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MERITAS CAPABILITY WEBINAR

LEGAL CANNABIS AND THE HEALTH CARE INDUSTRY

November 7, 2019
1:00 PM U.S. CST

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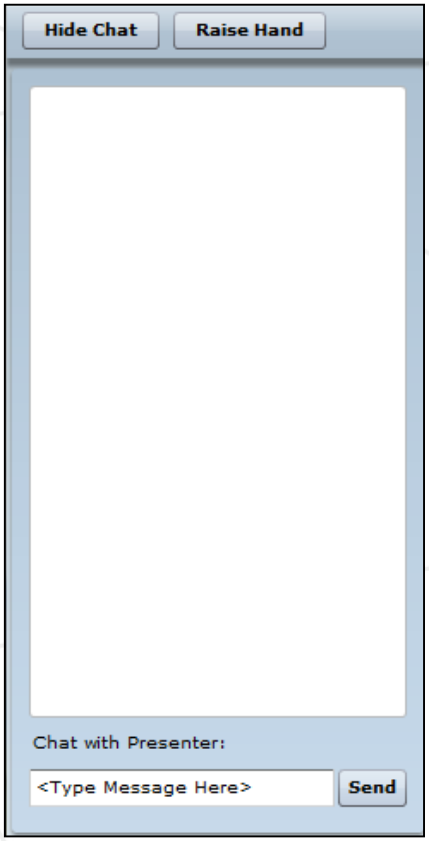

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NORRIS McLAUGHLIN | P.A.

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Legal Cannabis and the Health Care Industry

Integrating Medical Cannabis Into a Medical Practice

Svetlana (Lana) Ros, Esq.

Acceptance of Medical Marijuana

- Increasing accessibility – 33 States and DC
  - Example: New Jersey Expansion
    - Increase of Qualifying Conditions
    - Added Providers
    - Increase duration for marijuana authorization
- Standard of Care???
  - No CME requirement
  - Lack of disciplinary actions
  - Lack of malpractice cases
  - Developing area

Things to Consider

- Professional Liability Insurance
- Position of the hospitals where privileges are held.
- Position of employer.
- Implementation of written policies.
- Use of treatment agreement plan with patient.
- Know the State regulations.
- Stay CURRENT with the States requirements and position.
- Will history repeat itself?
- Proceed with CAUTION.

FSMB – Model Guidelines

- Physician-Patient Relationship
- Patient Evaluation
- Informed Decision by the Patient
- Treatment Plan
- Qualifying Condition
- Ongoing Monitoring
- Consultation and Referrals
- DOCUMENT!

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Questions

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A Meritas Webinar: Legal Cannabis and the Health Care Industry

Part II: "Up in Smoke" – When Medical Cannabis Meets the Great American Melting Pot

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Three Regulatory Approaches to Launching A Medical Cannabis Industry (DC, MD, VA)

Medical Cannabis Public Policy: A murky gumbo born at the intersection of medicine, economics, politics and the law:

- Selective Competition model (limitations on # of providers by category, highly selective criteria for subjective ranking of qualified provider license applications)
- Free market model(encourages large vertically integrated providers, objective supply-demand licensing standards, some ethical limitations on ownership)
- Economic Inclusion market model (politically influenced geographic distribution of licenses, intentional industry diversification with economic inclusion principles, limitations on ownership / vertical integration)

Key Licensing & Regulatory Criteria: Growers, Processors, Dispensaries, Physicians, and Patients

- Maryland
- Washington, DC
- Virginia

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Licensing Eligibility and Restrictions: **Growers**

	Maryland	Washington, DC	Virginia
Factors Considered: Operational, Safety and Security, Commercial horticultural or agricultural, production control, business and economic, additional factors (diversity plan, diverse ownership)	✓		
May only apply with interest in (1) grower application	✓		
Submit financial, personal and background information relevant to applicant's capacity to manage growing facility	✓	✓	
Must disclose investors with 5% or more interest	✓		
Less than 5% interest in license transferable w/o Commission involvement	✓		
May deny application if licensee is convicted of or pleads nolo contendre to crime of moral turpitude, in arrears on taxes, and/or fraudulently attempts to obtain license (some or all)	✓	✓	
Limitations on maximum number of licenses to be issued	✓ (15)	✓(2)	✓ (5)
Limitations on maximum number of licenses to be held by a single applicant entity or entity owner;	✓		
Requirements for vertical integration across different license types (e.g., a licensed dispensary must be formally affiliated with a licensed grower);			✓
Prohibitions against vertical integration of licensees of various types of licenses (e.g., qualified physician may not own interest in grower or dispensary; a licensed processor and its owners may not own an interest in a grower, or vice versa);	✓	✓	
Ranking of qualified license applicants based upon strength of application for purposes of issuance of provisional licenses	✓	✓	
Evaluation points assigned to each criteria for ranking purposes	✓	✓	
Objective standards for minimal qualifications for the award of licenses	✓	✓	

