



TEXAS CBD Today

SUMMER 2018

News from licensed CBD producer Compassionate Cultivation



Contact Us

General info

texasoriginalcc.com or 512-614-0343

Prescribers and patients 512-467-4118

On social media @CBDTexas

Compassionate Cultivation

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- 3 Compare regulated Texas products vs. online products
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Introduction to Cannabidiol for Epilepsy

Approximately 30 percent of people with epilepsy don't respond well to conventional treatments, but cannabidiol (CBD), a non-psychoactive compound found in the cannabis plant, has emerged as a promising alternative treatment option.

Research indicates CBD treatments may decrease the frequency of convulsive seizures in some patients suffering with intractable epilepsy, and numerous patients and caregivers have

come forward across the country in recent years reporting positive responses with integrated use of CBD, which is typically refined into an oil form and ingested.

The state of Texas created a medical cannabis program in 2015 with the passage of the Compassionate Use Act, which allows licensed dispensing organizations to grow cannabis and manufacture CBD products for treatment of intractable epilepsy.



Cannabis oil made at Compassionate Cultivation's Texas facility is refined into special formulations containing precise amounts of the plant compounds cannabidiol (CBD) and low amounts of psychoactive tetrahydrocannabinol (THC). (MaggieFitz Photography)

How the Texas Compassionate Use Act Works for Patients and Physicians

The Compassionate Use Registry of Texas (CURT) is the state-run platform used by physicians and licensed dispensing organizations to provide low-THC medical cannabis (CBD oil) to patients who hold a valid prescription.

PATIENT REQUIREMENTS

1. Be a permanent resident of Texas.
2. Have a diagnosis of intractable epilepsy.
3. Hold a valid prescription from a CURT-registered physician.

PHYSICIAN REQUIREMENTS

1. Must specialize in the field of examining, diagnosing and treating epilepsy.
2. Be registered with CURT as a prescribing physician.
3. Document patient prescriptions in the CURT database, including patient information and their treatment plan.

Essential Info on Adding Patient Treatment Plans Into the State Registry

The first step for physicians is to enroll with the state as a prescriber. Visit the Texas Department of Public Safety (DPS) Compassionate Use Registry Portal. Click the "Physician Registration" link located under the "Licensing" tab and follow the instructions. (See our complete registration how-to online at texasoriginalcc.com/physicians)

Your treatment plan must include: patient's name and date of birth; their prescribed dosage; the means of administration ordered; total amount of low-THC

cannabis required to fill patient's prescription; and how you will monitor patient's symptoms, tolerance and reactions.

Acquire a secondary approval by a fellow CURT-registered physician, and note the physician's CURT username; he or she is not required to have contact with the patient.

It should be noted that a patient can see a CURT-registered physician solely for the purpose of receiving a CBD oil prescription, while retaining their existing relationship with their primary physician/neurologist.

FIRST-TIME PRESCRIPTION ORDERS & REFILLS

To fill a prescription, patient (or guardian) must contact the licensed dispensing organization by phone to confirm the order details and set up a time for pickup at the dispensary or schedule a delivery. Please allow up to one week for deliveries.

CONTACT COMPASSIONATE CULTIVATION

*Prescribers and Patients:
call 512-467-4118*

*For general info, 512-614-0343
Email: info@texasoriginalcc.com*

Why It's Better to Stay In-State With Compassionate Cultivation

OUTSIDE OF TEXAS

Products often utilize industrial hemp grown and processed overseas from places like China and Ukraine.

No mandatory quality-control guidelines.

No purity testing standards.

Uncertainty about whether products are contaminated with heavy metals or pesticides, or if they actually contain the CBD levels they claim.

Anything shipped into Texas containing detectable amounts of THC is illegal, according to the Texas Department of Public Safety.

Since 2015, FDA has issued 40 warning letters to online CBD companies about products not containing amount of CBD on product labels and making unwarranted health claims.

Study by Penn Medicine published in the Journal of the American Medical Association (November 2017) found that nearly 70 percent of CBD-based products being sold online are mislabeled.

★ Need-based patient assistance program, and discounts for military families and in-dispensary pickup.

★ No pesticides used in plant cultivation.

★ Solvent-free extraction process to make CBD oil.

★ Transparency in test results, ingredients and labeling that meet or exceed all state regulations.

★ We make consistent, highly pure CBD medicine at our state-of-the-art facility in Manchaca, 10 miles southwest of downtown Austin.

★ Exceptional customer service in assisting patients, answering questions and fulfilling orders via pickup or statewide delivery.

★ Each batch of CBD medicine is lab-tested to ensure products are free from heavy metals, pesticides and contaminants.

