



EDUCATIONAL RESOURCES

ENTERING THE CBD ARENA – PITFALLS TO AVOID

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WHAT EVERYONE NEEDS TO KNOW ABOUT CBD

- In a July 2019 report from the Brightfield Group, a market research company, the growth statistics are staggering.
 - Brightfield is forecasting year-over-year CBD product sales growth in the United States of 706% in 2019 to around \$5 billion and sales of \$23.7 billion by 2023.
 - Comparatively, about \$620 million worth of CBD products were sold in 2018 in the United States (based on 706% growth to \$5 billion).
 - Growing CBD revenue from about \$620 million in 2018 to \$23.7 billion by 2023 works out to a compound annual growth rate (CAGR) of a whopping 107%!
- 62% of CBD users reported using it for a medical condition, with the top three reported conditions for use being pain, anxiety, and depression.

WHAT EVERYONE NEEDS TO KNOW ABOUT CBD

- There is, and will continue to be, a dramatic increase in demand for CBD products.
- Healthcare providers need to understand potential drug interactions between CBD and other pharmaceuticals.
- For some providers, this may be a market they wish to consider entering, but it is not without risks of which the pharmacies should be aware.

THE KEY TERMS

- There is, and will continue to be, a dramatic increase in demand for CBD products.
- THC (delta-9-tetrahydrocannabinol) – This is the psychoactive component of cannabis that is the primary cause of the “high” associated with cannabis in recreational users. THC has long been thought to have some medical benefits.
- CBD (Cannabidiol) – This is a cannabinoid that some think has more potential medical benefits than THC but with minimal psychoactive effects. CBD does not cause a “high.”
- CBD Oil – CBD Oil is derived from the cannabis plant through a distilling process.
- Marijuana – In the most basic form, marijuana is made of the dried flower buds of cannabis plants, which contain the highest concentrations of THC.

THE KEY TERMS

- Hemp – Hemp is a cannabis plant, particularly used for the soft fiber derived from the stalk of the plant. THC is present in hemp in trace amounts. In the United States, to be classified as “hemp,” the government requires that it contain no more than 0.3% THC.

WHAT DISTINGUISHES CBD PRODUCTS?

CBD	THC & Marijuana
Does not create a “high”	Does create a “high,” due to its psychoactive component
Under federal law, legal CBD products in the U.S. are derived from hemp; state laws may also allow marijuana-derived CBD	Marijuana has a higher THC than hemp
Typically said to treat seizures, depression, migraines, other mental disorders, and joint pain or swelling; both CBD and THC can be used to treat pain, anxiety, and nausea	Potential medical uses include glaucoma, muscle spasticity, and insomnia. Both CBD and THC can be used to treat pain, anxiety, and nausea.
Few known side effects. It may raise the level in the blood of certain medications.	Potential side effects may include <ul style="list-style-type: none"> • slower than average response time • memory loss • feeling of being “high” • coordination issues • increased heart rate • dry mouth • red eyes
Some research suggests that CBD is an inhibitor of CYP450 enzymes, common in drug metabolism, which creates more potential drug-to-drug interaction issues and safety concerns.	
The World Health Organization (“WHO”) reports that CBD shows no effects to indicate abuse or dependence potential	

HOW CAN CBD BE TAKEN?

- Inhalation (vaping or smoking) – This may expose the user to carcinogens from smoking and unknown potential long-term side effects of vaping.
- Sublingual Products – Sprays, oils, or lozenges that allow the CBD to be ingested without being subjected to the digestive track.
- Edibles – These include gummies, truffles, mints, baked goods, drinks, etc.
- Topicals – There are numerous CBD-infused lotions, balms, salves, and transdermal patches.

WHAT DOES CBD TREAT?

- Childhood Epilepsy Syndromes – The strongest scientific support for CBD use is for childhood epilepsy syndromes, such as Dravet syndrome and Lennox-Gastaut syndrome, which do not respond to antiseizure medications. The FDA approved Epidiolex, which contains CBD, to aid patients with these conditions.
- Anxiety, insomnia, other mental health issues – CBD is commonly used in association with these issues. There is, however, little scientific support.
- Chronic Pain – A European animal study showed CBD applied to skin could lower pain and inflammation due to arthritis.