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Licensing Eligibility and Restrictions: **Processors**

	Maryland	Washington, DC	Virginia
May deny application if licensee is convicted of or pleads nolo contendre to crime of moral turpitude, in arrears on taxes, and/or fraudulently attempts to obtain license	✓	✓	✓
Submit to background checks	✓	✓	✓
5% interest or more in license is not transferable w/o Commission involvement	✓		
Disclose experience with operation of laboratory, pharmaceutical manufacturing, and management of consumer products	✓		
Must disclose investors with 5% or more interest	✓		
Limitations on maximum number of licenses to be issued	✓ (28)	✓ (10)	✓ (5)
Limitations on maximum number of licenses to be held by a single applicant entity or entity owner;	✓		
Requirements for vertical integration across different license types (e.g., a licensed dispensary must be formally affiliated with a licensed grower); "Pharmaceutical Processors (VA)"			✓
Prohibitions against vertical integration of licensees of various types of licenses (e.g., qualified physician may not own interest in grower or dispensary; a licensed processor and its owners may not own an interest in a grower, or vice versa);	✓	✓	
Ranking of qualified license applicants based upon strength of application for purposes of issuance of provisional licenses	✓	✓	
Evaluation points assigned to each criteria for ranking purposes	✓	✓	
Objective standards for minimal qualifications for the award of licenses	✓	✓	

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Licensing Eligibility and Restrictions:

	Maryland	Washington, DC	Virginia
Factors Considered: Operational, Safety and Security, medical cannabis professionalism, retail management, business and economic, additional factors (diversity plan, diverse ownership)	✓		
**Submit to background check	✓	✓	✓
**May deny application if licensee is convicted of or pleads nolo contendre to crime of moral turpitude, in arrears on taxes, and/or fraudulently attempts to obtain license	✓		✓
Must disclose investors with 5% or more interest	✓		
Limitations on maximum number of licenses to be issued	✓ (2 per Senatorial district)	✓ (7)	✓ (5)
Limitations on maximum number of licenses to be held by a single applicant entity or entity owner;	✓		
Requirements for vertical integration across different license types (e.g., a licensed dispensary must be formally affiliated with a licensed grower);			✓
Prohibitions against vertical integration of licensees of various types of licenses (e.g., qualified physician may not own interest in grower or dispensary; a licensed processor and its owners may not own an interest in a grower, or vice versa);	✓	✓	
Ranking of qualified license applicants based upon strength of application for purposes of issuance of provisional licenses	✓	✓	
Evaluation points assigned to each criteria for ranking purposes	✓	✓	
Objective standards for minimal qualifications for the award of licenses	✓	✓	

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*Prescription** of Medical Cannabis*: **Physicians**

	Maryland	Washington, DC	Virginia
Physician must have an active/unrestricted license to practice medicine in the state, be in good standing with the Board of Physicians, and registered to prescribe controlled substances	✓	✓	✓
Bona fide Physician-Patient Relationship	✓	✓	✓
**Certifying providers restricted from accepting compensation from grower, processor, dispensary, or other physicians (certain exceptions apply)	✓	✓	✓

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Purchase of Medical Cannabis: **Patients**

	Maryland	Washington, DC	Virginia
"Qualifying Patients" may purchase (requires registration with Commission and meets certain inclusion criteria)	✓	✓	✓
Qualifying Patient must apply for a Patient ID Card/Register for a Written Certification	✓	✓	✓
Availability of edible products	✓		
**Patient must select dispensary to be provided on registration card		✓	
Minors may qualify as patients with parent or legal guardian consent		✓	

Key Differences: Regulatory Approaches to Launching Medical Cannabis Industry (DC, MD, VA)

A Summary of Key Restrictions on Ownership:

1. Limitations on single firm ownership of multiple licenses (e.g., no more than 1 grower license in MD);
2. Prohibition against physician acceptance of compensation from licensees (DC, MD, and VA)
3. Limits on maximum # of grower licenses issued - DC (2); MD (15); VA (5)

Key Differences: Regulatory Approaches to Launching Medical Cannabis Industry (DC, MD, VA)

Contrasts in Key Ownership Criteria & Limitations:

4. Limits on maximum # of processor licenses issued - DC (10); MD (28); and VA (5)
5. Limits on maximum # of dispensary licenses issued – DC (7); MD (2 per senatorial district - 94); and VA (5)
6. Licensed dispensaries must be formally affiliated with a licensed grower – VA
7. Prohibitions against vertical integration of various types of licenses – DC and MD

Key Differences: Regulatory Approaches to Launching Medical Cannabis Industry (DC, MD, VA)

Contrasts in Key Ownership Criteria & Limitations:

8. Criminal background checks affect eligibility for industry employment and licensed ownership (DC, MD, & VA)

Public Policy Considerations That Favor Economic Inclusion Market Model for Medical Cannabis

1. U.S. medical cannabis sales projected at $15 billion by 2025, with legalized marijuana sales approaching $22.5 billion; MD medical cannabis sales are doubling every year since 2015, currently at $220 million for 2019 and struggling to keep up with demand.
2. DC, MD, and VA all preclude participation in this emerging industry by persons that have been convicted for possession or distribution of marijuana.
3. In 2018, NERA reported significant racial disparities in African American wage and salary earnings, business owner earnings, and business formation within MD and ad related to the NAICS codes associated with all three medical cannabis license types.

