

Cannabis Legalization and Public Health Policy

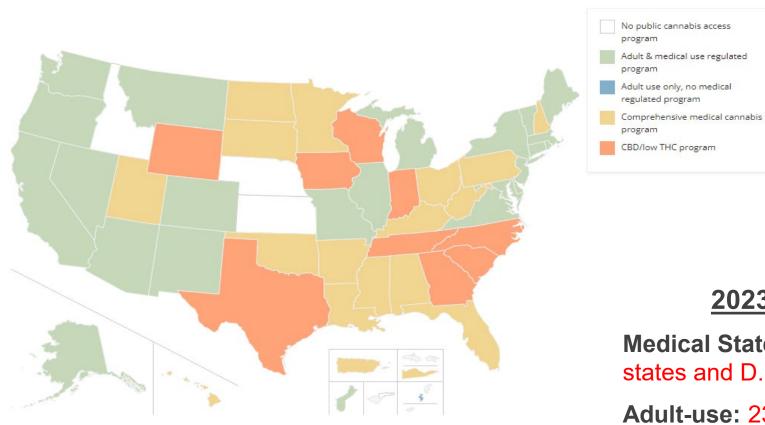
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9/21/2023



Cannabis Landscape 2023



2023

Medical States: 38

states and D.C.

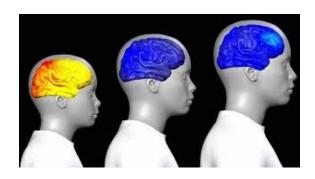
Adult-use: 23 states

and D.C.



Concerns Regarding Youth and Cannabis Legalization

- Exposure during critical period of cognitive development is associated with:
 - Cognitive Impairment (attention, memory, executive function, processing speed,)
 - Cannabis Use Disorder
 - Depression
 - Bipolar disorder
 - Schizophrenia
 - Psychosis
- Smoked cannabis involves many of the same toxins as smoking tobacco.
- Poison control and emergency room visits for over exposure to THC (edibles).









Reducing Youth Exposure: Advertising

Medium Based Restrictions (TV, Internet, Radio, Print,)

- Only allow advertising in a forum that is adult focused.
- Determined by the percentage of audience expected to be adults. (NM-70% vs. CT-90%)
- NM prohibits the use of broadcast media unless it is subscription service.

Content Restrictions

- Every state has an explicit prohibition against advertising content that targets children. The degree of detail in this prohibition varies considerably.
- NM Warnings: 21 and older, please consume responsibly, keep out of the reach of children, not FDA approved,

Physical Restrictions:

- Exclusionary zones around child focused locations (schools, day cares, churches, playgrounds, recreation centers, . . .)
- □ Schools: NM- 300 feet vs CT-1,500 feet









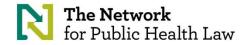
Reducing Youth Exposure: Product Packaging

- Opaque packaging
- Tamper evident
- Child Resistant
- Prohibit packaging that is appealing to children
- Prohibit packaging that resembles existing food products.
- Poison Control #
- Plain Packaging Requirement









Reducing Youth Exposure: Product Design

- Prohibition on attractiveness to children: "No edible cannabis products shall be manufactured, marketed, or sold that are in the shape of, or a shape bearing the likeness or containing characteristics of, a realistic or fictional human, animal, or fruit, or part thereof, including artistic, caricature, or cartoon renderings;"
- □ Prohibit products that imitate non-cannabis products that are appealing to children.
- ☐ Prohibit the application of cannabis extract to commercial foods.
- Restricting potency of cannabis edibles (NM Adult-use: 10mg/serving and 100mg/package: Medical 50mg/serving)







Reducing Youth Exposure: Education

- Education on the risks of cannabis consumption. Youth underestimate the risk.
- Education for parents on proper storage of cannabis in the home.
- New Jersey use 15% of cannabis tax revenue is allocated to the Underage Deterrence and Prevention Account
 - to fund private for-profit organizations, non-profit organizations, and local government programs that offer social services, educational, recreational, and employment opportunities. . . To support youthful community activities.

