Policy and Regulatory Considerations for Medical Cannabis Programs

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Brief Overview of CANNRA



- A national non-partisan, non-profit organization of cannabis regulators from more than 40 states and jurisdictions.
- Not an advocacy group; takes no formal position for or against cannabis legalization.
- Mission to equip policy makers with unbiased information from the front lines of cannabis legalization. To identify and share best practices that safeguard public health and safety and promote regulatory certainty for industry participants.
- Funded by member agencies.
- No industry or advocacy group membership or funding.
- An affiliate of the Council of State Governments (CSG).



www.cann-ra.org

Disclosures and Disclaimers

I do not have anything to disclose.

The findings and conclusions in this presentation are my own and do not necessarily represent an official position of CANNRA or of any of the state agencies with whom I work.

Agenda

- Current Regulatory Context
- Policy and Regulatory Considerations for Medical Programs
 - Market architecture
 - Policies to protect consumer (and patient) safety
 - Ways to distribute products to patients
- Potential Overlaps with Hemp
- Conclusions

Evolving context for cannabis legalization

- Broader focus than Cole Memo era
- Increased focus on:
 - Social equity and restorative justice
 - Public health and consumer safety
 - Overlap between hemp, medical, and adult use cannabis



U.S. Department of Justice

THE DENVER POST

Despite legalization, people of color still disproportionately targeted for marijuana, new studies say Researchers analyzed different sets of police data and found people of color were more likely to be searched and arrested



Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products

The Washington Post

Democracy Dies in Darkness

As more states legalize marijuana, more children accidentally ingest **THC-laced edibles**

Three key considerations for medical cannabis programs

- Market architecture
 - License types and structures
 - Who regulates and regulatory resources
- Policies to protect consumer safety
 - Product type
 - What is allowed to be in products
 - Product testing
 - Packaging and labeling
 - Product oversight
- Ways to distribute products to patients (who, where, how)

\rightarrow Policies for Medical Cannabis set the course for non-medical policies



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Market architecture



Consumer Safety

Product Types and Forms



Product ingredients

- Diluents and excipients
- Terpenes (cannabis-derived, botanical, synthetic)
- Quantity of additives in products
- →Full ingredient disclosure
- →GRAS requirements (for foods)
- \rightarrow FDA inactive ingredient list (for drugs)

Product testing

- Testing infrastructure
 - State reference/quality assurance lab
- Analyte testing
 - What are you testing for?
- Testing protocols
 - When and how are you testing?



Testing Accuracy and Issues

| FiveThirtyEight | a abonews |
|---|-----------|
| Politics Sports Science Podcasts Video | |
| America's Pot Labs Have A THC Problem | |
| By <u>Lester Black</u> Filed under <u>Marijuana</u> Published Jun. 29, 2021 | |
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CALIFORNIA

Industry Insiders Warn of Fraud at Marijuana Testing Labs

By Liz Wagner, Michael Bott, Mark Villarreal and and Michael Horn • Published November 16, 2017 • Updated on November 16, 2017 at 11:47 pm f y 🛛

| WASHINGTON | N STATE | | |
|-----------------------|----------------|-----|-----|
| Pot testing lab fudge | ed numbers ab | out | t |
| marijuana potency, Wa | ishington boai | d s | ays |

Home / All U.S.

False test results, lab shopping put cannabis consumers at risk

By Roger Brown

November 9, 2020 - Updated December 20, 2021

May 5, 2021

Lab Shopping: Highlighting the Need for Checks and Balances in Cannabis

By Josh Swider



Josh Swider, Co-Founder of InfiniteCAL, shares his concerns regarding labs working more like profit centers than public safety agents.

Cannabis IndustryJournal

No Comments

Product testing

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Packaging and Labeling

- Preventing youth appeal/consumption
 - Plain, uniform, opaque packaging
 - Childproof packaging

• Protecting/informing consumers:

- Labeling for total THC (vs. D9 only)
- Labeling with processing/manufacturing
- Universal symbol (on all products)
- Inclusion of poison center phone number or drug information website
- Rotating warning labels
- Challenges:
 - Products that still appeal to kids
 - Effectively reaching consumers with essential information









Product oversight, compliance, and monitoring

- Pre-market:
 - Product preapproval processes
 - Packaging review processes
- Post-market:
 - Point-of-sale education
 - Compliance checks
 - Post-market testing authority
- Throughout:
 - Seed to sale tracking --> can link to patient and provider registries



Distribution of products

Ways to distribute products to patients

- Budtenders
- Pharmacists or other clinicians
- Combination of the two

Ways to improve quality for patients:

- \rightarrow Budtender training requirements
- →Increased requirements for recommending clinicians



Additional consideration:

Hemp-derived novel cannabinoids



THC isomers and Novel Cannabinoids

Consumer Safety concerns:

- Not subject to the same packaging, labeling requirements
- Not subject to the same testing requirements
 - Some new cannabinoid products have no data from use in humans
 - Potentially dangerous manufacturing
 - Unknown byproducts
- Widely available in retail outlets and online
 → widely available to youth
- Legal products on the hemp marketplace with with >Delta-9 THC than is allowed in regulated cannabis markets.



Conclusions

- Medical marketplace sets the path for adult-use markets.
- Important to give adequate attention and resources to regulation.
- Consumer safety is paramount.
- Policies on allowable ingredients, required testing, packaging and labeling, and product oversight are vital.
- Imperative to consider hemp market and possible loopholes when developing a medical cannabis marketplace.
- Learn from and build on policies enacted by your peers in other states!

Thank you!

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