Public Policy Considerations for the Economic Inclusion Market Model for Medical Cannabis

4. The national marijuana possession arrest rate in 2010 was 256 per 100,000. The jurisdictions with the highest marijuana possession arrest rates per 100,000 were the **District of Columbia (846, which is 3.3 times greater than the national rate)**, New York (535, which is more than double the national rate), Nebraska (417), **Maryland (409),** and Illinois (389).

Public Policy Considerations for the Economic Inclusion Market Model for Medical Cannabis

5. The ACLU reported that in 2010:

   - African Americans comprised 51% of the population of **Washington, DC**, yet accounted for nearly 91% of the arrests for marijuana possession.

   - African Americans comprised 30% of the population of **Maryland,** yet accounted for nearly 58% of the arrests for marijuana possession.

   - African Americans comprised nearly 20% of the population of **Virginia**, yet accounted for over 43% of the arrests for marijuana possession.

Source: The War on Marijuana in Black and White (ACLU 2013)

Public Policy Considerations for the Economic Inclusion Market Model for Medical Cannabis

6. The Maryland Medical Cannabis Commission's first round for the issuance of grower licenses, processor licenses, and dispensary licenses resulted in the near total exclusion of African American license applicants from the emerging medical cannabis industry in Maryland. Possible factors included:
    - ❑ Insufficient outreach to small, local, M/WBE firms.
    - ❑ Key selective ranking criteria used were impacted by ongoing effects of marketplace discrimination (criminal background checks, unequal access to capital, unequal ownership of farmland (Pigford v. USDA)
    - ❑ Bias in favor of most well-capitalized, larger, more experienced firms by selection panel

Proposed Alternative Licensing Models: Promoting Competition and Maximizing Economic Inclusion of Small/Local/MBE Providers

- **Two-Stage Regulated License Application Process**
  - License eligibility of all applicants based upon satisfaction of objective minimal qualification standards.
  - Maximum number of licenses to be issued determined in accordance with objective qualifying patient / provider ratios by County; selection of qualified licensees thru random lottery replaces subjective rankings of "most" qualified.

OR

  - 25% of each category of licenses reserved for minimally qualified applicants that are also certified as Small Local Business Enterprises (no subjective rankings) / selection by random lottery.

Proposed Alternative Licensing Models: Promoting Competition and Maximizing Economic Inclusion of Small/Local/MBE Providers

- **Evaluation Preferences for S/L/MBEs in Competitive Ranking Process ("Strict Scrutiny" Factual Predicate Required)****
  - License eligibility of all applicants based upon satisfaction of objective minimal qualification standards.
  - Maximum number of licenses to be issued determined in accordance with objective qualifying patient / provider ratios by County; selection of qualified licensees thru rankings of "most" qualified.

However:

  - Up to 10 or 15% of all evaluation points used in competitive ranking process are reserved for applicants that are certified as small and local businesses that are at least 51% owned and controlled by minorities or women.

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Any Questions?

Send a chat message
or
flee@tydingslaw.com

parker hudson

Legal Cannabis and the Health Care Industry

Licensing and Market Restrictions
for Medical Marijuana Providers;
similarities to Certificate of Need

Seann M. Frazier

Legal Cannabis and Health Care Law

- On the federal level, cannabis remains illegal
- "The Marihuana Act of 1937" prohibited the recreational, industrial and therapeutic use of marijuana.
- The Controlled Substances Act of 1970 identified marijuana and derived cannabinoids as a Schedule 1 drug

Legal Cannabis and Health Care Law

- The Controlled Substances Act of 1970 equated cannabis with heroin and other Schedule 1 drugs, finding that marijuana has a high potential for abuse, and lacked an accepted medical use

- In 2009, the federal Department of Justice issued the "Cole Memorandum" that:
  - Confirmed that marijuana remained illegal under federal law; but
  - Directed U.S. Attorneys to use their resources prudently, employing discretion before prosecuting users of medical marijuana acting in compliance with state laws
- The Cole Memo provided some comfort to marijuana entrepreneurs seeking to establish businesses in states where marijuana was made legal

Legal Cannabis and Health Care Law

- In 2018, Attorney General Jeff Sessions issued a "Marijuana Enforcement" Memo, which:
  - emphasized that the Controlled Substances Act still prevented the cultivation, distribution and possession of marijuana, with serious criminal penalties
  - Directed prosecutors to follow well-established principles when deciding what crimes to prosecute, including federal law enforcement priorities set by the Atty. General
  - Rescinding guidance on prosecution offered by the Cole Memo