CBD Oil Comparison of Compassionate Cultivation and Popular OTC Products

% (mass/mass)

Actual measured contents of CBD and THC for Compassionate Cultivation products, compared with various CBD products purchased elsewhere by patients. Values represent a random sample analyzed by industry standard HPLC methods using a Restek Raptor ARC-18 and standards obtained from Restek. Analysis performed and reported by third-party testing lab.

Compassionate Cultivation	CBD	THC	CBD:THC	CBN	CBDA	THCA
CCTX Lone Star Peppermint MCT	10.38	0.45	23:1	0.11	0.00	0.04
CCTX Lone Star Cherry MCT	10.00	0.45	22:1	0.11	0.00	0.04
CCTX Lone Star Unflavored MCT	10.08	0.45	22:1	0.12	0.00	0.04
CCTX Lone Star Cherry Safflower	10.39	0.49	21:1	0.00	0.00	0.00
Others	CBD	THC	CBD:THC	CBN	CBDA	THCA
CW Plus Mint Chocolate (Hemp) 100mL	1.71	0.05	36:1	0.03	0.00	0.00
CW Plus Mint Chocolate (Hemp) 30mL	1.71	0.05	36:1	0.03	0.00	0.00
Palmetto Harmony (1) 100mL	1.70	0.06	28:1	0.03	0.05	0.00
Palmetto Harmony (2)	1.56	0.05	31:1	0.00	0.00	0.00
CW Advanced Olive Oil	6.55	0.20	33:1	0.00	0.00	0.00
CW Advanced Chocolate Mint	5.51	0.16	34:1	0.00	0.00	0.00

Our Mission

Compassionate Cultivation is a 100% Texan, state-licensed medical cannabis company dedicated to growing, processing and dispensing the purest, highest-quality CBD medicine to help reduce the suffering of qualifying patients in the Lone Star State.

WHERE THE MAGIC HAPPENS

Inside Compassionate Cultivation's Austin-Area Headquarters

Cutting-Edge Cultivation

Compassionate Cultivation's high-quality cannabis strains are grown from seed through harvest utilizing a strict nutrient management program, integrated pest management systems and horticultural techniques to ensure our plants receive the proper elements, nutrients and care for optimal growth. At our indoor cultivation facility, we adhere to strict sanitation guidelines and

utilize high-tech controls and sensors to monitor the environment and conserve energy during the growth process. Our selected CBD-rich cultivars are processed to yield products with less than 0.5 percent THC and at least 10 percent CBD, adhering to guidelines set out under the Compassionate Use Act.

—Taylor Kirk, Director of Cultivation



Photo: Bobby Scheidemann

State-of-the-Art Processing



Photo: Chris Reichman, Sum & Substance Photography

We utilize a hydrocarbon-free, high-purity CO₂ extraction process to extract pure plant oil from our feedstock. The process is finely tailored through manipulations in temperature and pressure to optimize the capture of components of interest, and performed in a certified, semi-automated, closed-loop system to facilitate the recapture of over 90 percent of the CO₂ used. After extraction, a series of purification, distillation and chromatography steps are implemented, resulting in oil products with cannabinoid purities as high as 99 percent.

—Geoff Young, Director of Processing at lab partner Xabis

About the Texas Compassionate Use Act

This state law enacted in 2015 created guidelines for a medical cannabis program. Under the CUA, the state licensed three businesses, including Compassionate Cultivation, to grow cannabis plants and process them into low-THC products rich in non-psychoactive cannabidiol (CBD) specifically for patients with intractable epilepsy. State-registered physicians can create treatment plans and prescribe CBD products to patients who are permanent Texas residents. Compassionate Cultivation opened the state's first licensed dispensary location in February 2018 and also offers delivery services statewide.



Compassionate Cultivation's Austin-area facility encompasses all aspects of modern medical cannabis cultivation, processing, testing and retail sales.

Advanced Laboratory Testing



Photo: Chris Reichman, Sum & Substance Photography

Product transparency is a key component to providing the quality and consistency of our medicine. Our facility is outfitted with over \$1 million of advanced lab equipment and utilizes state-of-the-art instrumentation and analytical methods to fully characterize each product and provide quality assurance to the patient. All of our products are free of any heavy metals, microbials and chemical contaminants, and they're labeled to clearly state the cannabinoid compositions, enabling patients to know they are using consistent medicine.

—Jason Hamilton, Director of Analytical Testing and Quality Assurance, Xabis

Texas' First Licensed Dispensary

With our Feb. 8 grand opening, Compassionate Cultivation's Austin-area dispensary became the first licensed medical cannabis dispensary to open its doors in the state of Texas. Our patient-friendly dispensary, located at 12701 Lowden Lane in Manchaca, is open to the public, although the purchase of cannabis-based medicine is limited to registered patients and legal guardians. Compassionate Cultivation's expert staff are equipped to answer any questions, as well as provide patient consultations, physician outreach resources and detailed information on our products and retail merchandise. Our high-quality CBD products are available at our dispensary location and through our delivery service, which accommodates patients across the state.

