

# Medical Marijuana and Health Care Providers

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& BYRON, P.A.

# Current Federal Law

- Marijuana/Cannabis remains classified as Schedule I drug
  - No currently accepted medical use
  - Cannot prescribe
  - High potential for abuse
  - Other schedule I drugs include LSD and heroin
- Manufacture, sale, distribution and use of medical marijuana violate CSA
- CBD (cannabidiol) now federally legal

# Current State Law

- California legalized medical marijuana in 1996
- 23 states have partial (medical) legalization
- Full legalization: Alaska, Oregon, Colorado, California, Nevada, Maine, Massachusetts, Michigan, Washington, Washington, D.C., Vermont (first legislative legalization)
- 33 states + D.C. have partial or full legalization

# The Ogden Memo (October 2009)

- Prosecutors “should not focus federal resources in [their] States on individuals whose actions are in clear and unambiguous compliance with existing state laws providing for the medical use of marijuana.”
- Prosecuting “individuals with cancer or other serious illnesses who use marijuana as part of a recommended treatment regimen,” or “caregivers” is not an efficient use of resources
- Listed several commercial enterprise “characteristics” that may trigger prosecution, including sales to minors, evidence of money laundering or other illegal activities

# The Cole Memo (June 2011)

- “Persons who are in the business of cultivating, selling, or distributing marijuana, and those who knowingly facilitate such activities, are in violation of the Controlled Substances Act, regardless of state law.”
- “Those who engage in transactions involving the proceeds of [large-scale cultivation and distribution] may also be in violation of federal money laundering statutes and other federal financial laws.”

# Cole II (August 2013)

- “Prosecutors should not consider the size or commercial nature of a marijuana operation alone as a proxy for assessing whether marijuana trafficking implicates the Department’s enforcement priorities...”

# Cole II (August 2013)

- New statement of federal prosecution priorities:
  - Distribution to minors
  - Criminal enterprises, gangs, and cartels
  - Diversion of marijuana to other states
  - Trafficking of other illegal drugs or other illegal activity
  - Violence and the use of firearms
  - Drugged driving and other adverse public health consequences
  - Preventing the growing of marijuana on public lands
  - Preventing marijuana possession or use on federal property

# Treasury Guidance (February 2014)

- Banks have responsibility to report suspicious or illegal activity via a “Suspicious Activity Report”
- Creates specific SAR filings for marijuana businesses: Limited, Priority, Termination
- Identifies “Red Flags”
- Suggests ways to stay out of hot water – due diligence responsibilities for financial institutions



# Treasury Guidance

- Stated goal of aiding in development of legal medical marijuana businesses
  - “So, from our perspective **the guidance is having the intended effect. It is facilitating access to financial services**, while ensuring that this activity is transparent and the funds are going into regulated financial institutions.”

Jennifer Shasky Calvery, Director of Treasury Department  
Financial Crimes Enforcement Network, August 12, 2014

# Sessions Memo (Jan. 2018)

- “Marijuana is a dangerous drug, and marijuana activity is a serious crime.”
- “Previous nationwide guidance specific to marijuana enforcement is unnecessary and is rescinded, effective immediately.”
  - Ogden Memo
  - Cole I
  - Cole II

# Federal Legislation

- VA clinical trial/research legislation
- Expanded research legislation (Repub.)
- Rescheduling legislation (Repub.)
- Rescheduling legislation (Dem.) – BATMF
- CAREERS Act (state safe harbor)
- Restore Cole II Memo
- SAFE Banking Bill (cleared committee)

# Rohrbacher-Blumenauer Amendment

- Enacted in 2014, repeatedly renewed
- Prohibits expenditure of funds on DOJ enforcement against state legal operations
- *Marin Alliance* (precluding DOJ enforcement of injunction)
- *Medpoint Management* (DOJ can use Asset Forfeiture Fund for forfeiture actions)

# State Legislation

- New Hampshire – full legalization approved by house and senate (gov. intends to veto)
- Several other states potentially legalizing in 2019 – New Jersey, Connecticut, Illinois, New York, Delaware, Rhode Island
- Overall trend continues to be decriminalization, increased access, more sophisticated regulation

# Minnesota

- Minnesota – referred to HHS committee in House, killed in Senate, Walz supports
- Additional qualifying conditions: autism, obstructive sleep apnea, Alzheimer's Disease, PTSD, intractable pain

# 2018 Farm Bill

- Legalized hemp
- 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
- Explicitly preserved FDA's authority to regulate products containing cannabis or cannabis-derived compounds

# Big Business

- Legal cannabis revenue = ~\$10 billion
- 211,000 directly employed
- Business partnerships/acquisitions:
  - Constellation Brands/Canopy, Altria/Cronos, Coca-Cola/Aurora



# Big Business

- Pharma:
  - GW Pharmaceuticals, Avicanna, Cardiol
- Ancillary businesses:
  - Accounting, greenhouse/ag supplies, security, chemistry/lab equipment
- Investment activity:
  - Dozens of marijuana stocks with market cap + \$200 million

