

Regulatory considerations and challenges for cannabis products with high THC concentration

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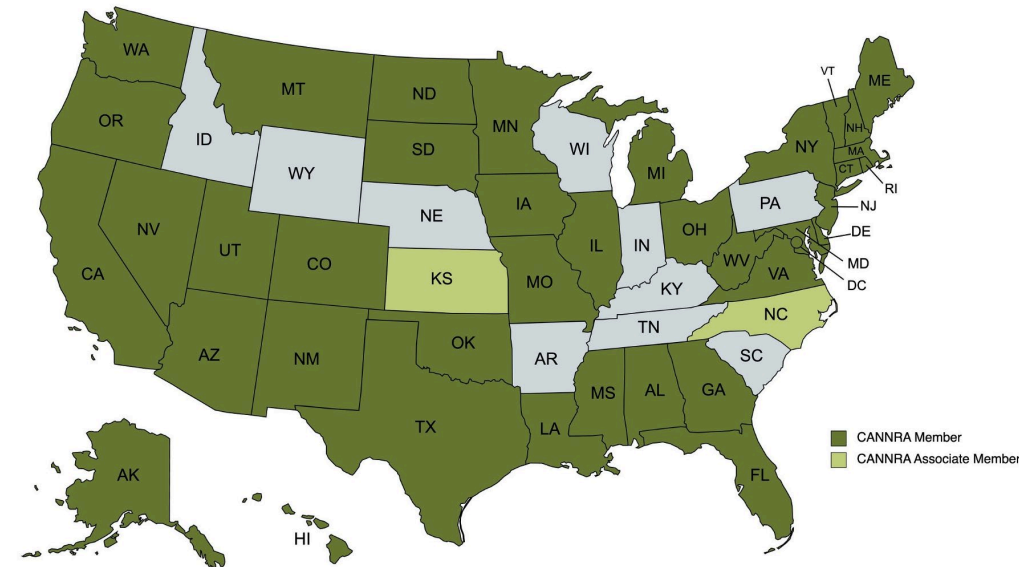
Disclosures and Disclaimers

I do not have anything to disclose.

This presentation is my own and does not necessarily represent an official position of CANNRA or of any of the state agencies with whom I work.

Brief Overview of CANNRA

- A **national nonpartisan nonprofit organization of government officials involved in cannabis regulation** in more than 40 states and territories.
- Not an advocacy group.
- Mission and goals:
 - To equip policymakers with unbiased information from the front lines of cannabis legalization.
 - To identify and share best practices that safeguard public health and safety, promote equity, and promote regulatory certainty for industry participants.
 - To harmonize policy across jurisdictions where possible.
- More than a dozen committees spanning the breadth of cannabis policy topics.
- Funded primarily by member agencies; no non-governmental membership.
- An affiliate of the Council of State Governments (CSG).



www.cann-ra.org

Guiding principles for cannabis regulations (generally)

Consumer safety

Public health and safety

Equity

Market stability

Economic growth

Timeline of Adult Use Cannabis Legalization, by State

State	Year adult use legalization passed	Ballot measure (% support) OR legislative passage	Date retail marketplace opened (opens)
CO	2012	Ballot measure (55%)	January 2014
WA	2012	Ballot measure (56%)	July 2014
OR	2014	Ballot measure (56%)	October 2015 (through medical dispensaries)
AK	2014	Ballot measure (53%)	October 2016
DC	2014	Ballot measure (65%)	No retail marketplace approved
CA	2016	Ballot measure (56%)	January 2018
ME	2016	Ballot measure (50%)	October 2020 (through medical dispensaries)
MA	2016	Ballot measure (54%)	November 2018
NV	2016	Ballot measure (54%)	July 2017 (through medical dispensaries)
VT	2018	Legislative	Expected late 2022
MI	2018	Ballot measure (56%)	December 2019
IL	2019	Legislative	January 2020 (through medical dispensaries)
AZ	2020	Ballot measure (60%)	January 2021 (through medical dispensaries)
MT	2020	Ballot measure (57%)	January 2022 (through medical dispensaries)
NJ	2020	Ballot measure (67%)	April 2022
SD	2020	Ballot measure (54%)	Legalization overturned by legal challenge
NY	2021	Legislative	Expected 2022 (or later)
VA	2021	Legislative	Expected 2024
NM	2021	Legislative	April 2022
CT	2021	Legislative	Expected 2022 (or later)
RI	2022	Legislative	Expected 2022 (through medical dispensaries)

What kinds of policies do adult use states have in place that can impact high THC products?