Cannabis & THC **Safe Storage Information**



Safe Storage

Young children may confuse cannabis & THC products for regular food or candy. Be sure all cannabis products are kept in childresistant packaging, clearly labeled, and locked up. Children should not be able to see or reach the locked



A safe storage plan can help lower the risk of accidental ingestion.

Making a Safe **Storage Plan**

- · Make a list of cannabis products in your home. Knowing exactly what cannabis products you have in your home can help with medical treatment in case of accidental ingestion.
- · Store cannabis products in their original containers and keep the label. Labels on cannabis products from licensed cannabis establishments will have important information including how much THC is in the product.
- · Keep cannabis in a secure and locked place. Cannabis products should be out of sight and out of reach of children and pets. Consider using a safe or lockbox with a combination lock or

Accidential Ingestion

If a child or pet consumes cannabis or THC, they may need immediate medical help. Symptoms to watch out for can include: problems walking or sitting up, difficulty breathing, or becoming sleepy.

If a child may have ingested cannabis or THC, call the Poison Control Hotline at (800) 222-1222. If symptoms are severe, call 911 or go to an emergency room immediately.

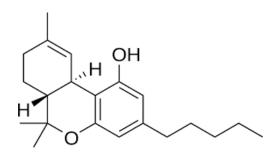
The Poison Help Hotline is available 24/7/365.





Cannabis Testing

- □ Potency- delta-9 THC, THC-A, CBD,
- Homogeneity
- ☐ Microbials and Mycotoxins: salmonella, e. coli, aflatoxin, . . .
- ☐ Heavy Metals: lead, arsenic, cadmium, mercury, . .
- Pesticides, fungicides, and growth inhibitors
- ☐ Residual Solvents: Acetone, Benzene, Chloroform,
- New Mexico's testing requirements
- States do not test for the same contaminates and do not have the same MAC. There is no federal testing standard for these products.
- □ Some states vary analytes and MAC by product type





State Reference Labs

■ Example: Maryland

- A reference library that contains cannabis testing methodologies for potency, homogeneity, and contamination.
- Create standard operating procedures for independent testing laboratories.
- Proficiency testing.
- Remediate problems with independent testing laboratories.
- Compliance testing.
- Test products for adverse events response.







Protecting Medical Cannabis Supply

- Adult-use legalization brings a huge influx of customers and increased demand for cannabis products.
- ☐ Can cannabis operations ramp up to meet the increased demand?
 - Capacity of existing growers.
 - How quickly can new licenses be issued?
- ☐ How do states ensure that medical cannabis patients will have access to their medicine?







State Protections for Medical Patients

Maryland

- Reserve high potency products for medical patients only.
- ☐ Require dispensaries to have a separate check out or reserve hours just for medical patients.
- ☐ General requirement to ensure sufficient inventory for medical patients.

Michigan

Requires separate inventories for medical and adult-use

<u>Missouri</u>

☐ Inventory plan explaining how they will serve both medical and adult-use markets.

New Mexico

- Empower regulatory agency to do the following to protect medical access:
 - Require cannabis establishments to reserve ten percent of their monthly stock for medical cannabis patients and their caregivers.
 - Restrict new licenses to serving the medical cannabis market for at least six months.
 - Require cannabis producers to reserve a specified quota of mature cannabis plants for the medical cannabis program.



