Learning Objectives

Upon completion of this program, participants should:

• Be able to identify current Federal and North Eastern States’ laws concerning medical and recreational marijuana consumption.
• Identify legal issues facing practitioners and institutions facilitating the use of marijuana.
• Be able to offer guidance to patients as to how to become a registered medical marijuana patient in Massachusetts.
• Be better able to explain to patients the legal limits of marijuana consumption.

Disclaimer

• The following presentation is not meant to be legal or medical advice.

Pre-Test

1) State marijuana possession laws supersede federal marijuana possession laws when:
   • a) A patient holds a current medical marijuana card
   • b) Lives in a state where marijuana is legal by state law
   • c) Prescribed by a physician
   • d) State marijuana possession laws do not supersede federal marijuana possession laws

Pre-Test

2) Allowing the use of marijuana obtained from a state approved dispensary within institutions reimbursed by Medicare or Medicaid:
   • a) Should not be a concern
   • b) May affect reimbursement by Medicare or Medicaid
   • c) Is fine if it is brought in by the patient
   • d) Is allowable if the patient has a state issued marijuana card

Pre-Test

3) Information pertaining to registering as a patient for medical marijuana use in Massachusetts can be obtained from:
   • a) The FDA
   • b) The DEA
   • c) The Massachusetts Cannabis Control Commission website
   • d) The local police
Pre-Test

4) Use of marijuana on federal lands or water ways is:
   • a) Illegal
   • b) Is allowed with a state issued marijuana card
   • c) Legal
   • d) Is allowed on federal water ways but not federal lands

The American Medical Association (AMA) Position on Marijuana

- Cannabis Legalization for Medicinal Use D-95.969
  Our AMA: (1) believes that scientifically valid and well-controlled clinical trials conducted under federal investigational new drug applications are necessary to assess the safety and effectiveness of all new drugs, including potential cannabis products for medical use; (2) believes that cannabis for medicinal use should not be legalized through the state legislative, ballot initiative, or referendum process; (3) will develop model legislation requiring the following warning on all cannabis products not approved by the U.S. Food and Drug Administration: “Marijuana has a high potential for abuse. This product has not been approved by the Food and Drug Administration for preventing or treating any disease process.”

The American Medical Association (AMA) Position on Marijuana

- (4) supports legislation ensuring or providing immunity against federal prosecution for physicians who certify that a patient has an approved medical condition or recommend cannabis in accordance with their state’s laws; (5) believes that effective patient care requires the free and unfettered exchange of information on treatment alternatives and that discussion of these alternatives between physicians and patients should not subject either party to criminal sanctions; and

American Pharmacists Association (APhA) Position on Marijuana

- Role of the Pharmacist in the Care of Patients Using Cannabis (2015)
  1. APhA supports regulatory changes to further facilitate clinical research related to the clinical efficacy and safety associated with the use of cannabis and its various components.
  2. APhA encourages health care provider education related to the clinical efficacy, safety, and management of patients using cannabis and its various components.
  3. APhA advocates that the pharmacist collect and document information in the pharmacy patient profile about patient use of cannabis and its various components and provide appropriate patient counseling.
  4. APhA supports pharmacist participation in furnishing cannabis and its various components when scientific data support the legitimate medical use of the products and delivery mechanisms, and federal, state, or territory laws or regulations permit pharmacists to furnish them.
  5. APhA opposes pharmacist involvement in furnishing cannabis and its various components for recreational use.

Marijuana

- The Controlled Substance Act (CSA) states: “The term ‘marihuana’ means all parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.” 21 U.S.C. § 802 (3)
Hemp-Cannabidiol (CBD)

- At the federal level, the *Agriculture Improvement Act of 2018*, Pub. L. 115-334, (the 2018 Farm Bill) was signed into law on Dec. 20, 2018. Among other things, this new law changes certain federal authorities relating to the production and marketing of hemp, defined 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." These changes include removing hemp from the CSA, which means that cannabis plants and derivatives that contain no more than 0.3 percent THC on a dry weight basis are no longer controlled substances under federal law. (10)

Legal Bodies Regulating or Impacting Cannabis and Hemp Use

- United States Drug Enforcement Administration (DEA)
- United States Food and Drug Administration (FDA)
- United States Department of Agriculture (USDA)
- State Cannabis Control Programs
- Centers for Medicare and Medicaid Services (CMS)
- State Agricultural Bodies (e.g., Massachusetts Department of Agricultural Resources)
- Various local municipal boards (e.g., Zoning Boards, Selectmen, City Councils etc.)

