

CANNABINOIDS:

A Fact Sheet for Health Plan Decision Makers

The Food and Drug Administration (FDA) has approved the marketing of four cannabinoid medications in the U.S. Marijuana and other products containing cannabinoids, such as cannabidiol (CBD) oil and vape cartridges containing delta-9-tetrahydrocannabinol (THC), have not been approved for therapeutic (or “medical”) use by the FDA and are illegal under federal law. Yet, most states now allow certain cannabinoid products to be used for various therapeutic purposes.

Additionally, lawmakers in multiple states have introduced legislation in recent years that would require health plans and workers' compensation programs to cover non-FDA-approved cannabinoid products for therapeutic use. However, such legislation could create conflicts with federal law, yield legal risk for employers, and pose health risks for employees.

This fact sheet for health plan decision makers, including employee benefits professionals and insurance agents, defines and identifies cannabinoids, discusses their regulation and legal status, and summarizes potential issues arising from coverage mandates for cannabinoid products.



DEFINITIONS

Cannabinoids

Cannabinoids are a group of substances found in the cannabis plant.¹ More than 100 cannabinoids have been isolated and identified.² The most commonly noted cannabinoids are delta-9-THC and CBD.³

Cannabis

Cannabis is a plant of the Cannabaceae family that includes multiple species. Cannabis sativa is grown to produce varying concentrations of cannabinoids, including THC and CBD.⁴ The terms cannabis and marijuana are often used interchangeably; however, they do not have the same meaning under federal law.

Marijuana

Under federal law, marijuana refers to all parts of the cannabis sativa plant, whether growing or not, that contain more than 0.3 percent delta-9-THC on a dry weight basis. The federal definition of marijuana includes seeds, the resin extracted from the plant, derivatives of the plant, and products manufactured from the plant. The definition of marijuana does not include hemp.

Hemp

Under federal law, hemp is any part of the cannabis sativa plant containing 0.3 percent or less delta-9-THC on a dry weight basis.⁵ Hemp is an industrial plant once cultivated exclusively for its fiber and edible seeds.⁶

Delta-9-THC

Delta-9-THC is the primary psychoactive cannabinoid that produces marijuana's intoxicating and impairing effects.⁷

CBD

CBD is one of the cannabinoids in cannabis.⁸ CBD does not have intoxicating effects, but it can cause drowsiness, changes in mood, and gastrointestinal distress.⁹

Non-FDA-approved cannabinoid products

This is a catch-all term used throughout this fact sheet. It includes products that are illegal under the Controlled Substances Act (CSA) and Food, Drug, and Cosmetics Act (FDCA). It does not include legal hemp-containing food products or legal CBD-containing cosmetics that do not make therapeutic claims.¹⁰

FEDERAL REGULATION

CSA

The CSA provides the Drug Enforcement Administration (DEA) with regulatory authority over the manufacture, distribution, dispensation, and possession of controlled substances.¹¹ The DEA categorizes controlled substances within five schedules based on their abuse potential and medical use.¹² Schedule I substances have a high potential for abuse and no currently accepted medical use for treatment in the United States; therefore, they are illegal to manufacture, distribute, dispense, or possess.¹³ Marijuana and THC (except for THC in hemp) are Schedule I controlled substances.¹⁴

FDCA

The FDCA provides the FDA with the authority to regulate drugs in the U.S.¹⁵ Under the FDCA, drugs are substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.¹⁶ Prior to marketing, drugs must meet the FDA's standards for safety and efficacy.¹⁷ Before FDA approves a product as a drug, the agency requires manufacturers to provide substantial scientific evidence to demonstrate that a product meets the safety and efficacy requirements for its intended use.¹⁸ A drug without the FDA's prior approval is deemed a "new drug" and cannot be introduced, distributed, or sold in interstate commerce.¹⁹

The FDA has approved one medication, Epidiolex, that contains purified CBD derived from marijuana.²⁰ The FDA has approved three synthetic marijuana-related medications, nabilone and two forms of dronabinol. These FDA-approved medications are only dispensed with a prescription.²¹