# Litigation

- Securities class action litigation (*Cronos, Medmen*)
- Product liability litigation (*Kirk, Flores*)
- Insurance litigation (*KVG*)
- Bankruptcy litigation (*Gavin*)
- Environmental litigation (*Trinity Action Assoc.*)
- Business Litigation (*Greensun*)
- Employment litigation

# Regulatory Thicket

- Manufacturer licenses
- Distribution licenses
- Waste management
- Financial regulations
- Permitting
- Tax regulations
- Advertising regulations

# FDA

- In 2018 approved first CBD based anti-epileptic drug
- Has issued warning letters for therapeutic claims about CBD
- “Botanical Drug Development” guidance applies to cannabis-related medicines

# FDA

- 3 cannabis-related drugs have been approved:
  - Epidiolex (CBD)
  - Marinol (synthetic THC)
  - Syndros (synthetic THC)

# FDA

- “FDA treats products containing cannabis or cannabis-derived compounds as it does any other FDA-regulated products – meaning they’re subject to the same authorities and requirements as FDA-regulated products containing any other substance.”

# FDA

- “The agency is committed to protecting the public health while also taking steps to improve the efficiency of regulatory pathways for the lawful marketing of appropriate cannabis and cannabis-derived products.”
- FDA hearing May 31, 2019 on FDA’s role in cannabis regulation – 526 comments thus far

# CMS

- Essentially silent (4 search results on CMS.Gov)
- Medicare condition of participation is compliance with all applicable federal laws
  - “...drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with federal and state law” – refers only to Schedule 2-5 substances



# CMS

- In a 2009 email to the California Association of Health Facilities, CMS stated:
  - “Section 1819(d)(4) of the Social Security Act (42 U.S.C. 1395i-e(d)(4)) provides that ‘[a] skilled nursing facility must operate and provide services in compliance with all applicable Federal, State, and local laws and regulations’...we conclude that federal law prohibits a [skilled nursing facility] from dispensing medical marijuana.”

# Physician Issues

- DEA prescribing license at risk – prohibits physician from prescribing or administering Schedule I substance

# Physician Issues

- Conant v. Walters (9th Cir. 2002)
  - Upheld permanent injunction against license revocation
  - First Amendment right to discuss medical marijuana with patients
  - However:
    - “A doctor would aid and abet by acting with the specific intent to provide a patient with the means to acquire marijuana. Similarly, a conspiracy would require that a doctor have knowledge that a patient intends to acquire marijuana, agree to help the patient acquire marijuana, and intend to help the patient acquire marijuana.”

# Physician Issues

- Nevada AG Opinion (2015):
  - “A licensee of the Board violates the CSA by becoming a shareholder, owner, investor, officer, employee or managing member of a medical marijuana dispensary or establishment.”

# Physician Issues

- Massachusetts Board v. Cushing (2017):
  - Standard of Care for physicians in certifying medical marijuana patients
    - Quality of legal v. illegal marijuana
    - Patient already smoking
    - Risks of buying illegal marijuana
    - Should physician have recommended edibles?
    - Marinol approval

# Professional Associations

- AMA (supports “free and unfettered exchange of information on treatment alternatives”)
- APhA (supports pharmacist involvement where permitted by state law)
- AAOHN/ACOEM (recommends policy to guide decisions on marijuana use distributed to all workers)

# WHCA Template Policy

- Supportive of use
- Provides patient requirements
  - Documented qualifying condition
  - Non-staff provider
  - Edibles only

# MHA Template Policies

- Several options (no use, unsupervised use, supervised use):
  - Patient access
  - Documentation
  - Storage
  - Administration



# Cannabis and Employment

- Most states offer limited or no employment protection
  - A handful offer protection for medical cannabis
- Legal and lawful? You can still get terminated.
  - *Coates v. Dish Network-Colorado*

# Cannabis and Employment

- Trend toward protecting medical cannabis in court decisions
- Unique factors related to healthcare providers
  - Safety
  - Federal grant compliance

# Drug-Free Workplace Act

- Federal contractors/grantees
- Must make “good faith” effort to maintain drug free workplace where controlled substances are not distributed, dispensed, possessed or used
- Courts are mixed:
  - *Barbuto* (Mass.)
  - *Carlson* (D. Mont.)
  - *Smith* (N.M. Dist. Ct.)
  - *Washburn* (Or. Ct. App.)

# Other Issues

- Advertising regulations
- Are medical marijuana dispensaries “covered entities” under HIPAA?
- MDS/RAI
- Transport of medication
- “Immaculate Conception” problems
- Insurance coverage

# State and Federal Trends

- Efforts to re-schedule cannabis
- Efforts to de-fund or discourage prosecution of lawful medical marijuana businesses
- Increased number of states with medical marijuana

# State and Federal Trends

- Increased access in states that already have medical marijuana
- Increased number of states with full legalization
- Business expansion

# Contact Information



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