathies
- Severe or persistent muscle spasms

DOH MM Criteria And MTG Conditions

NYS DOH's MM qualifying serious and associated conditions that are covered by NYS MTGs (cont'd)

- Any severe debilitating pain that the practitioner determines degrades health and functional capability...
- Severe or chronic pain resulting in substantial limitation of function
- Alternative to opioid use
- Opioid Use Disorder

Non-Acute Pain MTG and MM

The WC Non-Acute Pain MTG (NAP MTG) provides:

- A continuum of options for the assessment and management of patients with chronic pain
- **Focused on function**, alternatives to opioids, tapering and discontinuing opioids, as appropriate, with referral to addiction medicine specialists, as indicated.
- Virtually all of the MM variance requests received at this time relate to conditions covered in the NAP MTG
 - Meeting the medical necessity criteria for MM requests requires knowledge of the variance requirements with a focus on clinical outcomes (objective functional improvement and management of pain)

MG-2: Medical Necessity Refresher

All variance requests must include:

1. A medical opinion stating why the proposed care is appropriate and medically necessary for the patient,
2. Certification by the requesting provider that the patient agrees to the proposed care, and
3. **An explanation why alternatives under the MTGs are not appropriate or sufficient.**

MG-2: Medical Necessity Refresher

Additionally, requests to extend treatment beyond recommended maximum duration/frequency must include:

- Objective evidence that the requested treatment has produced functional improvement,
- Further improvement is reasonably expected with additional treatment.
- Proposed plan for additional treatment with the treatment duration and frequency, and functional goals.

MG-2: Medical Necessity Refresher

For treatment that is **not addressed** in NAP MTG, the following must be documented:

1. A description of any signs or symptoms which have failed to improve with previous treatments provided according to MTG recommendations.
2. Proposed treatment plan and an explanation of why proposed treatment is necessary at this time, including specific functional goals.
3. Medical evidence in support of proposed treatment (for MM refer to NYS Medical Marijuana Program).

Case Example

- 60 y/o male
- DOI: 1999
- S/P 4 lumbar surgeries
- Chronic back pain since injury
- Patient already taking MM
- Paying out of pocket
- **Variance request for 12 months of MM**

Case Example (cont'd)

- Able to discontinue opioids
 - Last used hydrocodone approximately 6 months ago
- Documentation supports that MM takes edge off symptoms, decreases back spasms, allows increased daily function and walking.
- UDT consistent

Case Example (cont'd)

Two month trial of MM authorized with re-evaluation (consistent with General Principles) to include:

- Objective documentation of the efficacy of MM
- Specific examples of improved/maintenance of function
- Improved pain management and participation in self management program
- No adverse effects
- Compliance with UDT, I-Stop

Case Example (cont'd)

Follow-up: A subsequent MG-2 request for MM was approved for 6 months as the criteria for the two month trial was met.

Example: MTG Alternatives Effective

- According to the provider’s documentation in support of MM, the patient’s
 - hydrocodone 10/325 TID PRN (max 30mg=30 MED) (EFFECTIVE),
 - Ibuprofen (EFFECTIVE) and
 - voltaren gel (VERY HELPFUL),
- These medications satisfactorily decrease pain and improve daily function, without side effects

BOP: “An explanation why alternatives under the MTGs are not appropriate or sufficient” has not been met

Examples: MM Related MG-2 Requests

- Reimbursement of cost of MM and continued use of the same. Patient has been doing well with this under directive of Dr. “X”
 - Documentation by the requesting physician: “Medications from an outside provider” and there is no further information provided.
- Reimbursement for E&M 99214 for completion of MM certification*
- The MG-2 cannot be used to request reimbursement for:
 - Past or current use of MM or E&M billing
- The certifying MM provider must be the treating provider submitting the MG-2

*Note: Patients cannot be billed directly for completion of MM certificates

NYS DOH Medical Marijuana Program

www.health.ny.gov/regulations/medical_marijuana

Department of Health Individuals/Families Providers/Professionals Health Facilities Search

Medical Marijuana Program

Program Information and News

Frequently Asked Questions

Patient Information

Designated Caregiver Information

Practitioner Information

Laws & Regulations

Registered Organizations

Medical Marijuana Program Applications

Contact the Medical Marijuana Program

Statistics as of July 16, 2019

- Registered Practitioners: 2,409
- Cardinal Patients: 106,000

The New York State Medical Marijuana Program

Patients, Click Here **Designated Caregivers, Click Here** **Practitioners, Click Here** **Looking for a Registered Practitioner? Click Here**

Department of Financial Services (DFS) Guidance to Health Insurers Regarding Coverage for Office Visits Related to Medical Marijuana

The New York State Department of Financial Services (DFS) recently issued guidance to health insurers regarding coverage for office visits related to medical marijuana. The guidance from DFS may be accessed by clicking on the following link: <https://www.dfs.ny.gov/act/press/act15812189>

The Department Announces Updates to the Medical Marijuana Program

- November 14, 2018: Medical Use of Marijuana Under the Compassionate Care Act Two-Year Report - 2018-2019 (PDF)
- July 17, 2018: New York State Department of Health Announces Opioid Replacement Now a Qualifying Condition for Medical Marijuana
- June 18, 2018: New York State Department of Health Announces Opioid Use to be Added as a Qualifying Condition for Medical Marijuana
- December 8, 2017: New York State Department of Health Announces New Medical Marijuana Regulations
- November 11, 2017: Governor Signs Bill Adding PTSD as a Qualifying Condition for Medical Marijuana
- August 10, 2017: New York State Department of Health Announces New Regulations to Increase State's Medical Marijuana Program for Patients, Practitioners, and Registered Organizations
- August 1, 2017: New York State Department of Health Announces New Development Opportunities to Medical Marijuana Program
- June 22, 2017: New York State Department of Health Announces Enhancements to Medical Marijuana Program
- May 5, 2017: New York State Department of Health Adds Thousands of New Patients to Medical Marijuana Program Following the Addition of Chronic Pain
- December 1, 2016: NYSDOH Announces Chronic Pain to be Added As Qualifying Condition for Medical Marijuana
- November 29, 2016: Satisfaction of Interest for Laboratories to Perform Testing of Medical Marijuana Products in NYS
- November 22, 2016: NYSDOH Announces Expansion of Medical Marijuana Program

Learning more about the Board



@NYSWCB



@NYSWorkersComp



Board Announcements

wcb.ny.gov

Instagram



#NYSWorkersCompBoard



youtube.com/c/NewYorkStateWorkersCompensationBoard

BETTER FOR WORKERS

New York State Workers' Compensation Board

57 BETTER FOR BUSINESS



Workers' Compensation Board

Thank you

Questions?

BETTER FOR WORKERS

New York State Workers' Compensation Board

58 BETTER FOR BUSINESS