The Evolution of Cannabis Regulation

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Brian Higgins

• Health Care Attorney
  1. Advised health systems, senior living facilities, and physicians on medical marijuana law.
  2. Counsels clients on Stark law/Anti-kickback statute, and HIPAA/privacy concerns.
  3. Assists healthcare clients on corporate transactions.
  4. Defends providers from Medicare/Medicaid overpayment recovery demands.
  5. Advises on general healthcare regulatory issues.
  6. Experience at Medpace, Inc. and The Christ Hospital.
Let’s have some pun

1. “Into the weeds…”
2. “Clear the legal haze…”
3. “States have ‘gone green’…”
4. “High risk, high reward…”
BREAKING NEWS

GREEN GRASS IN THE BLUEGRASS?

11:24 KENTUCKY HEALTH POLICY Focuses on MEDICAL MARIJUANA
Today’s Agenda

1. Marijuana history and regulation
2. Overview of current state medical marijuana laws
3. Federal marijuana law
4. How federal marijuana law has impacted states with legalized medical marijuana
“Cannabis,” explained

1. Umbrella term

2. Marijuana
   a. ↓CBD (cannabidiol)
   b. ↑THC (tetrahydrocannabinol)

3. Hemp
   a. ↑CBD
   b. ↓THC
Marijuana history and regulation
Marijuana history and regulation

1. Pre-early 1900’s – legal to grow and consume marijuana.

2. 1906 – Pure Food and Drug Act – marijuana products available without prescription but must be accurately labeled with contents and dosage.

3. Early 1900’s – states begin to criminalize marijuana products – marijuana regulation motivated by racism, xenophobia and its use was associated with crime and migrant Mexican and African-American workers.
Marijuana history and regulation (continued)

4. 1930’s – Harry Anslinger Commissioner of Federal Bureau of Narcotics (now Drug Enforcement Administration):

• “There are 100,000 total marijuana smokers in the US, and most are Negroes, Hispanics, Filipinos and entertainers. Their Satanic music, jazz and swing result from marijuana use. This marijuana causes white women to seek sexual relations with Negroes, entertainers and many others.”
Marijuana history and regulation (continued)


7. 1970 – Controlled Substances Act – federal government officially bans marijuana by placing it under federal jurisdiction regardless of state regulations and laws.
Marijuana history and regulation (continued)


9. 1996 – California’s Compassionate Use Act legalized medical marijuana.


Legalized medical marijuana states

- (33 States + D.C.)

33 Legal Medical Marijuana States & DC
11 Legal Recreational Marijuana States & DC
Notable health systems and medical marijuana

1. Mayo Clinic – Rochester, Minnesota
2. Mount Sinai Hospital – Manhattan, New York
3. The Christ Hospital – Cincinnati, Ohio
4. University of Pittsburgh Medical Center – Pittsburgh, Pennsylvania
State medical marijuana laws, generally

1. Certified physician visit
2. Most require certain medical conditions
3. Some home grow permitted
4. Possession limits (ounces, grams) or time-period (x-day supply)
5. Some allow minors to use
Critical points about Ohio’s medical marijuana law

1. Patients responsible for storage to prevent theft, loss, or access by persons not authorized by law.

2. Prohibits the disqualification of a patient from medical care or transplant list.

3. Medical marijuana made a Schedule II drug (with Adderall and morphine).

O.R.C. § 3796 et. seq.
Critical points about Ohio’s medical marijuana law (continued)

4. Professional immunization from disciplinary action for engaging in professional or occupational activities related to medical marijuana.

5. Patient not subject to arrest/criminal prosecution for medical marijuana related conduct.

6. Ohio residency required.

O.R.C. § 3796 et. seq.
Critical points about Ohio’s medical marijuana law (continued)

7. Public places are not (a) required to accommodate, or (b) prohibited from accommodating, a patient’s use of medical marijuana.

8. 21 qualifying medical conditions to get a recommendation.
   a. Chronic pain
   b. AIDs
   c. Cancer
   d. PTSD
   e. Alzheimer’s Disease

9. Only patients/caregivers allowed in dispensaries.

O.R.C. § 3796 et. seq.
How do Ohio patients get medical marijuana?

