

ACTION BRIEF

Employer Strategies that Drive Value



CANNABIS PRODUCTS ON THE FORMULARY

ADHERING TO EVIDENCE- AND VALUE-BASED STANDARDS

ACTION STEPS FOR EMPLOYERS:

1. Apply the same evidence-based and value-based standards to cannabis-derived products that are applied to all other drugs on your company's formulary.
2. Scrutinize the manufacturing and quality control standards that apply to non-FDA-approved cannabis products sold in your state.
3. Engage legal counsel when considering coverage for non-FDA-approved cannabis products.
4. Consider the implications of cannabis coverage policies that encourage greater cannabis use by employees, especially those in safety-sensitive positions.

"We have given marijuana the status of medicine with none of the standards."

— Keith Humphreys, professor of psychiatry and behavioral sciences, Stanford University.

As access to cannabis expands via state-level legalization, employers must address a variety of challenges resulting from employee cannabis use.

Most notably, employers need to confront workplace accommodation issues, workplace safety challenges, and coverage decisions. These issues are complicated by the fact that possessing cannabis and aiding and abetting the possession of cannabis remain illegal under federal law.

This *Action Brief* focuses on issues raised by health insurance coverage for employee use of non-FDA-approved cannabis products and offers action items employers can implement to achieve the most medically effective and cost-effective coverage for their workforce.

1. **Apply the same evidence-based and value-based standards to cannabis-derived products that are applied to all other drugs on your company's formulary.**

A benefit-risk assessment is the foundation of our system for approving medicines and protecting patient safety. Before a therapy can be delivered to patients, a comprehensive, rigorous review of the drug must be performed by the U.S. Food and Drug Administration (FDA) to determine if the drug is effective in treating, preventing or mitigating disease and that the drug's



What is Cannabis?

Cannabis sativa L., or marijuana, as it is commonly called, is a flowering plant that has been cultivated for centuries and used for a variety of purposes. Cannabis is also the source of more than 100 plant-derived chemical compounds called cannabinoids. The two most well-known and commonly occurring cannabinoids are tetrahydrocannabinol (THC) and cannabidiol (CBD).

(See the National Alliance Clinical Brief, Medicinal Uses of Cannabis-Derived Products, for more detail)

expected benefits outweigh its potential risks to patients.

Despite the serious adverse health effects associated with cannabis use (e.g., changes in brain structure and development of psychoses; increased risk of heart attack and impaired heart

“Cannabis and cannabis-derived products claiming they’re intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases...are considered new drugs or new animal drugs and must go through the FDA drug approval process for human or animal use before they are marketed in the US. Selling unapproved products with unsubstantiated therapeutic claims is not only a violation of the law, but can also put patients at risk, as these products have not been proven to be safe or effective.”

— U.S. Food and Drug Administration

functioning), robust studies assessing whether the benefits of non-FDA-approved cannabis products outweigh the risks have not been performed. Most evidence cited to support the therapeutic effects of unapproved cannabis products is anecdotal or comes from preclinical trials, or from ecological or observational studies that do not control for bias or other confounding factors.

These lower levels of evidence are not enough to permit conclusions regarding the effect of these products on health outcomes. And they do not demonstrate that cannabis use achieves favorable health outcomes relative to established alternative therapies. In fact, because unapproved cannabis products are so understudied, their utilization may result in negative health outcomes that harm patients and increase costs. For example, many “medical marijuana” patients use unapproved cannabis products as a component of cancer treatment, often to address nausea associated with chemotherapy. But recent research out of the University of California San Diego found that THC, one of the major cannabinoids found in cannabis, can accelerate cancer cell growth in patients with certain types of head and neck cancer.

Important questions need to be addressed before we reach conclusions about the safety and efficacy of cannabis as a medicine. Further study is needed to identify specific conditions that can be effectively treated with cannabis, and to determine what doses and delivery modes are safe and effective. Long-term use of these products needs to be studied to evaluate benefits and harms. FDA approval of specific formulations is also needed.¹

Today, the evidence does not exist to warrant coverage for non-FDA-approved cannabis products.

2. Scrutinize the manufacturing and quality control standards that apply to non-FDA-approved cannabis products sold in your state.

Consistent identity, purity and quality are hallmarks of the prescription medicines we use. Federally mandated manufacturing standards for FDA-approved drugs cover every aspect of the production process. Adherence to current “Good Manufacturing Practices” helps ensure batch-to-batch and dose-to-dose consistency, identity and purity in FDA-approved medicines. Non-FDA-approved cannabis products are subject to varying and inconsistent manufacturing and quality control standards at the state level. As a result, unapproved cannabis products frequently go to market with significant quality control issues; patients cannot rely on consistent identity and purity in these products. By way of example:

- ▶ Last year ABC News published a study in which the 240 most popular cannabidiol (CBD) products on the market were tested for 300 different contaminants. And after thousands



¹ There are, in fact, FDA-approved cannabis-derived medicines available. Epidiolex®, a highly purified CBD oral solution, is approved for the treatment of seizures associated with two forms of intractable epilepsy; nabilone is indicated for the treatment of nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments; and dronabinol is indicated for the same medical condition, as well as the treatment of anorexia associated with weight loss in patients with AIDS. Due to the rigor involved in obtaining FDA approval, many employers include these medicines on their formularies.

of tests, 70 % of products were found “highly contaminated” with heavy metals, herbicides and a host of other contaminants, including pesticides and toxic mold.