THC Caps

- Connecticut and Vermont (extremely similar policies)
 - Cannabis flower is limited to 30% THC on a dry weight basis
 - Other cannabis products are limited to no more than 60% THC
 - Exempts prefilled vape cartridges
- Potential limitations
 - Effectively outlaws most THC concentrates – unknown illicit market implications.
 - Could incentivize home production of concentrates

Serving size or package size in place for THC concentrates

- California, Colorado, New Jersey, Nevada, Vermont, Washington
 - CA – per package limit of 1000 mg THC for concentrates
 - CO – recommended visual serving for concentrates, recommended serving for vaped cannabis is two seconds of inhalation.
 - NJ – single serving of any cannabis product is limited to 10mg THC or the equivalent weight as determined based on THC potency.
 - NV – total THC is limited to 800mg/package
 - VT – per package serving size for all cannabis products is 50mg THC
 - WA – single serving of cannabis concentrate cannot exceed 1g
- Requires package to denote what the serving size is and/or the number of servings included:
 - MA, MT, NJ, OR, VT



COLORADO
Department of Revenue
Marijuana Enforcement Division

USE OF REGULATED MARIJUANA CONCENTRATE

Medical and Retail Marijuana Stores are required to provide this resource to individuals purchasing Regulated Marijuana Concentrate.

EXAMPLES OF A SERVING SIZE FOR EACH TYPE OF CONCENTRATE

Regulated Marijuana Stores offer various categories of marijuana concentrates. Stores may refer to marijuana concentrates using different names, including but not limited to terms like shatter, wax, butter, sugar, hash, resin, and rosin.

Start Low. Go Slow.

Vaping: Vaporizers heat marijuana concentrate to release THC for inhalation. The serving size should not exceed **1 inhalation** lasting **2 seconds** per serving.

Inhalation other than Vaping: When consuming regulated marijuana concentrate by inhalation other than vaping (e.g. dabbing) the recommended serving size is a sphere with the diameter no larger than the dot below:

Concentrate
Serving Size:



Purchase limits for THC and/or concentrates

Purchase limits often = possession limits

- For cannabis flower possession and/or purchase limits range from 1 to 3oz
- For concentrates that generally ranges from 500mg THC (IL) and 3.5g concentrate (NV), to 24g concentrate (NY).

Specific packaging & labeling requirements for concentrates

- **Colorado** – If product cannot be easily separated or measured into the recommended visual serving size, the container must have a measuring device, and must include labeling with instructions on how to measure.
- **Nevada** – Usable cannabis must have the concentration of total THC listed overall (mg/package), and as a percentage.
- **New Jersey** – All finished cannabis product labels must contain chemotypes: High THC/Low CBD (where ratio is > than 5:1), Moderate THC/Moderate CBD (where ratio is between 5:1 and 1:5), Low THC/High CBD (where ratio is <1:5 and total THC is <5%).

Warning labels related to THC concentration and/or the association between high THC consumption and brain development or mental health

- **Colorado** – "There may be long term physical or mental health risks from use of marijuana". Also require a tangible educational resource with several more warnings.
- **Nevada** - There may be mental or physical health risks associated with consumption of cannabis or cannabis products, including but not limited to cardiovascular problems, psychosis, or exacerbation of anxiety and/or depression.
- **New Jersey** - For any cannabis item that contains a total THC percentage >40%: "This is a high potency product and may increase your risk for psychosis" -- must be printed in no less than 10pt font on the front of the package and may not wrap around the side of the package.

Point of sale education re: concentrates

- **Colorado:** Retailers required to provide a tangible educational resource at point of sale
- **Nevada:** Retailers required to post warnings at point of sale

RISKS AND PRECAUTIONS

WARNING:

Use of Marijuana Concentrate may lead to¹:

1. Psychotic symptoms and/or Psychotic disorder (delusions, hallucinations, or difficulty distinguishing reality);
2. Mental Health Symptoms/Problems;
3. Cannabis Hyperemesis Syndrome (CHS) (uncontrolled and repetitive vomiting);
4. Cannabis use disorder / dependence, including physical and psychological dependence.

Consuming concentrate via inhalation will cause immediate effects.

