

The logo for Dentons, consisting of the word "DENTONS" in a white, sans-serif font inside a white arrow-shaped box pointing to the right. The background of the slide is a purple-to-white gradient with faint images of cannabis leaves and glass bottles.

DENTONS

Kentucky's New Regulations for Hemp-Derived Products: Navigating the Emerging Market Landscape

Grow | Protect | Operate | Finance



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Hannah is one of Maine's leading authorities on the highly regulated and complicated cannabis industry.

Hannah advises hundreds of cannabis businesses from small family-run businesses to large publicly traded, multi-state operators. Her work includes local and state licensing and permitting and regulatory compliance as well as assisting cannabis businesses navigate the cannabis laws in complicated commercial and financial transactions and litigation.

Hannah has substantial experience advising tribal nations across the country seeking to enter the cannabis and hemp markets on the status of state and federal marijuana laws, development of tribal regulatory regimes, negotiations for joint ventures with cannabis operators, and compact drafting and negotiations. She has also advised financial institutions on developing and implementing Marijuana Related Business programs that comport with the 2014 FinCen Guidance on "BSA Expectations Regarding Marijuana Related Businesses."



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Kristin McCall is a member of the Commercial Litigation practice, where she represents clients in state and federal courts in a variety of litigation matters, including business torts, breach-of-contract claims, cannabis, products liability, employment-related claims and discrimination claims. Kristin collaborates with in-house counsel to coordinate and develop litigation strategies. She is experienced in handling all stages of litigation from complaints to depositions to trials and has authored briefs for the Sixth Circuit Court of Appeals, Kentucky Court of Appeals and the Kentucky Supreme Court.

Kristin's practice includes helping businesses navigate the often complex and constantly evolving cannabis laws at the local and state levels regarding licensing and permitting, regulatory compliance and related litigation. Her clients include medical businesses, cultivators, retailers and testing labs.



Arin Aragona

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Arin assists clients with a broad array of legal services, especially mergers and acquisitions, divestitures, business organization, debt and equity investments, and capital raising. Leveraging his substantial in-house experience, Arin also provides general legal advice on all facets of clients' businesses.

Prior to joining Dentons, Arin was general counsel and chief operating officer of a boutique private equity firm primarily focused on the US cannabis industry. Through this role, he gained unique insight and experience relevant to those in the cannabis industry and the broader private equity world. Arin intimately understands clients' business goals and objectives and can anticipate needs and problems before they arise. He can assist businesses and investors with entity formation, regulations, licensing, raising capital, business disputes, capital deployment, and restructuring work.

U.S. HEMP MARKET

- The 2023 U.S. National Hemp-Derived Cannabinoid Report, published by **Whitney Economics** estimates the U.S. demand for hemp-derived cannabinoids in 2022 \$28.4 billion.
- According to **Whitney Economics**' report, the U.S. hemp industry in 2022:
 - Was larger than all state marijuana markets
 - Roughly equaled sales for craft beer nationally
- According to the Report, the hemp-derived industry employs 328,000 workers earning \$13 billion in wages and has an overall economic impact of \$79 billion.



FEDERAL HISTORY OF HEMP LEGALIZATION

- Marijuana Tax Act of 1937
- Controlled Substances Act of 1970
- Agricultural Improvement Act of 2014
- Agriculture Improvement Act of 2018
- Federal Food, Drug and Cosmetic Act



KENTUCKY HISTORY OF HEMP LEGALIZATION

2013

Senate Bill 50

Kentucky passed a state law, Senate Bill 50, allowing production for agricultural research purposes.

2021

Pursuant to the 2018 Farm Bill, USDA approved State Plan for regulating the domestic production of hemp.

Farm Bill

Pursuant to the 2014 Farm Bill, the Industrial Hemp Research Program was conducted through the Kentucky Department of Agriculture.

2014

EXECUTIVE ORDER

- On August 3, 2022, the Boone Circuit Court issued an opinion in Kentucky Hemp Association, et al. v. Ryan Quarles, et al. that Delta-8 THC is a derivative of CBD, which is a derivative of hemp, and therefore Delta-8 THC is a derivative of hemp under Kentucky law, and that any products that contain Delta-8 THC are legally compliant hemp under Kentucky and federal law.
- On November 15, 2022, in response to that opinion, Governor Beshear issued Executive Order 2022-799 to address the fact that at that time, there were no requirements in Kentucky applied to Delta-8 THC products for packaging and labeling.
- Executive Order 2022-799 ordered the Cabinet for Health and Family Services to apply the then-current regulations governing hemp-derived cannabinoid products to Delta-8 THC products.
- The then-existing regulations were very minimal in their requirements and contained no age restrictions.