Consumption Sites (Cannabis Café)

- □ Public establishments where cannabis consumption is permitted.
- Must be licensed.
- Restricted access to 21 older
- Prohibit sale and consumption of alcohol and tobacco.
- Indoor and Outdoor consumption
- Visibility restrictions
- Cannot serve individuals who are visibly intoxicated
- Provide information on safe consumption.
- Smokeable Products Policies
 - Isolated consumption area/smoke free area for employees to monitor consumption
 - Ventilation system requirements
 - Prohibit indoor smoking
 - Prohibit smokeable products all together
- Buffer Zone around schools and other child focused areas
 - NM: local government can create a buffer zone of up to 300 feet







Intoxicating Hemp Products: 2018 Agriculture Bill

- □Legalized hemp as an agricultural product.
- Removed Hemp from the Controlled Substance Act (no longer Schedule I substance).
- ■No longer restricted to research.
- ☐ Includes states, tribal governments, and territories.
- □ Permitted in interstate commerce.
- ☐States could develop their own hemp cultivation programs or utilize the USDA system. (most states have chosen to develop their own programs).
- Retained the FDA authority to regulate the products derived from hemp. (7 USC 1639r)







2018 Farm Bill-Hemp Defined

the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and <u>all derivatives</u>, <u>extracts</u>, <u>cannabinoids</u>, <u>isomers</u>, <u>acids</u>, <u>salts</u>, <u>and salts of isomers</u>, whether growing or not, with <u>a delta-9 tetrahydrocannabinol concentration</u> of not more than <u>0.3 percent on a dry weight basis</u>. (7 USC 16390)



50 grams x 0.3%=150mg



Lack of Federal Regulation: State Challenge

- Many forms of THC (isomers): Delta-8, Delta-10,
- □ CBD can be converted to Delta-8 and other isomers.
- Explosion of intoxicating hemp products at smoke shops.
- ☐ FDA has not proactively used authority to create regulatory system. Only minor reactionary measures.





FDA Response

Consumer Update: 5 Things to Know about Delta-8 Tetrahydrocannabinol – Delta-8 THC (Dec. 2021).

- 1. Delta-8 THC products have **not been evaluated or approved by the FDA** for safe use and may be marketed in ways that put the public health at risk.
- 2. The FDA has received **adverse event reports** involving delta-8 THC-containing products.
- 3. Delta-8 THC has **psychoactive and intoxicating effects**
- 4. Delta-8 THC products often involve use of **potentially harmful chemicals** to create the concentrations of delta-8 THC claimed in the marketplace.
- 5. Delta-8 THC products should be kept out of the reach of children and pets.







FDA Warning Letters

Issued warning letters to five companies for selling Delta-8 THC products in violation of the FDCA (May 2022)

- 1. Unapproved New Drug: based on diagnosis, cure, mitigation, treatment, or prevention of disease claims.
 - "Delta-8 THC can be used to suppress the immune response in your body. If a patient is suffering from autoimmune diseases, Delta-8 THC will offer some relief and support. Some of these diseases include lupus, HIV/AIDS, and multiple sclerosis."
- 2. Misbranded drugs-inadequate directions for safe use
- 3. Adulterated Food
 - No food additive regulation authorizes the use of Delta-8 THC.
 - Use of unauthorized food additive has adulterated the food products.



Intoxicating Hemp Derived Products: State Policies

Michigan:

Can only be sold in the licensed cannabis market.

New York:

- Created separate licensing system for these products
- Safety standards: product, packaging, labeling, and testing.

Oregon:

- Licensed not required to sell hemp products.
- Banned synthetic cannabis derivatives (see e.g., Delta-8 THC)
- Delta-9 THC Limits
- Age Restriction-21

Maryland:

- Allow unlicensed sales but only of low potency products.
- THC isomers included in potency restrictions.
- Age Restriction-21



Hemp Product Regulation NM

- Hemp cultivators regulated and licensed by NMDA.
- Hemp Processors regulated and licensed by NMDE.
- Do not need a hemp license to sell products.
- Use federal definition of 0.3% Delta-9 THC by dry weight as the only restriction on THC content.
- ☐ Do not regulate Delta-8, Delta-10,
- Some product testing required.
- Basic labeling requirements.
- No packaging restrictions.
- No product design restrictions.
- No advertising restrictions.







Thank you.

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