

A Risk Manager's Guide to Virginia's Medical Cannabis Program

Rebecca E. Gwilt, Esq.
Partner, Nixon Law Group PLLC

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RUNDOWN

- **Federal Cannabis Law and Policy**
 - Controlled Substances Act
 - Conan v. (McCaffery) Walters
 - The Cole Memo
 - The Sessions Memo
 - The Rohrabacher-Farr amendment
- **Virginia's Medical Cannabis Program**
- **Ethics, Malpractice, and other Provider Concerns**



Federal Cannabis Law & Policy

Controlled Substances Act (CSA)

- Marijuana is classified as a Schedule I drug under the CSA

Schedule I is for substances that the FDA and DEA have determined to have a **high potential for abuse, no currently accepted medical use, and a lack of safety for use under medical supervision.**

- Illegal to possess under Federal law and punishable under the CSA regardless of State law



Federal Cannabis Law & Policy

Prop 215 and Prop 200 (1996)

- California Proposition 215 and Arizona Proposition 200 (ballot initiatives)
 - Allowed physicians to recommend marijuana for medical purposes
- “The Administration’s Response to the Passage of California Proposition 215 and Arizona Proposition 200” (DOJ, HHS, DEA)
 - A doctor’s “action of recommending or prescribing Schedule I controlled substances is not consistent with the ‘public interest’ (as that phrase is used in the federal Controlled Substances Act)” and that such action would lead to revocation of the physician’s registration to prescribe controlled substances.



Federal Cannabis Law & Policy

Conant v. McCaffrey (N.D. Cal. 1997)

- **TRO and Preliminary Injunction**
 - Government “may not take administrative action against physicians for recommending marijuana unless the government in good faith believes that it has substantial evidence” that the physician **aided and abetted** the purchase, cultivation, or possession of marijuana, 18 U.S.C. § 2, **or engaged in a conspiracy** to cultivate, distribute, or possess marijuana, 21 U.S.C. § 846
 - Government prohibited from **threatening or prosecuting physicians, [or] revoking their licenses . . . based upon conduct relating to medical marijuana** that does not rise to the level of a criminal offense.



Federal Cannabis Law & Policy

Conant v. McCaffrey (N.D. Cal. 2000)

- **Permanent Injunction**
 - The district court rejected the government’s construction of the Controlled Substances Act (“CSA”), which read the CSA “to allow the Administrator of the Drug Enforcement Agency to revoke a physician’s registration if he or she merely **recommends** marijuana to a patient.”
 - Government is permanently enjoined from: (i) revoking any physician class member’s DEA registration merely because the doctor makes a recommendation for the use of medical marijuana based on a sincere medical judgment and (ii) from initiating any investigation solely on that ground.



Federal Cannabis Law & Policy

Conant v. McCaffrey (N.D. Cal. 2000)

The fundamental disagreement between the parties concerned the extent to which the federal government could regulate doctor-patient communications without interfering with **First Amendment interests**.



Federal Cannabis Law & Policy

Conant v. Walters (9th Circuit 2002)

- “Medical Information” v. Distribution of Drugs (*United States v. Oakland Cannabis Buyers’ Coop.*, 532 U.S. 483 (2001), rev’g *United States v. Oakland Cannabis Buyers’ Coop.*, 190 F.3d 1109 (9th Cir. 1999)).
 - Government argued the injunction protected criminal conduct and barred its right to investigate physicians
 - Court affirmed that the CSA does not provide the statutory authority to regulate the speech at issue (content-based restriction)

“The government’s license revocation policy violates the First Amendment rights of both physicians and patients...and cannot be justified as responding to incitement or criminal conduct”



Federal Cannabis Law & Policy

Conant v. Walters (9th Circuit 2002)

If, in making the recommendation, the physician intends for the patient to use it as the means for obtaining marijuana, as a prescription is used as a means for a patient to obtain a controlled substance, then a physician would be guilty of aiding and abetting the violation of federal law.

BUT

Holding doctors responsible for whatever conduct the doctor could anticipate a patient might engage in after leaving the doctor's office is simply beyond the scope of either conspiracy or aiding and abetting.