HOUSE BILL 544

- In the 2023 legislative session, the General Assembly passed HB 544, which ordered the Cabinet for Health and Family Services to immediately begin the process of regulating Delta-8 THC and other hemp-derived cannabinoid substances
- The Cabinet was required to promulgate emergency hemp-derived cannabinoid regulations by August 1, 2023
- In relevant part, HB 544 required the Cabinet to include the following in the emergency regulations:
 - Prohibit the sale or possession of hemp-derived cannabinoid products with intoxicating effects (“covered products”) to anyone under the age of 21
 - Require retailers to keep covered products behind the counter
 - Establish a laboratory testing and approval process for contaminants and phytochemicals of a covered product
 - Establish packaging and labeling requirements for covered products
- Governor Beshear signed HB 544 into law on March 23, 2023



PROCEDURAL/EFFECTIVE DATE OPPORTUNITY FOR CHANGES

- On August 1, 2023, the Cabinet for Health and Family Services promulgated 902 KAR 45:190E, emergency regulations governing hemp-derived cannabinoids
- These emergency regulations were effective immediately
- On October 13, 2023, the Cabinet issued amended emergency regulations that are now the effective version of the emergency regulations
- These emergency regulations will expire April 27, 2024
- It is our understanding that before the expiration of the amended emergency regulations, the Cabinet intends to promulgate replacement emergency regulations and proposed final regulations
- After the new emergency regulations and proposed final regulations are published, there will be a public comment period for each before the final regulations go into effect



EMERGENCY RULES

TYPES

PERMITTING AND
REGISTRATION
(OPERATOR)

LABELING

TESTING

INVENTORY
STORAGE/AGE
GATES

INTERNET
SALES/DIRECT TO
CONSUMER SALES

SOURCING

ENFORCEMENT

CANNABINOID TYPES

While some of the regulations apply to all hemp derived cannabinoids, others only apply to adult-use products (e.g., product registration and child-resistant packaging).

- An ingestible, inhalable, or cosmetic product that is processed or derived from hemp

HEMP-DERIVED CANNABINOID



- A product with intoxicating properties that changes the function of the nervous system and results in alterations of perception, cognition, or behavior (e.g., Delta 8 THC, Delta 9 THC, Delta 10 THC, THCA, and HHC)

ADULT USE CANNABINOID



- A product with non-psychoactive properties that does not change the function of the nervous system and does not result in alteration of perception, cognition or behavior (e.g., CBD, CBN, CBG, CBDA, and CBT)
- Shall have: (a) at least a 25:1 ratio of non-intoxicating cannabinoids to adult-use cannabinoids; and (b) contain 2.5mg or less of adult-use cannabinoids per serving

NON-INTOXICATING CANNABINOID



PERMITTING AND REGISTRATION

A person located in Kentucky seeking to process, manufacture, store, or distribute hemp-derived cannabinoid products must be permitted by the cabinet

Any out-of-state manufacturer or processor with hemp-derived cannabinoid products available in Kentucky shall register with the Cabinet

All hemp-derived cannabinoid products available in Kentucky must be registered with the Cabinet.

Adult use cannabinoids also require a \$200 registration fee per product

Retail establishments and food service establishments offering adult use cannabinoid products shall register with the Cabinet

PACKAGING AND LABELING

All packaging must comply with the federal Fair Packaging and Labeling Act

Packaging for all products must:

- List the common name of the cannabinoid product and the amount per serving and container
- Have tamper-evident seals
- Not contain any cartoons or likeness to commercially available products or things that appeal to children

Packaging for adult-use cannabinoid products must also contain specific warnings, which may be accessed via a QR code

TESTING



Products are specifically tested for cannabinoids, microbial impurities, mycotoxins, residual pesticides, heavy metals, and residual solvents.

Applies to products being shipped out of state unless the receiving state has equivalent testing requirements.

The purpose is to assess contaminants and ensure that cannabinoids are consistent throughout the product.

Testing for all hemp-derived cannabinoid products is required for each batch or process lot of the final product equivalent to what will be consumed.



INVENTORY STORAGE/AGE GATES



Storage

- Adult-use products in retail stores must be secured to prevent theft or other access by persons under 21 years old



Age Requirements

- A business that processes, manufactures, warehouses, distributes, sells, or serves adult-use products must only employ people who are 21 and older, though they may employ people over the age of 18 if they are supervised by somebody over 21
- Purchasers of adult use products must be 21 or older

INTERNET SALES/DIRECT TO CONSUMER SALES

Any retailer selling products in Kentucky through internet sales must also register with the Cabinet

All retailers selling adult use cannabinoid products to consumers, including through internet sales, must obtain proof of age of the buyer to verify that the buyer is 21 or older

Retailers may deliver or ship adult use cannabinoid products to consumers 21 or older in packages that are clearly marked “Adult-use only”

SOURCING (ingredients and value-added products)

Under the emergency regulations, “Approved Source” means:

- A Kentucky hemp grower or handler licensed by the Kentucky Department of Agriculture, or an out-of-state hemp grower or handler who is duly authorized to produce hemp under the laws of the applicable jurisdiction;
- A hemp product manufacturer or processor with a permit from the Kentucky Department for Public Health; or
- A manufacturer or processor with a permit from another state regulatory authority for hemp-derived cannabinoid products if that state has been approved by the department as having equivalent state standards for processing, laboratory testing, and labeling requirements