- ▶ A recent study published in the *Journal of the American Medical Association* tested 84 different cannabis products and observed that the CBD content in nearly 70% of products was inaccurately labeled, meaning the product contained significantly more or significantly less CBD than indicated on the label.
- ▶ In the first few months of 2020, numerous states, including Alaska, Colorado, Michigan, Nevada, Oklahoma, and Oregon, have recalled cannabis products due to contamination from pesticides, molds,



“Contaminated, adulterated, unregulated and unsafe cannabis products continue to be sold every day, with consumers generally unaware that in some states no one is regulating the process from growth to purchase.”

— Cannabinoid Clinical

fungus or other potentially harmful adulterants.

Such quality deficiencies can negatively affect health outcomes for patients using unapproved cannabis products. When considering coverage decisions regarding non-FDA-approved cannabis products, employers should scrutinize the manufacturing and quality control standards that apply to the products sold in their state.

3. Engage legal counsel when considering coverage for non-FDA-approved cannabis products, given their illegal status under federal law.

There are critical legal considerations inherent in an employer paying for employee cannabis use.

Cannabis remains a Schedule I controlled substance under the federal Controlled Substances Act (CSA) (“hemp,” defined as the cannabis plant and plant derivatives containing no more than 0.3% THC is exempt from the CSA). Possessing cannabis, even for medical purposes, is a violation of federal law. Federal law also prohibits aiding or abetting the commission of a federal crime.

Within the workers’ compensation context, state courts have determined that covering the cost of an injured worker’s cannabis use constitutes aiding and abetting the unlawful possession of cannabis under federal law. In 2018, the Maine Supreme Court held that an employer “... would act in contravention of the CSA if it were to fund [its employee’s] acquisition of medical marijuana.”² The consequences of violating the federal CSA could be severe, including criminal prosecution, fines and forfeiture of property. Further, the practical consequences for employers perceived as engaging in cannabis commerce could be difficult.



Under the federal tax code, employers may be barred from deducting business expenses incurred in connection with payments for cannabis because regular purchases of cannabis may be deemed “trafficking” in the drug.³ And employers could lose access to crucial business and financial services.

Employers should engage legal counsel to address these concerns as they consider covering employee use of non-FDA-approved cannabis products.

4. Consider the implications of cannabis coverage policies that encourage greater cannabis use by employees, especially those in safety-sensitive positions.

Covering cannabis as part of an insurance benefit may result in greater cannabis utilization among employees. But increased use of cannabis among employees can create a significant risk of injury to workers and members of the public.

The research is clear, THC in cannabis has an impairing effect, even at low levels, and can cause dizziness, disturbances in attention and concentration, disorientation, impairment of motor skills and loss of full control of bodily movements. For

² *Bourgoin v. Twin Rivers Paper Co., LLC*, 2018 ME 77. Earlier this year, the New Jersey Court of Appeals reached a different conclusion. That decision is under appeal to the state supreme court.

³ 26 U.S.C. § 280E (“No deduction or credit shall be allowed for any amount paid or incurred during the taxable year in carrying any trade or business [that] consists of trafficking in controlled substances ... which is prohibited by Federal law....”).



or acceptable for employees who work in safety sensitive positions.”

Employers have a duty to provide a safe workplace and to take all necessary steps to protect the health and safety of their employees and others in the workplace. When considering whether

employees with safety-focused positions, such as operating machinery or driving a vehicle, THC-induced impairment can have serious consequences. Studies indicate a link between cannabis use and adverse workplace consequences, including increased risk of injury or accidents. According to a study from the National Institute on Drug Abuse, workers who tested positive for THC had 55% more industrial accidents, 85% more injuries, and 75% greater absenteeism compared with those who tested negative for THC use.

Based on studies like these, in late 2019, the National Safety Council released a position paper concluding “there is no level of cannabis use that is safe

to cover cannabis use as an insurance benefit, employers should consider the potential for increased cannabis utilization among their employees, the impairing effects of THC, and the negative workplace safety implications that may result.

Because the cannabis industry is dynamic and rapidly expanding, it is important for employers to understand the market and make thoughtful formulary decisions. When faced with coverage decisions related to employees’ use of non-FDA-approved cannabis products, employers should apply the same evidence-based and value-based standards applied to all drugs on the organization’s formulary.

“Research clearly shows that cannabis impacts a person’s psychomotor skills and cognitive ability. In order to protect our employees and those around them, we need to acknowledge the impairing effects of cannabis. We urge employers to implement policies stating no amount of cannabis consumption is acceptable for those who work in safety sensitive positions.”

— Lorraine M. Martin, president and CEO of the National Safety Council.

RESOURCES FOR EMPLOYERS:

- [Clinical Brief: Medicinal Uses of Cannabis-derived Products](#)
- [Cannabinoidclinical.com](#)
- [Statement from FDA Commissioner on Signing the Agriculture Improvement Act](#)
- [National Institute on Drug Abuse \(NIDA\): Marijuana](#)
- [FDA Advances Work Related to Cannabidiol Products with Focus on Protecting Public Health, Providing Market Clarity](#)



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1015 18th Street, NW, Suite 730 · Washington, DC 20036

(202) 775-9300 (phone) · nationalalliancehealth.org

twitter.com/ntlalliancehlth

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