DEA

- Schedule I of the Controlled Substance Act
- Substances in this schedule have no currently accepted medical use in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse.
- Some examples of substances listed in Schedule I are: heroin, lysergic acid diethylamide (LSD), marijuana (cannabis), peyote, methaqualone, and 3,4-methylenedioxymethamphetamine ("Ecstasy"). (4)

FDA

- The FDA’s authority for regulating food and drugs comes from CFR 21-Food and Drugs. Goods produced by the Cannabis and Hemp industries which would fall under FDA regulations are:
  - dietary supplements
  - other food products
  - prescription drugs (both brand-name and generic)
  - non-prescription (over-the-counter) drugs
  - veterinary drugs

To date, the FDA has not approved a marketing application for cannabis for the treatment of any disease or condition. FDA has, however, approved one cannabis-derived and three cannabis-related drug products. These approved products are only available by prescription from a licensed healthcare provider.

- Epidiolex®-CBD derived
- Marinol®-Dronabinol
- Syndros®-Dronabinol
- Cesamet®-Nabilone

FDA

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- FDA Commissioner Scott Gottlieb M.D. On December 20, 2018, he states "it’s unlawful under the FD&C Act to introduce food containing added CBD or THC into interstate commerce, or to market CBD or THC products as, or in, dietary supplements, regardless of whether the substances are hemp-derived. This is because both CBD and THC are active ingredients in FDA-approved drugs and were the subject of substantial clinical investigations before they were marketed as foods or dietary supplements." (5) (6) (7) (8)

FDA-Compassionate Use Program

• Under the authority of the FDA, there is a Compassionate Investigational New Drug (IND) Program that supplies marijuana to qualifying patients.
• https://www.medicalcannabis.com/patients-care-givers/federal-ind-patients/
• https://news.olemiss.edu/federally-funded-marijuana-turns-50/

USDA

• Section 12619 of the Farm Bill removes hemp-derived products from its Schedule I status under the Controlled Substances Act, but the legislation does not legalize CBD generally. CBD generally remains a Schedule I substance under federal law. The Farm Bill—and an unrelated, recent action by the Department of Justice—creates exceptions to this Schedule I status in certain situations. The Farm Bill ensures that any cannabinoid—a set of chemical compounds found in the cannabis plant—that is derived from hemp will be legal, if and only if that hemp is produced in a manner consistent with the Farm Bill, associated federal regulations, association state regulations, and by a licensed grower.
  *https://www.brookings.edu/blog/fixgov/2018/12/14/the-farm-bill-hemp-and-cbd-explainer/

More on CBD

• The 2018 Farm Bill explicitly preserved FDA’s authority to regulate products containing cannabis or cannabis-derived compounds under the FD&C Act and section 351 of the Public Health Service Act (PHS Act). FDA treats products containing cannabis or cannabis-derived compounds as it does any other FDA-regulated products.

More on CBD

• (The FDA has repeatedly said that CBD can’t go in food or dietary supplements sold across state lines. However, the FDA’s light enforcement of that rule, combined with its statements that regulators are willing to consider over-the-counter CBD sales, has led to broad market activity in CBD sales with only sporadic product seizures or penalties for selling unapproved products.)
  *(8) (9) (10) (11) (12) (13) (14)

• For hemp entrepreneurs, the patchwork of state CBD rules is dashing hopes the Farm Bill solved the problem of allowing interstate commerce.

CMS

CMS does not have any regulatory authority concerning marijuana; however it does have the authority to deny payment of medical claims if a provider has been found to be in violation of The Joint Commission Standard MM.03.01.05 policy.
MM.03.01.05 states: “The hospital safely controls medications brought into the hospital by patients, their families, or licensed independent practitioners.”
  *https://www.deadiversion.usdoj.gov/schedules/marijuana/m_extract_7350.html

CMS

Because hospitals and other health care institutions are accredited through the Center for Medicare & Medicaid Services, these facilities could be found to be in violation, lose federal funding, and face penalties.
  *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5345918/
What Does All This Mean?