—Compassionate Cultivation Staff



Photo: Compassionate Cultivation Staff

GET THE LATEST CBD NEWS ON
COMPASSIONATE CULTIVATION'S BLOG:
[TEXASORIGINALCC.COM/BLOG](https://www.texasoriginalcc.com/blog)

Dosing Guidance for Physicians

Neurologist Dr. Karen Keough, Compassionate Cultivation's Chief Medical Officer, Shares Her Approach for Prescribing CBD Medicine

Determining a patient's ideal dose and formulation for cannabis-based medications is actually fairly similar to the process of dosing for all new pharmaceutical medications that hit the market.

Like most new medications, dosage recommendations and guidelines for cannabidiol (CBD) medicines are best established according to existing scientific research, anecdotal evidence and individual patient outcomes. Although newly FDA-approved drugs include dose ranges approved in clinical trials, the real-world dosing ranges become

apparent as more patients use the medication. Every new medication that's introduced to the market goes through this process, and CBD-based medicines are no different.

SOURCES OF CBD DOSING INFORMATION

Existing published trials and studies of CBD treatment for intractable epilepsy patients come from a variety of sources, including anecdotal reports from states with medical cannabis programs; a 2015 retrospective study from Israel, a country long considered to be at the

forefront of cannabis research; and placebo-controlled clinical trials of Epidiolex, a CBD drug manufactured by London-based GW Pharmaceuticals, whose results were published in the *New England Journal of Medicine* (2017) and *The Lancet* (2015). The findings indicate CBD-rich cannabis strains can be effective in the treatment of drug-resistant epilepsy, and are generally well tolerated by pediatric and adult patients, with minor side effects. Sleepiness, gastrointestinal upset and diarrhea were most commonly reported.

As with every new medication, conservative initial titration and slow dosage increases will minimize the chance of severe side effects, and avoid reaching a dose beyond that necessary to gain control of seizures.

DOSING RECOMMENDATIONS

For each patient, CBD dosing will depend on the following:

- » Formulation of product (e.g. CBD concentration, THC concentration). Compassionate Cultivation's Lone Star product is 100 mg/ml CBD with 5 mg/ml THC (0.5%).
- » Patient characteristics, including weight, age and the number and type of medications the patient is already taking.
- » Initial dose and rate of titration both need to be considered.

It's important to note that one common seizure medication often used in refractory patients that has a strong interaction with CBD is clobazam (Onfi). Patients taking Onfi should be started on lower CBD doses and titrated more gradually.

Prescription 411 for Physicians

When prescribing CBD for the first time, primary considerations are a patient's starting dose (in milligrams/daily) and rate of titration to maximize efficacy and minimize side effects. It is critical that each section of the patient treatment plan is completely entered and accurate for the prescription to "activate." Once the prescription is active, the prescriber or patient must call the licensed medical cannabis provider to verify and fill the prescription. CURT does not send out "alerts."

PRESCRIPTION FORM BREAKDOWN

Dosage: Number of milligrams of CBD to be taken daily (and frequency).

Administration: Compassionate Cultivation's CBD medication is

currently available in tincture form only. The bottle comes with a 1 mL polypropylene medical-grade syringe. Must specify either "Oral" or "G-Tube" to be in compliance with state regulations.

Amount: Total amount of CBD (in milligrams) for the prescription order. Please note that Compassionate Cultivation offers three sizes of tincture:

7.5 mL (750 mg CBD / 37.5 mg THC)
15 mL (1500 mg CBD / 75 mg THC)
30 mL (3000 mg CBD / 150 mg THC)

If the patient would like to pick up multiple bottles at the same time, the prescribing physician needs to enter the total amount to be picked up. For example, two bottles of 30 mL (containing 3,000 mg CBD each) would be 6,000 mg CBD total.

A Pediatrician Learns to Embrace Cannabis as Medicine

BY DR. KAREN KEOUGH, MD



When it comes to the healing potential of cannabis for people suffering from intractable epilepsy, I believe can-

nabis is medicine—a conviction that I developed gradually based on cumulative anecdotal evidence, but that is now also firmly rooted in recent research.

I didn't always see cannabis this way. When you're entrenched in the treatment of epilepsy, it's inevitable that you'll encounter cannabidiol (CBD), one of the active cannabinoid compounds found in cannabis. But when my patients first came to me years ago with the idea that CBD could be a game-changer, my initial reaction was to tell them, "Don't believe what you're seeing on the news."