Legal Status

Under federal law, the legal status of cannabis, marijuana, and delta-9-THC, and CBD is as follows:

Cannabis

Cannabis with 0.3 percent delta-9-THC or less is hemp. Hemp is legal under federal law.²²

Marijuana

Marijuana has not been approved as a drug by the FDA and has no currently accepted medical use under federal law.²³ It is illegal under federal law to manufacture, distribute, dispense, or possess marijuana.²⁴

Delta-9-THC

The delta-9-THC in hemp and hemp derivatives that contain 0.3 percent delta-9-THC or less is legal under federal law. All other delta-9-THC is illegal.²⁵

CBD

The FDA-approved prescription medication, Epidiolex, is the only legal CBD drug in the U.S.²⁶ CBD-containing cosmetic products, such as skin moisturizers, makeup, shampoos, and deodorants, are legal if they are safe to consumers and contain 0.3 percent delta-9-THC or less.²⁷



STATE REGULATION

While marijuana is an illegal Schedule I substance with no approved medical use under federal law, 37 states and the District of Columbia nevertheless allow marijuana products to be used for therapeutic purposes by qualified individuals.²⁸ The laws and regulations permitting marijuana possession, manufacture, distribution, and dispensing for therapeutic use vary widely from state to state. State medical marijuana laws effectively allow states to make their own assessments about the safety and efficacy of marijuana products, despite FDA having sole authority over drug approval and labeling.²⁹



STATE COVERAGE MANDATES

In recent years, lawmakers in several states have introduced legislation that would require insurers to cover non-FDA-approved cannabinoid products as a health benefit. While such legislation varies from state to state, these laws generally would require health plans to provide payment for non-FDA-approved cannabinoid products or employers to reimburse for those products as a workers' compensation benefit through their workers' compensation insurance carrier.³⁰ However, such legislation could be preempted by or otherwise inconsistent with federal law, create legal risks for employers, and pose health risks for employees. These potential issues are summarized below.

An in-depth discussion of these issues can be found in *Dazed and Confused: Making Sense of Employers' Risks from Mandated Coverage of Non-FDA-Approved Cannabis Products*, drafted by Aimed Alliance counsel and published in the *Seton Hall Legislative Journal* (2021).



STATE COVERAGE MANDATES

CSA

The CSA preempts state law if (1) a conflict exists between the CSA and the state law; and (2) compliance with the requirements of both is impossible.³¹ Cases from at least two state courts support the conclusion that the CSA would preempt a state law requiring coverage of non-FDA-approved cannabinoid products.

In 2018, the Maine Supreme Court held that employers are not required to reimburse employees for the cost of medical marijuana through workers' compensation programs. The court reasoned that a state order requiring reimbursement created a conflict between state law and the CSA because marijuana is illegal under federal law but permissible under the state's medical marijuana law, and that the order would essentially require the aiding and abetting of the illegal possession of marijuana.³² In other words, compliance with both the CSA and state law was impossible. The Massachusetts Supreme Judicial Court issued a similar holding in 2020 under similar facts.³³ As such, the same rationale potentially could be used to assert that a state law mandating health insurance coverage of medical marijuana is preempted by the CSA.

FDCA

State laws mandating the coverage of non-FDA-approved cannabinoid products undermine the purpose and intent of the FDCA. These laws would permit parties to introduce, or cause to be introduced, non-FDA-approved cannabinoid products into interstate commerce. To the extent that they are used, or intended for use, to treat a medical condition, such products are considered unapproved new drugs and are illegal under the FDCA.³⁴

STATE COVERAGE MANDATES

ERISA

The Employee Retirement Income Security Act of 1974 (ERISA) establishes minimum standards for most voluntarily established employer sponsored health plans in private industry to protect enrollees and provide a system of uniform plan administration.³⁵

ERISA imposes a fiduciary duty on plan administrators to comply with all federal laws.³⁶ Given that non-FDA-approved cannabinoid products are illegal under federal law, plan administrators would breach their fiduciary duty to comply with federal laws by offering payment for or coverage of such products.³⁷