*There is still very little scientific research on the effectiveness of CBD and even fewer human studies. As the ability to access CBD and hemp increases, more studies will be conducted.

FEDERAL LAW: THE 2018 FARM BILL

- The Agriculture Improvement Act of 2018 (Farm Bill) was passed in December 2018.
- It established a new category of cannabis: Hemp, defined as cannabis containing 0.3% or less of THC. The Act also noted that marijuana (a Schedule 1 illegal substance), as defined in the Controlled Substance Act (CSA), does not include “hemp.”
- This does not make all CBD products legal under federal law.
- The Farm Bill provides that state governments may create regulatory frameworks for industrial production of hemp.

WHAT CAN AND CANNOT BE DONE UNDER FEDERAL LAW

- The Farm Bill only legalized products derived from hemp that are produced in accordance with the Farm Bill, which requires hemp be grown by licensed producers pursuant to state or federal regulations.
- The FDA Commissioner stated that the Farm Bill “explicitly preserved the FDA’s current authority to regulate products containing cannabis or cannabis-derived compounds under the Federal Food, Drug and Cosmetic Act and Section 351 of the Public Health Service Act.”

WHAT CAN AND CANNOT BE DONE UNDER FEDERAL LAW

- So, what does this mean? If the CBD is derived from hemp produced in accordance with the Farm Bill, it may be legal under federal law, depending on the purpose for which it is grown.
- To date, with the exception of Epidiolex, no product containing cannabis or cannabis-derived compounds has been approved as safe and effective for use in any patient population.

FEDERAL PITFALLS

- CBD cannot be sold as a dietary supplement or food additive, according to the FDA, because CBD is the active ingredient in an FDA-approved drug, Epidiolex.
- Until the FDA approves CBD as a supplement or food additive, there are legal risks, including licensure and DEA action, involved with selling these types of CBD products.
- Unless dictated otherwise by state law, the CBD products currently on the market are not regulated. Unregulated CBD products are often the subject of poor-quality control.
- Some CBD sellers and manufacturers have made egregious, unproven claims about CBD products.
- The FDA has issued numerous warning letters.

FEDERAL PITFALLS

- Some lessons can be derived from these warning letters
 - Avoid CBD products with over-the-top therapeutic claims, such as that a CBD product may cure cancer, arthritis, Alzheimer's, bipolar disorder, or opioid addiction.
 - Avoid CBD products that make “drug-like” claims that they prevent, treat, or cure pain, anxiety, inflammation, etc.
 - Be aware that claims on social media are also being monitored and referenced in warning letters.

THE BOTTOM LINE UNDER FEDERAL LAW

- At first glance, the Farm Bill appears to throw open the CBD door. Proceed with caution, however, because it becomes quickly apparent that the wide-open door is largely an illusion.
- Consider all the carve outs:
 - No products with THC over 0.3%
 - No unapproved health products, dietary supplements, or food (which means literally almost everything but the one drug approved by the FDA and possibly some topical items)
- The FDA can pursue these violations, but it has limited staff for enforcement and only warning letters have been issued to date.
- What are left are very few “legal” products under federal law.

WHAT ABOUT STATE LAW?

- While federal law does not give clear guidance, state laws add another layer of complexity that providers must wade through in evaluating whether or not to enter the CBD arena.
- The answer to almost every question under state law is, “It depends.”
- There are scenarios in which activities are legal under federal law but prohibited under state law and vice versa.
- To further complicate matters, a number of states have statutes that legalize CBD products derived from marijuana, with varying degrees of carve outs and regulations.
- Even the “pitfalls” now have “pitfalls.”

STATE LAW LIMITATIONS

- Does the state's law apply to all entities?
 - Each state's law is different. A state's law will normally specify who can grow, manufacture, or sell a CBD or THC product. A state's law may designate a process for licensure. In Kentucky, for example, there is not a limitation on who can have a CBD product derived from industrial hemp. However, CBD derived from marijuana is only excepted when "transferred, dispensed, or administered" pursuant to the order of a physician practicing at a hospital or clinic associated with a Kentucky public university or medical school.
- Many state laws dictate when CBD can be dispensed by limiting its use to certain medical conditions or modifying the amount of THC a product can contain to be excepted from prosecution.
- In light of the Farm Bill, many states are expanding the allowed use of hemp-based CBD.