Federal Cannabis Law & Policy

Conant v. Walters (U.S. Supreme Court 2003)

The government petitioned the U.S. Supreme Court for review of the Ninth Circuit's decision. The petition was denied.



Federal Cannabis Law & Policy

[Cole Memo](#) (2013)

- “A guide to the exercise of investigational and prosecutorial discretion”
- “Enforcement of state law by state and local law enforcement and regulatory bodies should remain the primary means of addressing marijuana-related activity.”

[Sessions Memo](#) (2018)

- Instructed U.S. Attorneys to follow “the well-established principles that govern all prosecutions”
- Generally seen as a rescission of the Cole Memo



Federal Cannabis Law & Policy

The Rohrabacher-Farr Amendment

- First introduced in the US House of Representatives in 2001
- Intended to prohibit the US Justice Department from spending any funds on actions designed to interfere with implementation of state level medical cannabis laws.
- Passed in December 2014 (part of funding bill) and renewed in 2015, 2016, 2017, and 2018.

On August 16, 2016, the Ninth Circuit Court of Appeals told the DOJ that the Rohrabacher-Farr Amendment unequivocally *“prohibits DOJ from spending funds from relevant appropriations acts for the prosecution of individuals who engaged in conduct permitted by state medical marijuana laws and who fully complied with such laws.”*



Federal Cannabis Law & Policy

Federal Cannabis Legislation in 2020

[H.R. 3884](#): the Marijuana Opportunity, Reinvestment, and Expungement (MORE) Act

[H.R. 1595](#): Secure And Fair Enforcement (SAFE) Banking Act of 2019



Virginia's Medical Cannabis Program

2015

- **HB1445, SB1235**
 - Grants an **affirmative defense** in a prosecution for the possession of cannabidiol oil or THC-A oil IF possessed pursuant to a valid **written certification** issued by a practitioner of medicine or osteopathy licensed by the Board of Medicine for purposes of treating or alleviating a patient's symptoms of **intractable epilepsy**.
 - Protects practitioners from prosecution *for dispensing or distributing cannabidiol oil or THC-A oil for the treatment or to alleviate the symptoms of a patient's intractable epilepsy pursuant to a written certification*



Virginia's Medical Cannabis Program

2016-2017

- **SB701**
 - Creation of Pharmaceutical Processors regulated by BOP
 - Only a licensed practitioner of medicine or osteopathy **who is a neurologist or who specializes in the treatment of epilepsy** may issue a written certification to a patient for the use of cannabidiol oil or THC-A oil.
 - Practitioner (and patient/patient rep) **must register** with the BOP

****Law did not become effective until reenacted by the 2017 Session of the General Assembly (SB1027)**



Virginia's Medical Cannabis Program

2018: "Let Doctors Decide"

- **SB726, HB1251 (VA Code § 18.2-250.1)**
 - Provides that a practitioner may issue a written certification for the use of **cannabidiol oil** or **THC-A oil** for the treatment or to alleviate the symptoms of **any diagnosed condition or disease** determined by the practitioner (MD/DO) to benefit from such use.

*****This bill was a recommendation of the Joint Commission on Health Care***

- **SB330**
 - Practitioner who issues a written certification for **CBD oil** or **THC-A oil** must check the VPMP to see what other covered substances the patient is prescribed



Virginia's Medical Cannabis Program

2019

- **SB1557**
 - Authorizes PAs and NPs to issue a written certifications
- **HB1826**
 - Makes it a misdemeanor to advertise the sale or distribution of marijuana in the Commonwealth without a PP permit
- **SB1719**
 - Authorizes designation of BOP “registered agents” for the purposes of receiving cannabidiol oil or THC-A oil pursuant to a valid written certification.