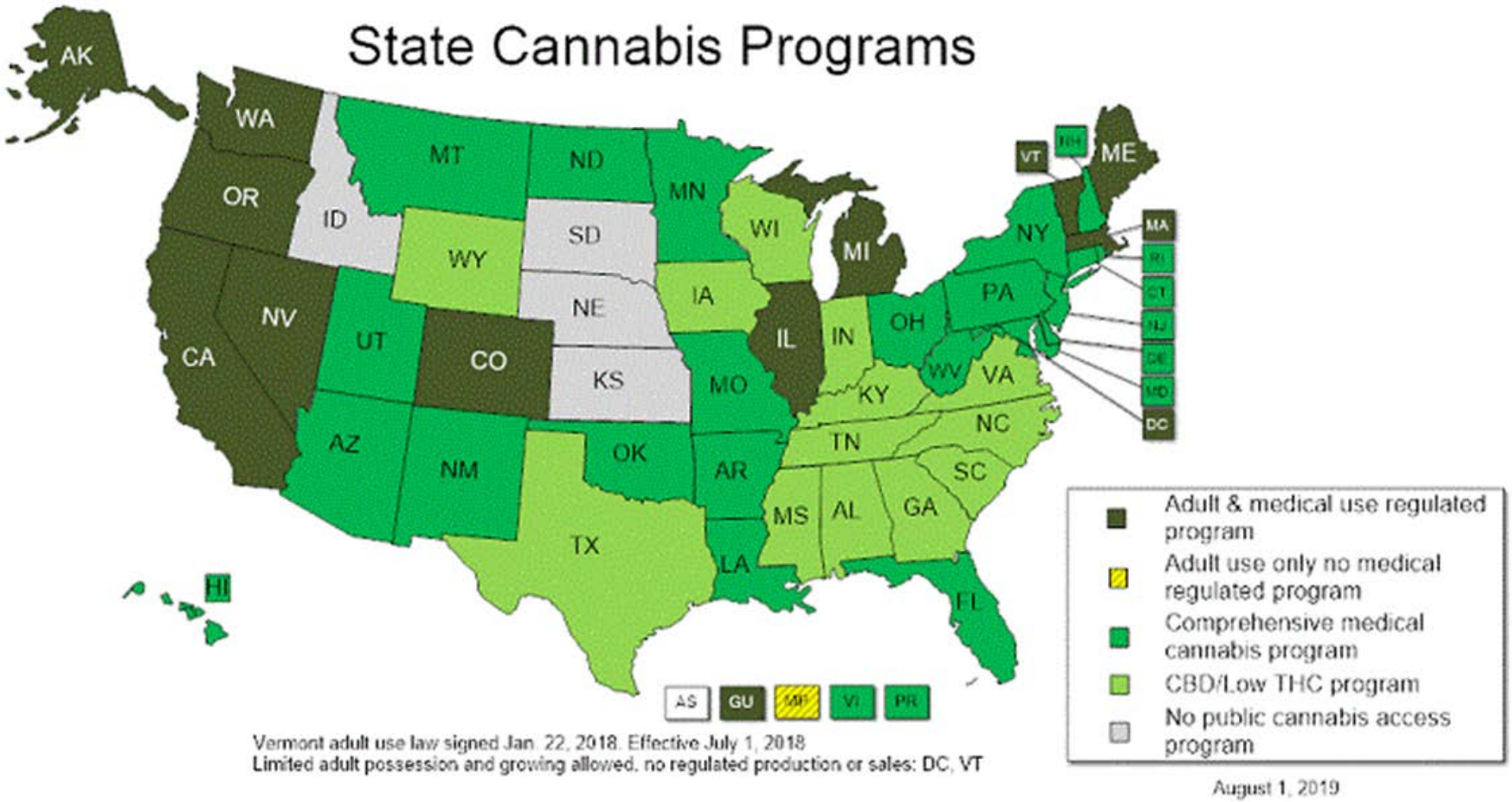
Legal Cannabis and Health Care Law

- In 2019, newly appointed Atty. Gen. William Barr testified before the U.S. Senate regarding enforcement priorities. Atty. Gen. Barr testified that:
  - He would personally prefer that federal and state laws regarding marijuana did not conflict, but that
  - the Office of the Attorney General would return to the Cole Memo for guidance
  - allowing individual U.S. Attorneys to determine the best approach in their state , while adding that he had not heard any complaints from the states that have legalized marijuana

