Center for Health and Wellness Law, LLC

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Spring 2019 Newsletter

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Wellness Professionals and Integrative Medicine Practitioners Who Bill Insurance May Benefit from *Wit v. United Behavioral Health* Decision

On March 5, 2019, the U.S. District Court of the Northern District of California ruled that United Behavioral Health ("UBH"), which also operates OptumHealth Behavioral Solutions, breached its fiduciary duties under the federal Employee Retirement Income Security Act ("ERISA") because UBH had a financial conflict of interest when it developed and implemented its Level of Care Guidelines and Coverage Determination Guidelines.

ERISA requires health plans, and those who administer health plans, such as UBH, to:

- Operate the plan for the exclusive purpose of providing benefits to participants and their beneficiaries;
- Defray reasonable expenses of administering the plan; and
- Operate the plan in accordance with the governing documents of the plan.

29 USC § 1104(a)(1)(A), (B), & (D).

UBH operated both insured and self-insured plans and the court found it had a conflict of interest in both types of plans because its aim was to keep expenses down rather than following generally accepted standards of care. In other words, UBH developed internal guidelines that its hired clinicians used to accept or deny claims for behavioral health treatment, rather than relying on criteria developed by the American Society of Addiction Medicine, which have achieved widespread acceptance among behavioral health professionals. *Wit v. UBH*, 14-cv-2346, at 27 (March 5, 2019). Furthermore, the court noted that UBH failed to insulate the individuals who developed its internal guidelines from UBH's financial considerations. Indeed, administrators from UBH's Finance and Affordability Departments helped approve the guidelines. Because UBH's guidelines were based more on its own bottom line than on the interests of plan members (such as whether the plan member needed

residential mental health treatment), the court found that UBH breached its fiduciary duties of a duty of loyalty, duty of due care and duty to comply with plan terms.

What might this decision mean for other wellness professionals?

If you are a wellness or integrative health professional who:

- Bills insurance (particularly employer-based plans);
- Your profession has generally accepted standards of care
- You feel like insurance denies coverage in violation of those standards

You or your patients may be able to use this court decision to argue that the insurer denials are in breach of the insurer's fiduciary duty. Other wellness professionals may have standards that relate to treatment of chronic conditions that health plans frequently ignore in exchange for higher profit margins. The *Wit v. UBH* case is significant because it calls into question a very large insurer's internal guidelines that the court found benefitted the plan's bottom line rather than the plan's beneficiaries.

If you need assistance in determining whether this case may benefit your practice do not hesitate to contact the Center for Health and Wellness Law, LLC.

Cannabidiol (CBD) and the Wellness Industry: Know What You are Getting Into, Legally

By Barbara J. Zabawa, JD, MPH and Joe Forward, JD, Center for Health and Wellness Law, LLC

Marijuana has captured a lot of attention lately, as 34 states have legalized medical marijuana. But marijuana's cousin, Cannabidiol (CBD), derived from hemp, is making major waves. Hemp and marijuana are varieties of the same Cannabis plant, but hemp contains less than 0.3 percent of tetrahydrocannabinols (THC), marijuana's psychoactive component. In other words, an individual can't get high on hemp.

Industrial hemp has thousands of applications. In many countries, hemp fibers are used for paper and textiles, strings and ropes. Hemp grains are cultivated for food. And hemp and CBD oil, generally produced through different extraction processes, are used in beauty products, like soap, or nutritional supplements.

The U.S. health and wellness industry, in addition to the food and beverage industry, has jumped head first into hemp-based CBD, with proponents touting a myriad of nutritional and lifestyle benefits, including therapeutic benefits, from relieving inflammation, pain, or anxiety, to preventing cancer.

It's a full-blown CBD craze. Health and wellness retailers are selling CBD-infused oils, candies, pills, and powders. Cafes and bars are selling CBD-infused drinks. Restaurants are creating CBD-infused menus. The beauty industry is selling CBD lotions and creams. Even pets are gaining access to CBD products, through CBD pet supplements. The market for CBD products is expected to surpass $20 billion by 2022.

But lurking behind the CBD craze is a legal maze. Food and drugs are highly regulated. Health and wellness professionals, and those in other industries selling CBD products, must be well-informed about CBD laws and regulations to ensure their industry practices do not run afoul of the law. The good news is that state and federal law on CBD is starting to develop. The bad news is that it's still very complex.

