I. BACKGROUND

In July 2014, Chapter 90 of the Laws of 2014 established a requirement that practitioners who wish to register with the New York State Department of Health Medical Marijuana Program complete a two- to four-hour course on the medical use of marijuana. Practitioners who may register with the Department include

- Physicians licensed under article 131 of the New York State Education Law,
- Nurse practitioners certified under article 139 of the New York State Education Law, and
- Physician assistants licensed under article 131-B of the New York State Education Law. Physician assistants who wish to register and certify patients must be practicing under the supervision of a physician registered with the program.

The medical use of marijuana regulations at 10 NYCRR §1004.1(b) provide the required educational content of such course. After completing this course, practitioners, as defined above, can register with New York’s Medical Marijuana Program to certify patients for medical marijuana.

The regulations (10 NYCRR §1004.21) further established a requirement that any physician, nurse practitioner, physician assistant or pharmacist who counsels or directly supervises the counseling of a registered patient or designated caregiver in a dispensing facility on the use, administration of, and the risks associated with approved medical marihuana products must complete a four-hour course. The statute and/or regulations apply to the following professionals:

II. MEDICAL USE OF MARIJUANA COURSE GOALS

1. Educate the target audience about the pharmacology of marijuana; contraindications; side effects; adverse reactions; overdose prevention; drug interactions; dosing; routes of administration; risks and benefits; warnings and precautions; and abuse and dependence.

2. Provide practitioners with information that may be helpful as they weigh risks versus benefits of medical marijuana for their patients.
For courses designed to meet the requirement of 10 NYCRR §1004.21, provide practitioners and pharmacists employed by registered organizations information that will help as they counsel their patients.

III. COURSE FORMAT

The course may be live or in an online format.

IV. TIME REQUIREMENT

Practitioners must complete a two to four-hour course including all content defined in 10 NYCRR §1004.1(b).

Pharmacists and any practitioners working at New York State registered organizations’ dispensing facilities who counsel or directly supervise counseling of a registered patient or designated caregiver in a dispensing facility must complete a four-hour course including all content defined in 10 NYCRR §1004.1(b).

The content may be covered by a single, comprehensive presentation or by multiple individual presentations for a total of two to four hours.

V. CONTINUING MEDICAL EDUCATION (CME) CREDITS

Course providers may develop a course that offers CME credits, however, CME credits are not required by statute or regulation.

Courses accredited for the continuing education of physicians, physician assistants, nurse practitioners and pharmacists and which include all the required topics above, will be considered by the New York State Department of Health (Department) for the number of hours for which they are accredited.

VI. REQUIRED CONTENT

All content must be referenced using a common reference system (i.e. the American Psychological Association (APA) style, MLA (Modern Language Association) style).

a. THE PHARMACOLOGY OF MARIJUANA:

Content must include, at a minimum, the topics below.

i. A description of the endocannabinoid system
ii. A description of the components of marijuana, including the major cannabinoids and terpenes
iii. the basic pharmacology of the major cannabinoids

b. CONTRAINDICATIONS: ABSOLUTE AND RELATIVE
Content must address, at a minimum, the topics below.
   i. History of psychotic illness or a family history of a first degree relative with schizophrenia
   ii. 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
   iii. Any other relevant contraindications such as but not limited to: cardiovascular, liver or kidney disease

c. SIDE EFFECTS:
Content must address, at a minimum, the side effects listed below and include factors which may influence the side effect profile (dosage form, route of administration, cannabinoid profile, patient comorbidities, or any other factors).
   i. Dysphoria; sometimes severe
   ii. Nausea at high doses
   iii. Dizziness
   iv. Ataxia
   v. Dry mouth
   vi. Bronchitis

d. ADVERSE REACTIONS:
Pursuant to 10 NYCRR §1004.19(c), practitioners must report patient adverse events related to medical marijuana to the Department of Health within five business days of becoming aware of the adverse event.

   Serious adverse events related to medical marijuana must be reported by the practitioner to the Department within one business day after the practitioner becomes aware of the event.

   The report must be filed via the Person Electronic Response Data System (PERDS) application within the Department’s Health Commerce System (HCS). Information about how to report an adverse event can be found on the practitioner tab of the medical marijuana program webpage (https://www.health.ny.gov/regulations/medical_marijuana/).