Legal Cannabis and Health Care Law

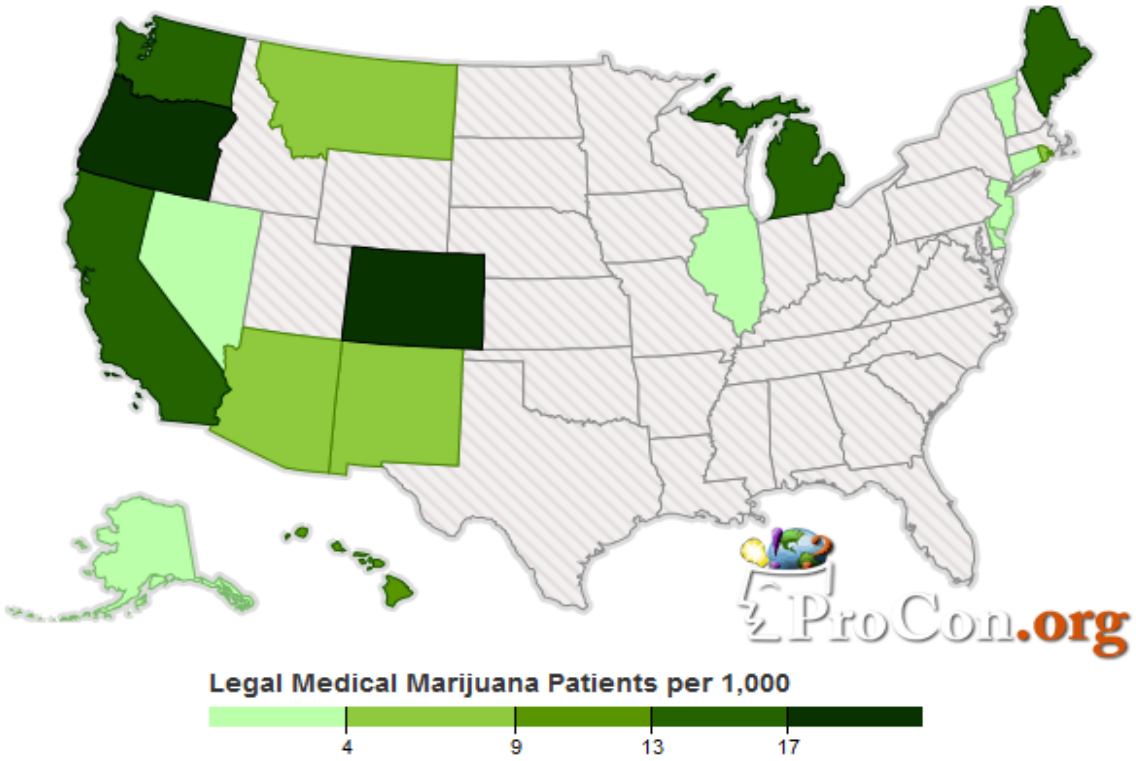
- Against this federal backdrop, some states introduced constitutional amendments and state laws that would allow for the use of medical marijuana, and in some states, recreational marijuana.
- According to the National Conference of State Legislatures, 33 states now allow some form of medical marijuana, and another 11 states allow for the legal use of cannabis by adults.