• The DEA considers marijuana, THC and CBD derived from cannabis illegal. CBD derived from hemp is considered legal by the DEA as clarified in the 2018 Farm Bill.
• Because there are THC and CBD prescription products now available, the FDA considers all other THC and CBD products unapproved products, including CBD derived from hemp.
• Clinicians, prescribing, supplying or otherwise facilitating (i.e. pharmacists) the use of cannabis or hemp products at institutions receiving reimbursement from Medicare or Medicaid, would violate JCAHO standards and therefore violate CMS rules which in turn could affect reimbursement.

State Cannabis Control Programs

• State cannabis control programs or commissions are responsible for overseeing the actions of all aspects of cannabis dispensaries including licensing, cultivation, dispensing, transportation, patient registration and regulation enforcement.
• In states where hemp is legal to grow, state agricultural departments may oversee the hemp industry. Massachusetts’ hemp industry is overseen by the Massachusetts Department of Agricultural Resources-MDAR.

North East States with Marijuana Dispensaries

<table>
<thead>
<tr>
<th>State</th>
<th>Medical</th>
<th>Recreational</th>
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<tbody>
<tr>
<td>Connecticut</td>
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<tr>
<td>Washington D.C.</td>
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</tbody>
</table>

*No recreational dispensaries approved for sale as of 7/1/2019

How A Massachusetts Medical Use of Marijuana Patient Becomes Registered

• A patient must be certified by a health care provider registered with the Massachusetts MMJ (Medical Marijuana) Program (the “Program”).
• A certification is given after a patient is seen by an MMJ healthcare provider* and a diagnosis of a debilitating medical condition is established.
• A patient 18 years of age or older can either register online at sso.hhs.state.ma.us/VGPortal/faces/SelfReg.jspx or by calling the Program at (617) 660-5370 to request a paper registration form.
• Patient registration guidance is available at www.mass.gov/eohhs/gov/departments/dph/programs/hcq/medical-marijuana/
• If the qualifying patient is under 18 years of age, an attestation from a parent or legal guardian granting permission for the child to register with the department must be given and the underage qualifying patient must have a designated caregiver, who shall be his or her parent or legal guardian.

* MMJ healthcare providers are physicians and nurse practitioners certified by The Massachusetts Department of Public Health to prescribe medical marijuana. They must also have a current Massachusetts Controlled Substance Registration.

How a Massachusetts Medical Use of Marijuana Patient Becomes Registered

• If approved a patient will be able to print a temporary paper Program ID Card which is valid for four weeks and will receive a plastic Program ID Card in the mail in 1-2 weeks.
• Cost of registration is $50 which must be renewed annually unless hardship can be established.
• The website below offers a good tutorial on step by step registration. (16) (17)


New Immediate Access Program

• In response to the lag in medical marijuana registration by the DPH, the Massachusetts Cannabis Control Commission has created a program to allow immediate access to patients awaiting approval.*

Patient Legal Limits of Marijuana Consumption—Rights and Obligations (Massachusetts)

- Patients must carry their MMJ Program ID Card while in possession of MMJ.
- Patients are limited to 10 ounces of MMJ every 60 days unless otherwise certified.
- Patients may designate up to two caregivers that can assist in transporting the patient, purchase MMJ on their behalf and prepare or administer MMJ to the patient.
- If hardship is established a patient or the patient's registered caregiver may cultivate for the patient's personal use a limited number of plants to maintain a 60-day supply.
- Patients may not use MMJ in public.

Patient Legal Limits of Marijuana Consumption—Rights and Obligations (Massachusetts)

- The protections conferred by The Acts of 2012, for possession of marijuana for medical use are applicable only within Massachusetts.
- Patients in possession of MMJ are not protected from laws outside of Massachusetts' Jurisdiction (Such as Other States, Federal Laws including but not limited to the DEA, Federal Waters Acts and FAA Regulations).
- Nothing in Massachusetts law or the Department of Public Health (DPH) regulations, 105 CMR 725.000, requires the violation of federal law, purports to give immunity under federal law, or poses an obstacle to federal enforcement of federal law.

Individual North East States Differences

- Each state has their own set of guidelines and regulations concerning medical marijuana. Some differences include:
  - Use restrictions
  - Possession and purchase quantities
  - Home cultivation limits
  - Patient age
  - Caregiver limitations
  - Type of products available
  - Qualifying medical conditions
Becoming Involved as a Healthcare Provider

• Only Licensed Medical Doctors, Doctors of Osteopathy and Certified Nurse Practitioners may become a marijuana certified healthcare providers.