WHAT DOES THE BOARD OF PHARMACY SAY?

- Each pharmacy must check the Board of Pharmacy's rules for the state(s) in which the pharmacy operates.
- For example:
 - The North Carolina Board of Pharmacy answered a question in its FAQ page stating pharmacies cannot legally sell CBD "supplements."
 - The West Virginia Board of Pharmacy initially voted to prohibit the sale of non-FDA approved CBD products in the pharmacy setting, but then withdrew that prohibition. It cautioned pharmacies to carefully consider the impact state and federal laws might have on sales and noted that over a third of the samples of CBD oil tested contained THC, a Schedule 1 controlled substance.

WHO CAN BUY CBD PRODUCTS?

- Can a minor buy CBD? Possibly, depending on the product and jurisdiction. While the Farm Bill paved the way for hemp-derived CBD products to be widely available, there are, however, other factors that should be considered. Vaping or Juuling is not permitted for minors. Depending on the type of CBD product, a minor may not be able to buy or legally possess it. Local law enforcement branches have differing views on whether an individual under 21, and certainly under 18, can possess CBD.
 - As the law continues to develop on CBD, more definitive rules will likely come forth regarding what CBD products minors of different ages can purchase and possess.
- State laws govern what is required for an individual to obtain CBD, and this is further controlled by the type of CBD product, amount of THC in the product, etc.
- Some states require a physician prescription or recommendation for certain products, while others do not.

TO CBD OR NOT TO CBD

- Scenario 1: Provider A is located in State A that allows the sale of CBD to any individual with no restrictions. Can a Provider A sell CBD-infused drink? What about CBD-infused moisturizer?
 - The law of State A allows Provider A to sell both. However, selling the CBD-infused drink would be prohibited under federal law. The legality of the moisturizer under federal law would depend on the THC content and whether any health claims are being made.

TO CBD OR NOT TO CBD

- Scenario 2: Provider A is located in State A where the sale of industrial hemp and CBD oil is prohibited. (1) Can Provider A sell CBD-infused moisturizer to a resident of State A? (2) Pharmacy A is also licensed in a State B where all CBD is legal. Can Provider A sell CBD products to residents of State B?
 - Answer to First Question: No, even though the sale of the CBD-infused moisturizer might be legal under federal law, it is prohibited under the law of State A.
 - Answer to Second Question: Maybe. This would require an analysis of the laws of both states to ensure that Provider A would not be jeopardizing its license in State A. It would also be wise for Provider A to consult with State A's Licensure Board.

IS THIS THE TWILIGHT ZONE?

- The CBD arena potentially puts providers in situations where an activity may be prohibited under federal law but acceptable under state law. Though CBD can be seen in stores, pharmacies, and gas stations around the country, this does not mean that the products are being legally sold under federal and state law.
- Providers, in particular, should exercise caution. They must comply with (i) federal and state law addressing CBD, (ii) state licensure laws, and (iii) third party payor requirements.
- Before entering the CBD arena, providers would be wise to seek a legal opinion on what products they can legally sell, what form of CBD products are permitted, and what, if any, physician recommendations or requirements are required.

TEST QUESTION #1

- Which of the following is another name for CBD?
 - A. Cannabidiol
 - B. CBD oil
 - C. Cannabis
 - D. Hemp

ANSWER TO TEST QUESTION #1

- Which of the following is another name for CBD?
 - A. Cannabidiol
 - B. CBD oil
 - C. Cannabis
 - D. Hemp

TEST QUESTION #2

- From a federal standpoint, when is it appropriate for a pharmacy to sell CBD?
 - A. Joint Pain
 - B. Depression
 - C. Certain epilepsy disorders
 - D. When state law allows the sale

ANSWER TO TEST QUESTION #2

- From a federal standpoint, when is it appropriate for a pharmacy to sell CBD?
 - A. Joint Pain
 - B. Depression
 - C. Certain epilepsy disorders
 - D. When state law allows the sale



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QUESTIONS?

Email us at auweb@achcu.com



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THANK YOU

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