Marijuana concentrates ARE NOT recommended for inexperienced marijuana users. THC concentration (% THC), amount of concentrate consumed, and frequency of use can result in both short and long-term effects. There is moderate evidence that individuals who use marijuana with THC concentration greater than 10% are more likely than non-users to be diagnosed with a psychotic disorder, such as schizophrenia.

Marijuana concentrate is not approved by the FDA and claims of medical benefits are not supported by the FDA.

Marijuana concentrates ARE NOT recommended for anyone under age 25, except if recommended by a doctor. People under 25 may be at greater risk of potential harm because the brain is not fully developed.

Regulated Marijuana Stores cannot provide medical advice. Any questions related to the health or safety of marijuana concentrates should be discussed with a patient's recommending physician or an adult consumer's primary care physician.

¹ These risks are based on CDPHE evidence statements where there is either moderate or substantial evidence. Where moderate means strong scientific findings that support the outcome, but these findings have some limitations and substantial means robust scientific findings that support the outcome with no credible opposing scientific evidence. <https://marijuanahealthinfo.colorado.gov/glossary>

OTHER STATUTORY & REGULATORY LABELING REQUIREMENTS

The following warning statements must be included on every Container of Regulated Marijuana:

- "Keep away from Children."
- "This product was produced without regulatory oversight for health, safety, or efficacy."
- "There may be long term physical or mental health risks from use of marijuana including additional risks for women who are or may become pregnant or are breastfeeding. Use of marijuana may impair your ability to drive a car or operate machinery."

Universal Symbol - Caution Symbol for Regulated Marijuana THC

All Regulated Marijuana must be sold in a Container that displays the Universal Symbol to caution that the product contains THC.



PENALTIES

The sale, transfer, or dispensing of marijuana in violation of Colorado law is a felony punishable by a prison sentence up to 32 years and/or fines up to \$1,000,000.00.

A felony conviction can have serious consequences including the inability to vote while incarcerated, prohibition on obtaining a passport which is required to travel internationally, disqualification for employment, the inability to obtain housing and other serious consequences.

Inhaling more than 10 mg of THC within 10 minutes can lead to a blood THC level above 5 ng which can be used to support a conviction for driving under the influence.

THC-based tax approaches

- **Connecticut**

- Point of sale consumer tax of 0.625 cents/mg THC in cannabis plant material, and 0.275 cents/mg total THC in edibles, and **0.9 cents/mg of THC concentrate**

- **Illinois**

- Cannabis with a delta-9 THC level at or below 35% is taxed at 10% of the purchase price; cannabis infused products are taxed at a rate of 20%; **cannabis (other than infused-cannabis) with a delta-9 THC level above 35% is taxed at a rate of 25% of the purchase price**

- **New York**

- Tax per mg THC at the wholesale level of **\$0.008 for concentrate products**

No policies in adult use states for:

- Age limitations related to concentrates
- Advertising limitations on concentrates
- Complete product class bans on concentrates

Challenges related to regulation of high THC products

- Insufficient scientific research
 - Existing research generally encompasses all THC currently on the market
 - Lack of studies on THC concentrates as a class of products
 - Lack of studies about the impact of different potential policy levers on consumer behavior, youth access, etc.
- Complex topic with implications for a range of outcomes
 - Mental health and public health outcomes
 - Illicit market outcomes
 - Post Vaping Lung Injury outbreak considerations
- Lack of federal resources
 - Lack of safety profiles on additives, manufacturing methods
 - No approved ingredients lists

A cautionary tale: Vaping Lung Injury Outbreak (VALI)

- Peaked in 2019
- 68 confirmed deaths across 29 states and DC; 2,807 hospitalizations across 50 states and DC
- Largely unregulated products from illicit or informal sources
- Unsafe byproducts and diluents (Vitamin E Acetate was named as one cause)
- Labeling and recall issues in a number of states



Conclusions and Public Policy Implications

- There is an absence of science to guide policy making related to concentrates
- U.S. states are implementing a range of different policy approaches to address THC concentrates
- These policy approaches have typically been initiated through legislatures (not through regulatory rule making)
- Current policy options being undertaken have generally not been evaluated and outcomes in terms of consumer behavior are unknown
- CANNRA continues to facilitate multi-state discussion about regulatory approaches to high THC products and how they are working in states.

Questions?

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