The remainder of this article provides an overview of the current legal status of CBD, and provides some insight on what wellness and other professionals should do to avoid and minimize legal risks in this area.

Hemp Production Legalized

Until recently, hemp was considered a controlled substance under federal law. Hemp's family ties to marijuana meant industrial hemp could not be produced legally in the United States. That changed in 2014, when Congress authorized state-licensed pilot projects for the cultivation of industrial hemp.

A majority of states implemented industrial hemp pilot projects, and the industrial hemp harvested through these pilot projects could be sold in the U.S. hemp market, in pilot project states, consistent with applicable laws. That produced a major wave of hemp-based products sold in the U.S. market today, including CBD.

The most recent Farm Bill, enacted in 2018, legalized industrial hemp production in the U.S. as an agricultural product and allows hemp-based products to be sold across state lines, regardless of pilot project status. Any industrial hemp cultivation and production must adhere to state and federal laws, and state-based legislation is currently focused on licensing, seed certification, and other requirements.

The FDA is Watching

Regulation of CBD products by the U.S. Food and Drug Administration (FDA) is where it gets murky. As its name implies, the FDA regulates foods and drugs, and it has been actively monitoring the CBD market. The FDA is specifically looking to see if CBD products are marketed as "drugs" and/or dietary supplements.

CBD products are often marketed for their healing properties. For instance, one FDA warning noted a company that marketed CBD products online through testimonials, attesting that

"scientific research by doctors have shown it actually kills cancer cells and provides a protective coating around brain cells."

Such marketing claims imply that CBD is a "drug" and puts the targeted CBD products within the purview of the FDA as "drugs" intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.

Drugs must be FDA-approved. Only one product containing CBD is currently FDA-approved as a safe and effective drug, and that is Epidiolex for the treatment of seizures for patients with certain syndromes.

Thus, any company or person that makes claims about the therapeutic benefits of its CBD products could face FDA enforcement actions for marketing the product as a non-FDA-approved drug. Recently, the FDA Commissioner reiterated that CBD products marketed with claims of therapeutic benefit, for animals or humans, must be FDA-approved for their intended uses before they are marketed and sold in the U.S.

What About CBD as Dietary Supplements or CBD-Infused Food or Drink?

Companies that market CBD products as dietary supplements must be mindful of the Food, Drug, and Cosmetic Act (FDCA), which says manufacturers and distributors of new dietary ingredients must submit premarket safety notifications to the FDA before introducing them into the market. The FDA has expressly said products containing CBD cannot be sold as dietary supplements without pre-approval.

In addition, the FDA has expressly said that introducing CBD-infused food or beverage into interstate commerce is unlawful without prior approval. "Under the FD&C Act, it's illegal to introduce drug ingredients like these into the food supply, or to market them as dietary supplements," the FDA Commissioner said.

Some cities and states are responding by ordering the removal of CBD-infused beverages and food items from menus, and those types of regulatory steps will likely continue until more definitive research concludes that CBD is both safe as a dietary supplement or can be safely used as an over-the-counter drug.

At least 18 states limit use of CBD products to medical use, meaning a physician or health professional with prescribing authority must determine that CBD could benefit the patient. Thus, wellness or other vendors who sell CBD products at retail should ensure such activity meets legal requirements.

Enforcement of CBD-related laws may vary by state, but don't be fooled when someone tells you CBD is "totally legal in all 50 states." There are facts and circumstances that alter that

conclusion, and health and wellness professionals would be wise to understand the legal ramifications of introducing a CBD product.

The CBD market enthusiasts will be pushing for a "generally recognized as safe" designation from the FDA, which would allow the sale of CBD products as dietary supplements without FDA approval, but that has not happened yet, at least with CBD. But, it HAS happened with hemp seed-derived ingredients for use in human food. The FDA recently evaluated three ingredients and did not object to the conclusion that these products are generally recognized as safe (GRAS):

1. Hulled hemp seed (GRN765)
2. Hemp seed protein powder (GRN771)
3. Hemp seed oil (GRN778).

Speaking with experienced legal counsel is your best bet before taking the CBD plunge.

So What is a Wellness Professional To Do?