   Patients should be advised to report adverse events related to medical marijuana to their practitioner and to call 911 in the event of a life-threatening emergency.
Content must address, at a minimum, the adverse reactions listed below and include factors which may influence adverse reactions (dosage form, route of administration, cannabinoid profile, patient comorbidities, or any other factors).

i. Cardiovascular
   Tachycardia, palpitations, hypertension

ii. Respiratory
    Coughing, wheezing, sputum production

iii. Central Nervous System
    Lethargy, sedation, dizziness, slowed reaction time

iv. Psychological
    Impaired coordination, memory formation, recollection, focus

v. Visual Disturbances

vi. Cannabis Hyperemesis Syndrome

e. DRUG INTERACTIONS:
   i. Substrates
   ii. Inhibitors
   iii. Inducers

f. OVERDOSE PREVENTION:
   At a minimum, the topics listed below must be addressed.

   i. Onset of action with various dosage forms and when to repeat a dosage
   ii. Maintain medical marijuana products in the packaging in which they were dispensed
   iii. Store medical marijuana products securely and keep out of reach of children
   iv. Summarize risk factors and data related to overdose and consequences of an overdose, including with high tetrahydrocannabinol (THC) versus high cannabidiol (CBD) content strains
   v. Provide information regarding median lethal dose

g. ROUTES OF ADMINISTRATION AND DOSING:
   i. Describe the administration methods authorized in New York State.
      1. Metered liquid or oil preparations
      2. Solid and semisolid preparations (e.g. capsules, chewable and effervescent tablets, lozenges)
      3. Metered ground plant preparations
      4. Topical forms and transdermal patches
5. Medical cannabis 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

ii. Describe dosing strategies in cannabis naïve vs experienced cannabis users.

iii. Dosing must include differences between dosage forms and routes of administration in dosing and effects, including onset and duration of action, and frequency of dosing.

iv. At a minimum, dosing for the administration methods listed below must be addressed.

1. Vaporization
2. Oromucosal preparations (e.g. tinctures, sprays)
3. Oral Solid Dosage Forms (e.g. capsules, tablets)
4. Topical Preparations (e.g. creams, lotions, oils, patches, salves)

NOTE: Any content on dosing or administration methods that are prohibited in New York State must explicitly state that the administration method or form is prohibited in New York State.

h. RISKS AND BENEFITS:
Explain factors to consider when weighing risks of medical marijuana versus benefits of medical marijuana for a patient, including, but not limited to, the factors listed below.

i. Patient’s condition and comorbidities
ii. Patient’s age
iii. Co-administration of other drugs/medicine

NOTE: Practitioners certifying patients for the medical use of marijuana must explain the potential risks and benefits of the use of medical marijuana to the patient and document in the patient’s medical record that this explanation has been provided.

i. WARNINGS AND PRECAUTIONS:
At a minimum, the warnings and precautions listed below must be addressed.

i. Medical marijuana may impair the ability to drive
ii. KEEP MEDICAL MARIJUANA PRODUCTS AWAY FROM CHILDREN (unless medical marijuana product is being given to the child under a practitioner’s care)

iii. Keep medical marijuana products in the original packaging in which they are dispensed to the patient

j. ABUSE AND DEPENDENCE:
   i. Address Cannabis Use Disorder and provide information on where patients can go for help, including, but not limited to contact information for the Office of Alcoholism and Substance Use Disorder (OASAS) in New York State

   ii. Describe physical dependence, addiction and tolerance with medical marijuana

VII. DOCUMENTATION INSTRUCTIONS FOR COURSE PARTICIPANTS

After the course is completed, the course provider must provide participants with a course evaluation survey. A course completion certificate must be provided to individuals who successfully complete the course and provide the course evaluation to the course provider. The certificate must include, at a minimum, the course provider name, course name, location of the course, date the course was completed, and number of hours completed. The course provider must maintain records of course completions and course evaluations for a minimum of five (years) from the date of completion and made available to the Department upon the Department’s request.

The course must instruct practitioners who will be certifying patients for the medical use of marijuana as well as practitioners and pharmacists working for registered organizations in a capacity where they are supervising, or providing, counseling to certified patients and their designated caregivers, that they must maintain their course completion certificate for a minimum of five (5) years from the date of completion for audit purposes.