State Cannabis Programs



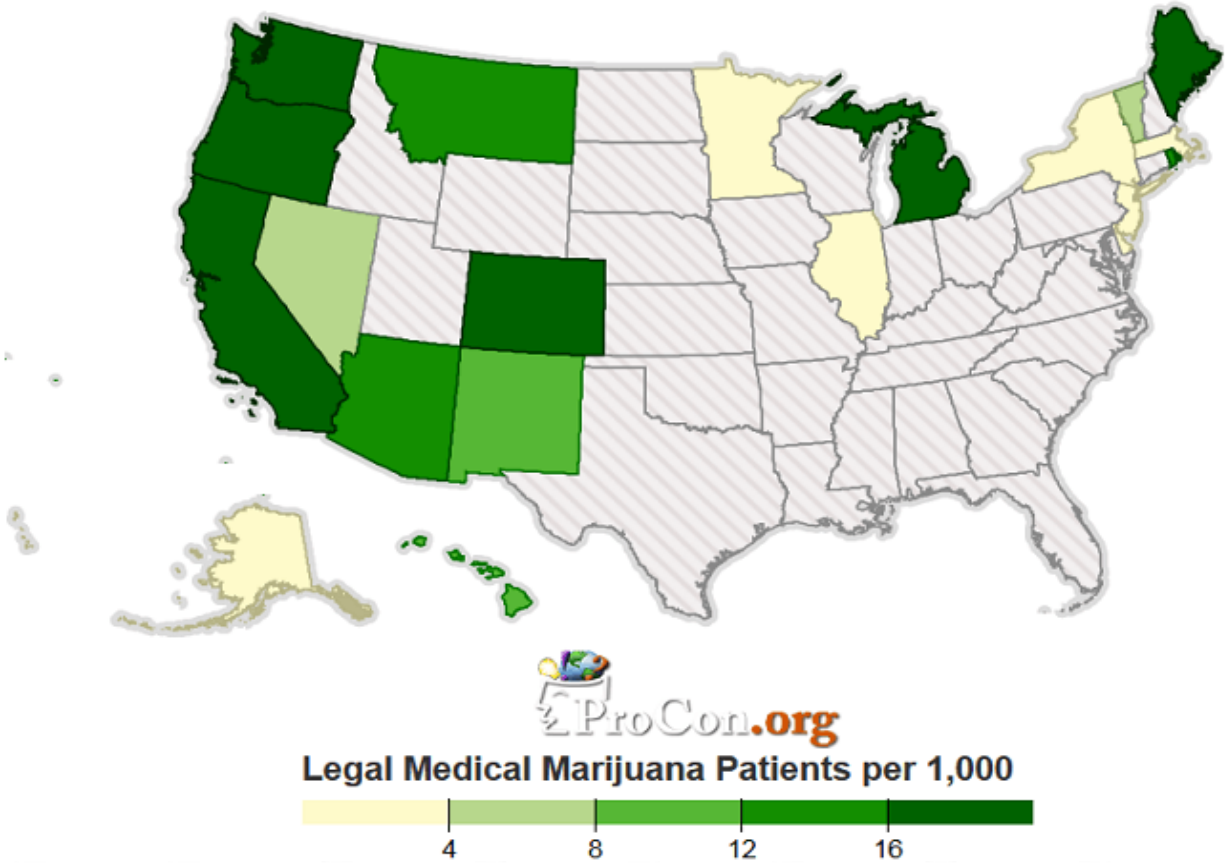
Legal Cannabis and Health Care Law

2014 No. of Medical Marijuana Patients



Legal Cannabis and Health Care Law

2016 No. of Medical Marijuana Patients



Legal Cannabis and Health Care Law

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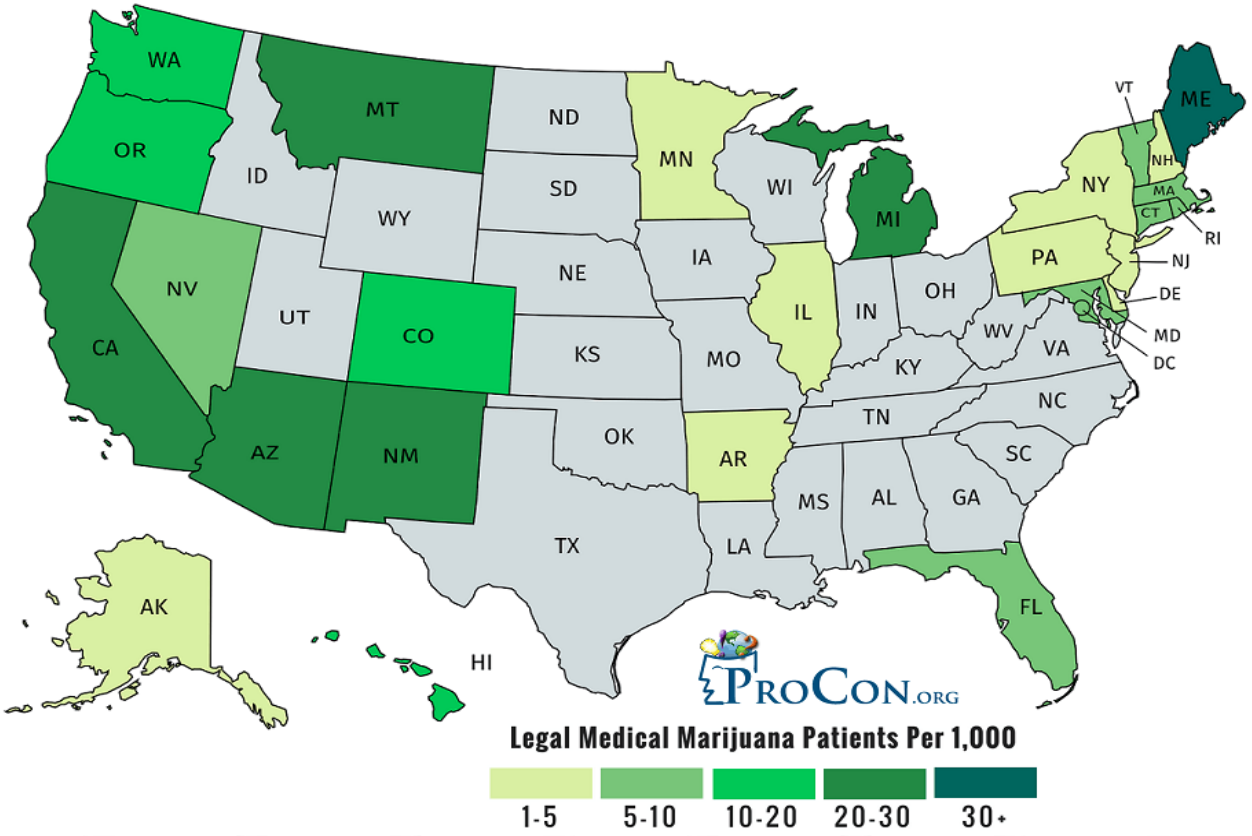
2018 No. of Medical Marijuana Patients



Legal Cannabis and Health Care Law

Differences among states have resulted in a wide variety of licensing requirements for marijuana cultivators, distributors and retailers

- Some states require vertical integration, so-called "seed-to-sale" delivery
- Other states allow for a horizontal platform, where growers, distributors and retailers are separately licensed

Legal Cannabis and Health Care Law

Examples of State Regulatory Programs

- California

The Medicinal and Adult-Use Cannabis Regulation and Safety Act (MAUCRSA) separately licenses

  - Cultivation Sites
  - Manufacturers
  - Testing Laboratories
  - Distributors and
  - Retailers and Microbusinesses

Only cultivation sites may grow, and only retailers and microbusinesses may sell marijuana, etc.