ERISA also preempts state laws that relate to employer-sponsored health plans, including state laws that mandate benefit structures or their administration, and those that prevent uniform administrative practice.³⁸ Pursuant to the law's preemption provisions and their interpretation by the U.S. Supreme Court, ERISA would preempt any state law mandating coverage of non-FDA-approved cannabinoid products by self-funded employee health plans. With respect to fully insured plans, ERISA likely would preempt such mandates because they would interfere with plan administrators' abilities to administer uniform plans nationally.³⁹

SHOP Plans

Under the Patient Protection and Affordable Care Act (ACA), states have regulatory authority over some types of group health plans, including plans offered to employers through the Small Business Health Options Program (SHOP).⁴⁰ SHOP plans are likely prohibited from covering non-FDA-approved cannabinoid products because:

- The ACA requires pharmacy and therapeutics committees to refer to scientific evidence and standards of practice, and the therapeutic advantages of drugs in terms of safety and efficacy, when deciding which drugs to include on an exchange plan's formulary.⁴¹ However, the safety and efficacy of non-FDA-approved cannabinoid products has not been demonstrated through FDA approval, and such products are Schedule I controlled substances lacking scientific evidence to establish therapeutic value.⁴²
- The ACA's preemption provisions permit states to adopt stronger, but not weaker, consumer protections. Yet, requiring coverage of non-FDA-approved cannabinoid products would weaken federal protections designed to ensure consumers receive safe medications.⁴³

Workers' Compensation

Workers' compensation laws vary by state, including whether cannabinoid products are a covered benefit. Some states provide that insurers cannot be required to cover such products or that only FDA-approved drugs will be covered. Some others permit coverage of cannabinoid products, but do not require it.⁴⁴ As explained above, any coverage mandates potentially could be preempted by federal law.

STATE COVERAGE MANDATES

Drug Free Workplace Act

The Drug Free Workplace Act (DFWA) requires employers that enter into federal contracts to make good faith efforts to maintain a drug-free workplace.⁴⁵ Failure to maintain a drug-free workplace pursuant to the DFWA can lead to termination of a federal contract, suspension of payments under the contract, or suspension or debarment of the contractor.⁴⁶

If an employer is required to cover non-FDA-approved cannabinoid products through a health plan or workers' compensation, then it may be difficult for employers to make good faith efforts to maintain a drug-free workplace. Even if employees only use non-FDA-approved cannabinoid products away from work, such substances may remain in employees' systems during work hours.⁴⁷

Occupational Safety & Health Act

The Occupational Safety and Health Act (OSH Act) imposes a general duty on employers to "furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees."⁴⁸ Violations of the OSH Act can result in civil penalties of up to \$70,000 and imprisonment.⁴⁹

Requiring employers to cover non-FDA-approved cannabinoid products may contribute to hazards in the workplace if employees are impaired on the job. The risk of impairment from marijuana use is generally recognized by industries with safety-sensitive positions. Physical harm or death is foreseeable when an impaired employee performs safety-sensitive tasks due to impacts on the employee's psychomotor skills and cognitive abilities.⁵⁰

Tort Liability

Employers can be vicariously liable for the actions of an employee acting within the scope of employment under the common law tort doctrine of "respondeat superior." Therefore, an employer could be liable for acts of an impaired employee that injures a third party or damages the third party's property while acting within the scope of employment. If employers are required to cover non-FDA-approved cannabinoid products through workers' compensation or a health plan, it is foreseeable that an employee could be impaired while acting within the scope of employment as a result of using such products.⁵¹

Health & Safety Risks

Coverage mandates would promote the distribution of products that the FDA has not deemed to be safe and effective.⁵² FDA has noted that non-FDA-approved cannabinoid products "can have unpredictable and unintended consequences, including serious safety risks."⁵³ For example, non-FDA-approved CBD products have been found to contain illegal levels of THC and harmful metals, toxins, and mold. One study found illegal substances that cause impairment, such as "spice" or "K2," in one third of the CBD vape oils analyzed.⁵⁴

MORE INFORMATION

For more information on the health and safety risks of marijuana and other non-FDA-approved cannabinoid product use, see Aimed Alliance's [Cannabinoids: A Fact Sheet for Consumers](#).

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