Virginia's Medical Cannabis Program

Practitioner Protocol – pre-certification

- Register with Board of Pharmacy (\$50/year)
- Conduct an in-person assessment and evaluation of the patient;
- Diagnose the patient;
- Be of the opinion that the potential benefits would likely outweigh the health risks
- Explain proper administration and the potential risks and benefits prior to issuing the written certification;
- Ensure you have not exceed the 600-patient cap



Virginia's Medical Cannabis Program

Practitioner Protocol – pre-certification

- Access the Virginia Prescription Monitoring Program for the purpose of determining which, if any, covered substances have been dispensed to the patient.
- No Telemedicine for at least one year
- No delegation of diagnosis or certification
- Provide instructions for the use of cannabidiol oil or THC-A oil to the patient **and securely transmit such instructions to the permitted pharmaceutical processor****



Virginia's Medical Cannabis Program

Practitioner Protocol – post-certification

- Be available or ensure that another practitioner is available to provide follow-up care and treatment to determine the efficacy
- Comply with generally accepted standards of medical practice
- Maintain medical records for all patients for whom the practitioner has issued a certification in accordance with 18VAC85-20-26



Virginia's Medical Cannabis Program

Practitioner Protocol – post-certification

- Report to the BOP the death of a registered patient or a change in status involving a registered patient for whom the practitioner has issued a certification if such change affects the patient's continued eligibility to use cannabidiol oil or THC-A oil, or the practitioner's inability to continue treating the patient



Virginia's Medical Cannabis Program

Practitioner Prohibitions

- Financial relationships with a pharmaceutical processor or product vendor
- Examining a qualifying patient for purposes of diagnosing at a location where cannabidiol oil or THC-A oil is dispensed or produced; or
- Directly or indirectly benefitting from a patient obtaining a certification (does not bar charging for visit)
- Issuing a certification for himself or for family members, employees, or coworkers



Ethics, Malpractice, and other Provider Concerns

•Patient
Safety

Federal
enforcement

State
enforcement

Joint
Commission

Malpractice
Risk

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Ethics, Malpractice, and other Provider Concerns

Patient Safety

- Lack of clinical data on efficacy
 - Hard for U.S.-based research because of Schedule I status
- Lack of specificity of form, contents, dosage, mode of delivery, and type cannot be specified, as they would be in a typical drug prescription
 - The type of marijuana and mode of delivery is determined by the recommendations of pharmacists in Virginia
- Lack of strict standards for cultivation, manufacturing (e.g. risk of adulteration by pesticides, molds, and other contaminants)

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Ethics, Malpractice, and other Provider Concerns

Federal Enforcement

- Generally not permitted if practitioner in compliance with State medical cannabis program (First Amendment Protections)
- No funding available for federal investigation or prosecution (Rohrbacher-Farr)



Ethics, Malpractice, and other Provider Concerns

State Law and Licensure Risk

- Unanimous passage of legislation (including physician as chief patron)
- Regulating body is BOP (under DHP)
- Support from Medical Society of Virginia and other reputable orgs

AAP	AMA
AAFP	ACS
NEJM	NMSS
APHA	L&LS....
APhA	



Ethics, Malpractice, and other Provider Concerns

Joint Commission Standard MM.03.01.05

“The hospital safely controls medications brought into the hospital by patients, their families, or licensed independent practitioners.”

- Define when can medications brought into the hospital can be administered
- Identify and visually evaluate medication integrity before use/administration
- Inform “prescriber” and patient when medication is not permitted



Ethics, Malpractice, and other Provider Concerns

Malpractice Risk and Coverage

- Contraindications and Adverse Patient Outcomes
- “Negligent Referral”
- Practitioner education and training
- Informed Consent (benefits vs. risks)
- Standard of Care and “Acceding to patient demands”
- FDA Compassionate Use (Expanded Access) Policy
- Clear and consistent guidelines for recommendations



Ethics, Malpractice, and other Provider Concerns

Malpractice Risk and Coverage

- Establishment of a practitioner-patient relationship
- Ongoing treatment relationship (monitoring)
- Follow any changes in State/Federal law
- No “touching the plant”
- Procedures for cannabis brought on-site by patients and employees
- Check your carrier’s liability policy language (“non-FDA approved medications”)



Ethics, Malpractice, and other Provider Concerns

Malpractice Risk and Coverage

Look to other “mature” states for guidance...

- CA Medical Board – Physician Guidance
- WA Health Care Association – Template Hospital Policy

NEXT: Drug Free Workplace and Employment Policies
Andrew Sherrod, Hirschler Fleischer, P.C.



Questions?

Rebecca E. Gwilt

Partner, Nixon Law Group

757.846.4936

rebecca.gwilt@nixonlawgroup.com