Legal Cannabis and Health Care Law

Examples of State Regulatory Programs

- California

As a result of limited market restrictions

- In 2018, California has 10,940 active licenses
  - Though only a few dozen were annual licenses, as opposed to temporary

Examples of State Regulatory Programs

- **California**

However, California laws do include some market restrictions, MAUCRSA:

- Makes it unlawful for any person to monopolize the commerce related to cannabis
- Authorizes regulators to deny license approval or renewal if excessive concentration exists
  - Ratio of licenses to population in the census tract exceeds the ratio of licenses to population in the county (unless denial would limit development of legal market)
  - Ratio of retail or microbusiness licenses exceeds local ordinance requirements

Legal Cannabis and Health Care Law

Examples of State Regulatory Programs

- **Florida**
- Requires Vertical Integration, "seed-to-sale" marijuana providers
- Requires licensure of Medical Marijuana Treatment Centers that ensure reasonable statewide accessibility and availability of medical marijuana through MMTC's that
  - Cultivate
  - Process
  - Transport
  - Dispense

Examples of State Regulatory Programs

- **Florida**
- Limits the Number of MMTCs that may be authorized
  - Only 13 MMTCs are currently authorized to dispense
  - With 8 more licensees in development

Florida's Licensing Laws have been challenged as restricting "access" to medical marijuana required by a Florida Constitutional amendment.

Fla. Dep't of Health v. Florigrown. LLC, et al., __ So.3d __, 2019 WL 2943329 (Fla. 1st DCA 2019), pending review before the Florida Supreme Court, Case No. SC19-464

Legal Cannabis and Health Care Law

- Business Valuation Differences

Florida

  - In 2017, Florida MMTC (Chestnut Hill) sold to Canadian-backed firm for $40 million
  - In June 2018, MedMen purchased a Florida MMTC licensee (Treadwell) for $53 million
    - with 5 acre cultivation facility
    - License to Operate 25 dispensaries throughout the state
  - License Values tied more to market opportunity than to real estate and equipment values

Legal Cannabis and Health Care Law

- Business Valuation Differences

California

  - Fully Licensed Marijuana Manufacturer/Processor listed for sale at $650,000
  - Another Manufacturer and Distributor advertised for sale at $500,000
  - Business Values tied more to traditional business valuations criteria like asset value, existing market share and branding

Legal Cannabis and Health Care Law

- Competition for limited licenses raises questions regarding how states decide which licenses should be granted or denied
- Introduce comparative Review Principles
- Much like Certificate of Need Programs

Legal Cannabis and Health Care Law
Federal and State Certificate of Need Regulation

The Development of Federal and State Certificate of Need Programs

- Certificate of Need requirements first appeared as state laws.
  - The State of New York created the first certificate of need requirement in in 1964, in the Metcalf-McCloskey Act.
- By 1972, the U.S Government created the first federal certificate of need requirement, in Section 1122 of the Social Security Act of 1972.

Legal Cannabis and Health Care Law
Federal and State Certificate of Need Regulation

- Federal law required all states to implement their own version of certificate of need requirements before new health care facilities or programs could be developed
- The federal program imposed a duty on states to provide some sort of CON approval process, with only general standards to guide the details of those state programs
- The result was a great deal of variety of regulated services and regulatory processes

Legal Cannabis and Health Care Law
Federal and State Certificate of Need Regulation