Processors and manufacturers may not treat or otherwise adulterate a cannabinoid product with any non-cannabinoid additive that increases toxicity or addictive potential, excluding caffeine; alcohol; nicotine; or other chemicals that may increase carcinogenicity or cardiac effects

Processors and manufacturers may only use the solvents listed in the emergency regulations

ENFORCEMENT

The Cabinet of Health and Family Services and its authorized agents shall conduct onsite inspections of all hemp-derived cannabinoid processing and manufacturing establishments, storage warehouses, distribution centers, and retail establishments offering adult use cannabinoid products

The Cabinet and its authorized agents may inspect retail establishments that offer only non-intoxicating cannabinoid products if they receive a complaint, a report of a serious adverse event, or at the Cabinet's discretion

The permit holder shall take immediate steps to correct conditions that have caused an imminent health hazard

If the Cabinet has evidence that a processing or manufacturing facility has failed to act to correct an imminent health hazard, the Cabinet shall suspend the permit, or the portion of the processing or manufacturing operation affected by the imminent health hazard]

If a permitted facility has a suspended permit twice or more within a five-year period, the Cabinet shall initiate permit revocation proceedings

LITIGATION

- To the extent that a person believes the regulations exceed the Commonwealth's authority or are arbitrary and capricious, the validity of the regulations could be challenged through litigation
- In other states, for example, parties have challenged state laws or regulations on hemp-derived cannabinoids as being preempted by the 2018 Farm Bill
- There is currently a split amongst courts on these issues:
 - For example, a federal court in Arkansas ruled at the preliminary injunction stage that the plaintiffs in that case are likely to succeed on the merits of their claim that Arkansas' ban on "synthetically produced" hemp-derived cannabinoids is preempted by the 2018 Farm Bill.
 - Meanwhile, a federal court in Virginia denied the plaintiffs' motion for preliminary injunction regarding Virginia's law that imposed a limit on substances containing THC according to the concentration of total THC rather than the concentration of Delta-9 THC as defined in the 2018 Farm Bill.



TRENDS IN STATE REGULATION

States are increasingly regulating or prohibiting hemp derived products, with each generally falling under one of the following categories:

Hemp products are not prohibited, and the state has yet to pass legislation addressing it (e.g., NJ, NC)

Hemp products are regulated as part of the state's legal cannabis market (e.g., CA, CT)

Hemp products are regulated on their own (e.g., LA, TN)

Hemp products are banned (e.g., CO, ID)



The background of the slide features a golden scale of justice and a gavel, symbolizing law and equity. The scales are positioned in the upper half, with the gavel resting on the right pan. The background is a warm, golden-yellow color with faint architectural details and a grid pattern. A dark purple banner covers the bottom half of the slide, containing the main title and three agency names in white rounded rectangles.

PROSPECTIVE CHANGES IN FEDERAL LAW

U.S.
CONGRESS

DRUG
ENFORCEMENT
AGENCY

FOOD AND
DRUG AGENCY

PROSPECTIVE CHANGES IN FEDERAL LAW

U.S. Congress

- Because the 2023 Farm Bill has been pushed back to 2024 and there will be no Farm Bill in 2023, any changes made through the Farm Bill could be a year or more away.
- However, in reauthorizing the Farm Bill or in legislation separate from the Farm Bill, Congress could:
 - make no change to the hemp provisions of the 2018 Farm Bill;
 - clamp down on the 2018 Farm Bill's alleged loopholes. For example, Congress could entirely prohibit "intoxicating" hemp-derived cannabinoids;
 - broadly liberalize federal hemp policy. For example, it could clarify that certain intoxicating cannabinoids are legal under federal law as well as increase the delta-9 THC percentage in hemp; or
 - liberalize hemp policy but mandate increased regulation by, for example, expressly granting added regulatory powers to the FDA.



PROSPECTIVE CHANGES IN FEDERAL LAW

Drug Enforcement Agency

- Through guidance or “clarifying” rulemaking the DEA could take the position that THC that is produced from another cannabinoid, regardless of whether or not that cannabinoid was a derivative of hemp, is synthetic THC and, thus, a controlled substance.
- The DEA issued similar guidance regarding THCO earlier this year.
- Since most delta-8 THC and other hemp-derived, intoxicating cannabinoids are produced via a chemical process from CBD source material they would become controlled substances.



PROSPECTIVE CHANGES IN FEDERAL LAW

Food and Drug Agency

- Increase enforcement.
- Adopt regulations (likely pursuant to a mandate from Congress).





PROSPECTIVE CHANGES IN STATE REGULATORY REGIMES

23 states do not impose any restrictions on the production and sale of hemp-derived cannabinoid.

9 states expressly allow the production and sale of hemp-derived cannabinoid products with certain restrictions.

19 states ban the sale of certain hemp-derived cannabinoid products.