1. Schedule appointment;

2. Be evaluated by physician with certificate to recommend;

3. Be diagnosed with qualifying medical condition;

4. Receive a recommendation and have physician register patient (pay $50 for card); and

5. Purchase product at dispensary.
Ohio’s in-person evaluation

• Physician must:
  1. assess medical history, Rx history, SUD history;
  2. review current medications for interactions;
  3. perform physical examination relevant to patient’s current medical condition; and
  4. determine whether patient suffers from qualifying medical condition.
Ohio’s in-person evaluation (continued)

• If qualifying medical condition diagnosed (or confirmed), then physician must:
  1. develop treatment plan;
  2. review OARRS report (review for indicators of possible abuse or diversion);
  3. explain risks and benefits of treatment; and
  4. obtain the patient's consent prior to completing a recommendation.
Ohio administration methods

1. No smoking/combustion
2. Vaporization permitted
3. Ingestion
4. Topical
Ohio forms available

1. Oils
2. Tinctures
3. Plant material
4. Edibles
5. Patches
But what about federal marijuana law?
The Federal Controlled Substances Act

• Designates marijuana as Schedule I controlled substance (along with LSD and heroin):
  a. high potential for abuse.
  b. no currently accepted medical use in treatment.
  c. there is a lack of accepted safety for use of the drug under medical supervision.
The Federal Controlled Substances Act (continued)

1. Marijuana itself is not an FDA-approved drug.

2. FDA-approval requires clinical research.

3. Marijuana use in clinical research requires special licensure and registration requirements for the investigator and the site where the study will be conducted (21 C.F.R. 1301.18).

4. Historically, hard to research, but that may change.

FDA-approved Epidiolex


2. CBD does not cause intoxication/euphoria/high – that is Tetrahydrocannabinol (THC).

3. Treats Dravet syndrome and Lennox-Gastaut syndrome, two conditions associated with seizures.

4. No other FDA-approved drugs with CBD or other cannabis or marijuana-derived products.
Legal implications of labeling marijuana “medical” or a “medicine,” according to the FDA

1. Any medical product or product intended to affect body = drug.
2. Making unsubstantiated medical claims about an unapproved drug product is illegal because it is not known:
   a. whether the product will work;
   b. how to properly dose the product;
   c. how the product interacts with other drugs; and
   d. whether the product will cause side effects or have other effects.
3. Concern is consumers may be influenced not to use approved therapies to treat serious diseases.

What does the Federal Controlled Substances Act prohibit?

1. Pretty much everything that a state’s medical marijuana law allows.

2. Prohibits possessing, prescribing, distributing, dispensing, and administering marijuana.

3. Prohibits conspiring to violate, and aiding and abetting the violation of, the CSA.
Legal implications for a violation of the Federal Controlled Substances Act

1. Imprisonment and fines
2. Loss of federal benefits, contracts, licensure, grants and payments (Medicare/Medicaid enrollment)
3. Loss of federal tax exemption
4. Loss of industry accreditations
How has federal marijuana law impacted states with legalized medical marijuana?
Federal enforcement actions for violating the Federal Controlled Substances Act

1. 30+ jurisdictions with medical marijuana – no examples?

2. Massachusetts doctors crossed line.
Why has federal law enforcement been so limited?

1. The Rohrabacher Amendment
2. Prescription v. recommendation
3. The Cole Memorandum
Restraints on Federal law enforcement – The Rohrabacher Amendment


2. Prohibits DOJ from using federal funds to interfere with those strictly complying with a state’s medical marijuana law. *United States v. McIntosh*, 833 F.3d 1163, 1179 (9th Cir. 2016).

3. However, violations can be prosecuted for up to 5 years after occurrence.

4. Must be continually extended in appropriations bill (Rohrabacher lost seat).
Restraints on Federal law enforcement – “prescription” v. “recommendation”

1. Medical marijuana laws allow “recommendations,” not “prescriptions.”

2. Derived from *Conant v. Walters*, 309 F.3d 629 (9th Cir. 2002) decision.
   a. Federal government cannot prosecute physicians or revoke a DEA license for a recommendation.
   b. First amendment right.
Restraints on Federal law enforcement – the Cole Memorandum

1. Guided U.S. attorneys to only enforce federal marijuana laws in certain situations:
   a. prevent distribution to minors;
   b. prevent marijuana money from going to gangs; and
   c. prevent diversion from legal states to non-legal states.

2. Rescinded in January 2018 by former Attorney General Jeff Sessions.
Federal law enforcement under current Attorney General

1. William Barr


3. “Will not go after those who relied on Cole Memorandum”

4. “Pleased” that DEA is reviewing applications for those who seek to grow marijuana legally for research purposes.
STATE AND FEDERAL MEDICAL MARIJUANA LAW TAKE AWAYS

While a state may have legalized medical marijuana, federal law is supreme and designates marijuana as illegal.

However, the federal government’s enforcement of marijuana laws has been limited due to various restraints.

This does not mean such enforcement will remain limited, though – “it depends.”
Concluding thoughts

- Good policy needs good fact-finding
- Look to other states for models
- Make sure approach is right for your constituents
thank you