I was skeptical, and I didn't expect much to come of it.

When Compassionate Cultivation—one of only three businesses awarded a license in Texas to grow CBD-rich, low-THC cannabis—approached me in early 2017 to ask if I would work with them, I immediately agreed to offer input, but I had to dig deeper on the question of whether I could make a more public declaration of support.

There's still a fair bit of stigma regarding cannabis in the med-

ical world, and I had to better understand what was known and what was not yet known. I had to convince myself that I could stand behind advocating for CBD as an option for therapy, regardless of how that might impact my professional reputation. After doing more research and discussing the idea with my partners at Child Neurology Consultants of Austin, I came to the conclusion that I did very much want to be involved.

The good news is that in the process of assisting Compassionate Cultivation with its license

I myself have gone from cautioning patients not to expect too much from CBD, to realizing that, for many patients, CBD not only meets their needs but exceeds all of our expectations.

application, the legitimacy of this endeavor became much clearer to me. I found more rigorous data have finally started trickling out, including trial results on drug-resistant seizures published in 2017 in the *New England Journal of Medicine*. The timing of this publication was quite fortuitous, since this is exactly the condition that can now be legally treated with CBD under the Texas Compassionate Use Act. That publication meant everything because it was a legitimization of the effectiveness of CBD for the treatment of epilepsy at a level of scientific proof that hadn't been there before. Given promising case reports and successful results

in groups of patients treated in open trials without placebo controls, there are many controlled studies being initiated in the effort to confirm the efficacy of CBD, including a collaboration between the National Institute on Neurological Disorders and Stroke and the National Institute on Drug Abuse.

As a board-certified pediatrician, child neurologist and epilepsy specialist, I understand better than most that you can write anecdotal reports until the cows come home, but physicians won't give that any credence until

there's more controlled data out there. But now that we're starting to see legitimate data, I'd like to encourage my fellow physicians and prescribers to review this important research. I myself have gone from cautioning patients not to expect too much from CBD, to realizing that, for many patients, CBD not only meets their needs but exceeds all of our expectations.

Dr. Karen Keough, M.D. is a Board Certified Child Neurologist and Epileptologist with fellowship training in Neurophysiology, who specializes in treating intractable epilepsy at Child Neurology Consultants of Austin. Keough is also the Chief Medical Officer for Compassionate Cultivation.

This column was originally published on TribTalk, a publication of The Texas Tribune.

Product Information

Lone Star is a panel of condition-specific cannabidiol (CBD) tinctures that are specifically formulated and lab tested to treat qualifying patients with intractable epilepsy under the Texas Compassionate Use Act. Formulated with high CBD levels, low levels of psychoactive tetrahydrocannabinol (THC) and minimal inactive ingredient additives, the Lone Star line is produced using hydrocarbon-free, high purity CO2 extraction processes and rigorous state-of-the-art testing to ensure consistent medicine that is free of heavy metals, microbes and chemical contaminants. As part of Compassionate Cultivation's commitment to transparency, test results are publicly available.

ACTIVE INGREDIENTS (SINGLE CONCENTRATION)

100 mg CBD per 1 mL of tincture

5 mg THC per 1 mL of tincture

SIZES

7.5 mL (750 mg CBD / 37.5 mg THC)

15 mL (1500 mg CBD / 75 mg THC)

30 mL (3000 mg CBD / 150 mg THC)

PRICES

7.5 mL: \$105

15 mL: \$200

30 mL: \$380

Note: The retail cost for a single milligram of CBD is approximately 13 cents.

FLAVORS

Cherry, Mint, Unflavored

INGREDIENTS

CO2 extracted cannabis oil

USP-grade coconut MCT oil*

Food-grade essential oil flavoring

**Safflower oil is available for patients with an aversion to MCT oil. All safflower oil products are unflavored.*

PACKAGING

Tamper-evident, child-resistant clear glass bottle labeled with traceability and dosing information

Box is also fully labeled with traceability, dosing, manufacturer and nutritional information

1 mL medical-grade syringe

Patient slip includes dosing information, plus patient specifics, conversion chart and product overview



PATIENT DISCOUNTS / FINANCIAL ASSISTANCE

Compassionate Cultivation has partnered with Texas Epilepsy Foundation affiliates to create the Compassionate Use Patient Assistance Program (CUPAP), a need-based funding initiative.

To apply or donate, contact your regional affiliate: Epilepsy Foundation of Central and South Texas (efcst.org / 210-653-5353), or Epilepsy Foundation Texas-Houston/Dallas-Fort Worth/West Texas (eftx.org / 888-548-9716).

There is a 10% discount for in-dispensary pickup (cannot be combined with other discounts).

Military families receive a 10% discount with valid proof of service (active or retired).