Although the legal landscape for CBD oil is complex, it is not necessarily a roadblock. Wellness professionals interested in this area should weigh several considerations. First, would the wellness professional benefit by working with hemp seed-derived products instead of CBD oil? Working with hemp seed-derived products may prove less risky until the FDA loosens its stance on CBD oil. Second, the FDA has noted that there are pathways to legally provide CBD-based products, such as through FDA approval. Third, the wellness professional's state and local rules can matter. Looking at the wellness professional's local legal environment and marketing practices is important to determining the risk of an enforcement action. Wellness professionals who want to incorporate CBD oil into their practice or service/product offerings should seek legal counsel who can help them navigate these choppy and evolving waters.

This article is intended as educational and informational only. It is not legal advice.

Frequently Asked Workplace Wellness Compliance Questions

Our workplace wellness program administers the "Par-Q+" questionnaire to employees before they engage in a physical activity as part of our program. **The Par-Q+ asks individuals the following Yes/No questions:**

1. **Has your doctor ever said that you have a heart condition or high blood pressure?**
2. **Do you feel pain in your chest at rest, during your daily activities of living, OR when you do physical activity?**

3. **Do you lose balance because of dizziness or have you lost consciousness in the last 12 months?**
4. **Have you ever been diagnosed with another chronic medical condition (other than heart disease or high blood pressure)? Please list conditions here.**
5. **Are you currently taking prescribed medications for a chronic medical condition?**
6. **Do you currently have (or have had within the past 12 months) a bone, joint, or soft tissue (muscle, ligament, or tendon) problem that could be made worse by becoming more physically active? Please list conditions here.**
7. **Has your doctor ever said that you should only do medically supervised physical activity?**

Do we need to provide employees with the EEOC notice before administering the Par-Q+?

Arguably yes. Enforcement guidance by the Equal Employment Opportunity Commission (EEOC) (the federal agency that enforces the ADA) shows that disability-related inquiries and medical exams are much broader than HRAs and biometric screens. These inquiries and exams include:

1. Asking employees whether they are currently taking any prescription drugs or medications;
2. Asking employees whether they have any impairments;
3. Testing an employee's blood pressure or cholesterol levels;
4. Range of motion tests that measure muscle strength and motor function;
5. Psychological tests designed to identify a mental disorder or impairment;
6. Measuring heart rate

See https://www.eeoc.gov/policy/docs/guidance-inquiries.html.

One can imagine that administering a Par-Q+ questionnaire or asking employees to wear a device that monitors their heart rate could fall within the ADA definition of disability-related inquiry or medical exam.

If your workplace wellness activity falls within the category of a disability-related inquiry or medical exam, the ADA requires the employer to give the employee a notice *before* the information is collected. See 29 CFR § 1630.14(d)(2)(iv). You can find a sample notice on the EEOC website. However, you do not have to use the sample notice as long as your notice essentially informs the employee:

- What information you are collecting
- Why you are collecting it
- What you will do to protect it from improper disclosure (and with whom the information will be shared).

So, while it may be an excellent idea to administer the Par-Q+ questionnaire before implementing a physical activity wellness program, it is an equally good idea to assure employees that the information they are disclosing to you is necessary and safe from improper redisclosure or use. The ADA notice is arguably also a good idea for employer wellness programs that are collecting health information through wearable devices, such as heart rate measurements. Many employees may also want that assurance that the display or uploading of their fitness information will be protected and not improperly shared with their employer.

Listen to Barbara Zabawa's Latest Radio Interview on the State of the ACA and CBD Oil!

The Center for Health and Wellness Law's founder, Barbara Zabawa, was interviewed on the Lake Effect show on March 1, 2019.

Need CEUs? Wellness Compliance Institute's Self-Study Course has been Approved for 21 CEUs by HRCI, ACSM, MCHES, CHES and the States of Wisconsin, Indiana and Michigan Insurance Commissioners!

The Wellness Compliance Institute, (WCI) a 501(c)(3) nonprofit, is now offering a self-study course on wellness compliance. The course has been approved for 21 Continuing Education Credits or Units from HRCI, ACSM, MCHES, CHES and the insurance commissioners for Wisconsin, Indiana and Michigan (Ohio approval is pending). Visit the WCI webpage under Continuing Education to learn more and register for the course.

Have you ordered Rule the Rules of Workplace Wellness Programs yet?

The first comprehensive book regarding workplace wellness program compliance is now available for purchase. Order online at www.wellnesslaw.com!

Center for Health and Wellness Law, LLC

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