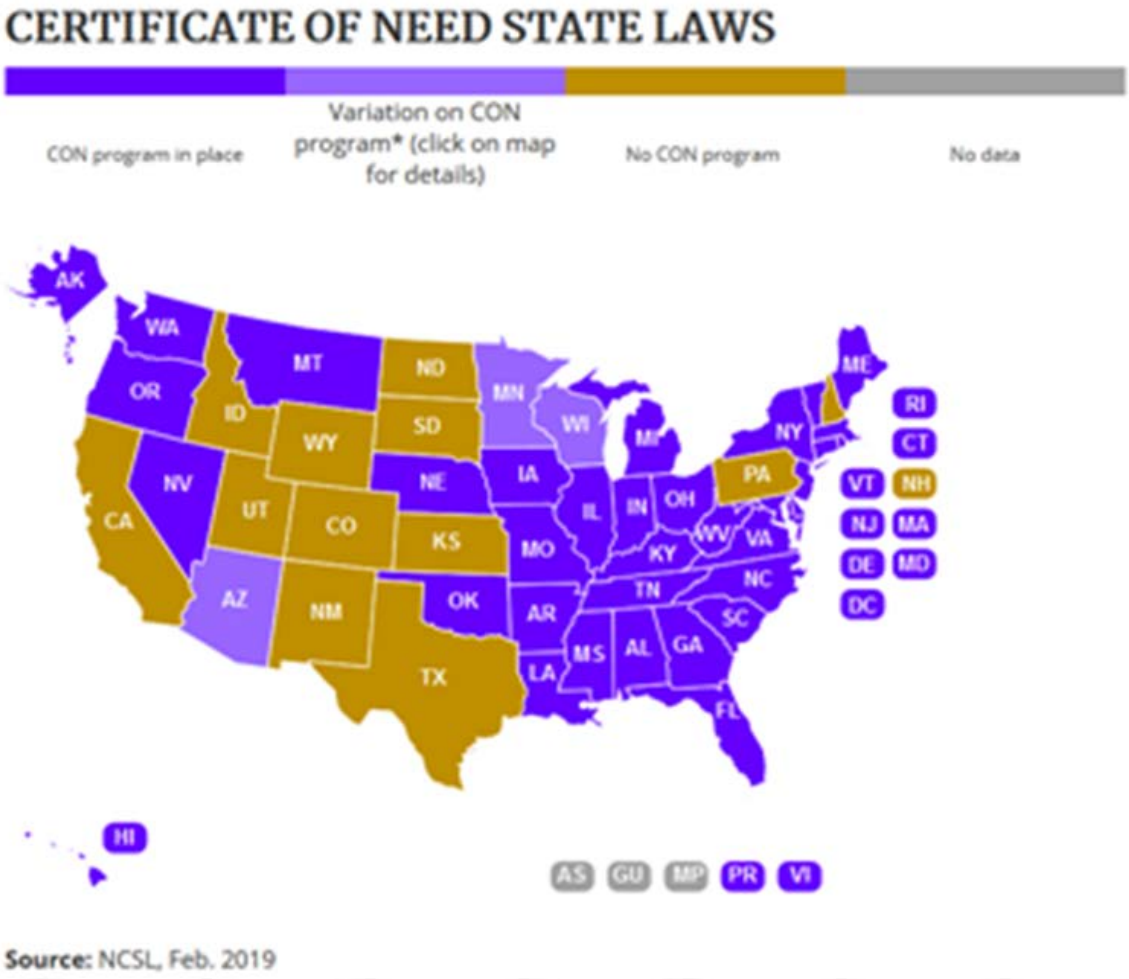
- The federal requirement for state certificate of need programs was repealed in 1983, slightly after new federal payment systems were implemented, and dis-incentivized over-utilization.

- Since the repeal of the federal requirement to employ state CON programs, the diversity of regulation has become even greater

Legal Cannabis and Health Care Law
Federal and State Certificate of Need Regulation

- Most states continued to regulate new health facilities and services through certificate of need programs.
- However, many states have elected to remove their CON requirement, or to greatly reduce the number of programs governed by the CON process.

Legal Cannabis and Health Care Law
Federal and State Certificate of Need Regulation



Legal Cannabis and Health Care Law
Federal and State Certificate of Need Regulation

- Because they restricted access to markets and limited the number of licenses that may be awarded, the CON award process often involved comparative review.
- This requirement for comparative review stems from the a due process requirements imposed by the courts.
- If only a limited number of licenses are to be awarded, then the competition for those limited prizes should be fair and open for all to compete. *Ashbacker Radio Corp. v. F.C.C.*, 326 U.S. 327 (1945).

Legal Cannabis and Health Care Law
Federal and State Certificate of Need Regulation

- Potential Framework for Federal Legislation and more Uniformity
- Hemp is a derivative of cannabis, and received the same treatment under federal law, as a banned Schedule I drug
- Regulation of Hemp travelled a circuitous course
  - Agricultural Act of 2014
    - Created an agricultural hemp pilot program allowing states to create program regulations
    - Left growers uncertain as to how federal authorities respond to state laws allowing production. DEA enforcement remained a threat

Legal Cannabis and Health Care Law
Federal and State Certificate of Need Regulation

- Potential Framework for Federal Legislation and more Uniformity
- Regulation of Hemp travelled a circuitous course
  - Agricultural Improvement Act of 2018 (2018 Farm Bill)
    - Defined Hemp as cannabis sativa with a delta-9 THC concentration of not more than 0.3% THC by dry weight
    - Removed hemp from list of Schedule I drugs in Controlled Substances Act
    - Sketched a federal regulatory program intended to approve individual state hemp licensing programs
  - On Oct. 31, 2019, USDA released interim final rule establishing Domestic Hemp Production Program
    - New rules are currently subject to comment
    - Early critics note that regulations may favor industrial farming of hemp

Legal Cannabis and Health Care Law
Federal and State Certificate of Need Regulation

Questions?

Thank you

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