• Other healthcare providers such as pharmacists and nurses may become registered institutional caregivers. (17)

Practitioner Registration (Massachusetts)

• Practitioners seeking certification can register at the following website:


Caregivers (Massachusetts)

• Caregiver means a personal caregiver or institutional caregiver. This includes:
  • Personal Caregivers
  • Caregiving Institutions
  • Institutional Caregivers

Caregivers

• Personal Caregiver means a person, formerly and validly registered by the Department or currently and validly registered by the Commission, who is at least 21 years old, who has agreed to assist with a registered qualifying patient’s medical use of marijuana and is not the registered qualifying patient’s certifying healthcare provider. A visiting nurse, personal care attendant, or home health aide providing care to a registered qualifying patient may serve as a personal caregiver, including to patients younger than 18 years old as a second caregiver. Except in the case of a visiting nurse, personal care attendant, or immediate family member of more than one registered qualifying patient, an individual may not serve as a personal caregiver for more than one registered qualifying patient at one time.

  • https://www.mass.gov/files/documents/2018/12/24/How%20to%20Register%20with%20the%20Medical%20Use%20of%20Marijuana%20Program%20Instructions%20for%20Personal%20Caregivers_0.pdf

Caregiving Institutions

• Massachusetts Medical Use of Marijuana 935 CMR 501.021 Registration of Caregiving Institutions states:

  Prior to facilitating the medical use of marijuana to a registered qualifying marijuana patient, a hospice program, long-term care facility, or hospital shall obtain a certificate of registration as a caregiving institution. Institutional caregivers must also be registered. (16) (17)

Final Thoughts From the Road, Personal Experiences

- If you decide to recommend marijuana to patients, here are some thoughts to consider:
  - Currently there is no standardization of product potency in the industry
  - From personal experience with Homeland Security and former DEA field agents, unless there is large quantities of marijuana involved, marijuana is not high on the radar
  - I have not heard of any instances where reimbursement has been affected due to the use of marijuana in healthcare facilities

Post Test

1) State marijuana possession laws supersede federal marijuana possession laws when:
   • a) A patient holds a current medical marijuana card
   • b) Lives in a state where marijuana is legal by state law
   • c) Prescribed by a physician
   • d) State marijuana possession laws do not supersede federal marijuana possession laws
   Answer: d - State marijuana possession laws do not supersede federal marijuana possession laws

Post Test

2) Allowing the use of marijuana obtained from a state approved dispensary within institutions reimbursed by Medicare or Medicaid:
   • a) Should not be a concern
   • b) May affect reimbursement by Medicare or Medicaid
   • c) Is fine if it is brought in by the patient
   • d) Is allowable if the patient has a state issued marijuana card
   • Answer: May affect reimbursement by Medicare

Post Test

3) Information pertaining to registering as a patient for medical marijuana use in Massachusetts can be obtained from:
   • a) The FDA
   • b) The DEA
   • c) The Massachusetts Cannabis Control Commission website
   • d) The local police
   • Answer: c - The Massachusetts Cannabis Control Commission website

Post Test

4) Use of marijuana on federal lands or water ways is:
   • a) Illegal
   • b) Is allowed with a state issued marijuana card
   • c) Legal
   • d) Is allowed on federal water ways but not federal lands
   • Answer: a - Illegal

North East State Government Websites

Connecticut
- https://portal.ct.gov/DCP/Medical-Marijuana-Program/Medical-Marijuana-Program

Maine
## North East State Government Websites

<table>
<thead>
<tr>
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<td><a href="https://mcc.maryland.gov/Pages/law.aspx">https://mcc.maryland.gov/Pages/law.aspx</a></td>
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</tr>
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## References

4. [https://www.deadiversion.usdoj.gov/schedules/](https://www.deadiversion.usdoj.gov/schedules/)
10. [https://www.brookings.edu/blog/fixgov/2017/02/06/cannabidiol-illegal-and-always-has-been/](https://www.brookings.edu/blog/fixgov/2017/02/06/cannabidiol-illegal-and-always-has-been/)
11. [https://www.law.cornell.edu/uscode/text/7/5940](https://www.law.cornell.edu/uscode/text/7/5940)
References

• 15) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5345918/
• 16) https://mass-cannabis-control.com/