WHAT PROVIDERS NEED TO KNOW ABOUT MARIJUANA
legal perspective

BY NATALIA MAZINA
OF-COUNSEL AT KLEIN, HOCKEL, IEZZA & PATEL, P.C.
nmazina@khiplaw.com 415-802-4057

FEDERAL LAW

SCHEDULE I:

- Has a high potential for abuse
- Has no currently accepted medical use
- Lack of accepted safety

No prescription may be written for Sch. I drug, and such substances are subject to production quotas by the DEA

"'[M]arihuana' 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."

21 USC § 802(16)

Gonzales v. Raich, 545 U.S. 1 (2005):
Marijuana users and growers in California sought declaratory relief declaring the CSA unconstitutional as applied to their activities permitted by the Cal. CUA.
Holding: Congress's power under the Commerce Clause includes the power to prohibit local cultivation and use of marijuana because such local activity can substantially affect interstate commerce.

2009 Ogden Memo:
• Guide to the exercise of investigative and prosecutorial discretion
• Generally will not pursue "individuals whose actions are in clear and unambiguous compliance with state laws."

CALIFORNIA LAW

Cal Compassionate Use Act (CUA) (1996) (amended by SB 420) in 2003:

Legalized for treatment of many medical conditions (including HIV/AIDS) and "any other illness for which marijuana provides relief" (open to broad interpretation)
Removes state penalties for use, possession or growth with a physician's recommendation.
Unlike other medications, providers do not prescribe amount, number of refills, content of medication or route of administration (dispensary's function).

Adult Use of Marijuana Act (AUMA) 2016

- Adults over 21 can possess, transport, purchase, consume and share up to 1oz of non-medical marijuana and 8 grams of concentrates. Allows to grow up to 6 plants for personal use.
- Designates Department of consumer affairs as the lead regulatory agency. Local control provisions
- Requires state agencies begin issuing licenses by Jan. 1, 2018

Conflict between medical and recreational laws, Med. Cannabis regulation and Safety Act (MCRSA) and AUMA.

Physician's responsibilities when recommending Med. Marijuana:

- Possess a license to practice medicine or osteopathy
- Perform a medical examination of the patient
- Document that the patient has a serious medical condition and that the medical use of marijuana is appropriate
- Have the patient sign an authorized medical release of information (necessary for the county program)
- Provide the patient with copies of med. records stating that he/she has been diagnosed with a serious med. condition and med. use of marijuana is appropriate.
- Develop a treatment plan (ongoing monitoring)
- Disclose the risks

FEDERAL LAW & RELEVANT CASES

2011 Cole Memorandum:

- Recognized increased scope of commercial sale, cultivation, distribution and use of marijuana for "purported medical purposes."
- Clarified that Ogden Memo was not a shield from federal prosecution of such activities.
- Persons in such businesses and those who "knowingly facilitate such activities are in violation of the Controlled Substances Act."

2013 Cole Memorandum:

- DOJ's guidance rests on its expectation that states have strong and regulatory and enforcement systems

2015 Appropriations Act:

- Section 538 was included in the Appropriations Act of 2016: Prohibits use of funds to prevent States from implementing their own State laws that authorize the use, distribution, possession, or cultivation of medical marijuana. Will expire this month.

United States of America v. Marin Alliance For Medical Marijuana ("MAMM") (N.D. Cal. Oct. 19, 2015):

- Medical marijuana dispensary asked the court to dissolve a permanent injunction that prohibited it from dispensing medical marijuana under CUA because Congress prohibited the DOJ from using any resources to interfere with a state's ability to implement its own medical marijuana laws.
- Holding: As long as 538 is in place, the DOJ can only enforce federal controlled substances laws against dispensaries if they are not in compliance with Cal. laws.

Attempts to minimize conflict with state laws:

- Ending Federal Marijuana Prohibition Act of 2013
- Compassionate Access, research Expansion, and respect States Act of 2015
- Respect State Marijuana Laws Act of 2015

Dec. 14, 2016 DEA issued a final rule expanding definition of Cannabis.

Conant v. Walters, 309 F.3d 629 (9th Cir. 2002):

- Patients and physicians brought class action to enjoin, as First Amendment violation, enforcement of government policy that threatened to punish physicians for communicating with their patients about the medical use of marijuana.
- Holding: (1) DEA's policy of threatening revocation of a physician's DEA registration based solely on the physician's professional recommendation of the med. marijuana is invalid;
  (2) injunction that prohibited DEA from conducting an investigation of a physician based solely on the physician's recommendation of med. marijuana, was upheld; and
  (3) government could not justify policy that threatened to punish a physician for recommending to a patient the medical use of marijuana on ground that such a recommendation might encourage illegal conduct by the patient.

BEST PRACTICES DISCUSSION

If prescribing:

- follow CMB & AMA's guidelines
- Prescribe FDA approved THC compounds
- Keep abreast of emerging literature on the subject of med. marijuana

A study in med. marijuana laws determined that most recommendations take place under the following circumstances:

(1) no prior relationship exists between the patient and physician;
(2) the recommender is not a specialist in treating the underlying condition; and
(3) no follow-up appointments are scheduled.

This puts physicians into the following areas of risks:

(1) licensing issues;
(2) ethical duties; and
(3) negligence-styled, standard-of-care lawsuits.

Hospital Policy:

What if a patient brings med. marijuana into the hospital?

Legal implication if a hospital confiscates (and return later) med. marijuana? Aiding and abetting?

What if the cannabis product used during a clinical trial?

If a patient is admitted to a hospital, which is not taking part in the study, hospital should permit the patient's continued use of marijuana depending on whether the clinical study has approval under 21 USC 823(f), which allows a Schedule I substance to be dispensed by a practitioner for research purposes if the research is approved by the Secretary and not denied by the AG.

Hospital policies addressing marijuana:

- Self-administration of medications by patients
- Handling personal property
- Alternative supplements
- Patient care order
- Hospital security practices
- Inpatient patient medication

3 approaches that hospitals take:

(1) Allow med. use of marijuana in the facilities: with patients registered with the state's program who come in with a product in its original container as dispensed by an approved dispensary. The admitting physician must decide whether to continue and is it appropriate for hospital stay. Only capsules or oral liquid should be allowed, no self-administration.
    - Could be a proper approach if state standards for ensuring quality control are quite strong, and manufacturers are required to demonstrate consistency of product content, purity, stability, and accuracy of labeling.

(2) Prohibit any use of marijuana in the facilities:
Concerns
- losing federal licenses,
- drug interactions, lack of research on cannabis, etc.
- loosing Medicare and Medicaid reimbursements.
- loosing accreditations (JCAHO)?

(3) Shifting rules: clinicians recommending med marijuana in accordance with state laws. Pediatric cases – solid research.

Providers with licensure in multiple states:

- Legal conduct in one state could result in suspension or revocation in another state
- How about tribal lands?

Will anything change with the new administration? More or less enforcement?

- New Federalism Fund (NFF)
- States' letter to AG Sessions and Treasury Secretary Steve Mnunchin
- AG's statements re enforcement of CSA
- Trump's willingness to give "more flexibility to the states."
- New US drug czar (Morino)