



Sep 13, 2021

Categories:

[Blogs](#)

[Health Law Matters](#)

Authors:

[Andrea Hope J. Steel](#)

Texas Compassionate Use Institutional Review Boards to Monitor Medical Marijuana Research – Newly Proposed Rule; Comment Period Open

New rules are coming regarding the creation of Institutional Review Boards (“IRBs”) for the Texas Compassionate Use Program (“TCUP”). These Compassionate Use IRBs (“CIRBs”) can be formed by eligible third parties affiliated with one of the licensed TCUP dispensing organizations and will allow for limited medical marijuana research, but the proposed rules lack detail on how researchers can participate.

As mentioned in one of [my recent articles](#), the last legislative session made slight expansions to TCUP, which serves as the state’s only pathway to legally access non-hemp cannabis (a/k/a marijuana or “marihuana”). TCUP is an extremely restrictive medical marijuana program compared to other states, allowing registered patients with qualifying conditions to use a limited array of low-THC cannabis products (as of September 1, 2021, the THC cap will increase from 0.5% to 1%).

One of the provisions of the new law provides for the Health & Human Services Commission (“HHSC”) to create CIRBs.^[1] Generally, an institutional review board is an administrative body or formal committee, often within an academic setting, that reviews and oversees research on human subjects to ensure protection of their rights and welfare and compliance with ethical guidelines. [HHSC has already established two institutional review boards](#), but they do not appear to be connected to the newly authorized CIRBs. The new law allows these CIRBs to be created to research low-THC cannabis medical use for *any* condition designated by the HHSC Executive Commissioner (not just the nine named diagnoses).^[2]

A proposed rule relating to CIRBs was published in the August 20th edition of the Texas Register, but it is broad in nature and lacks details. Though the stated purpose of the proposed rule is to provide guidelines for CIRBs, it essentially reiterates the recently passed legislation but fails to provide interested parties with any substantive details on how to participate.

Background – What Does the New Law Say?

Before detailing what is in the proposed rule, it is helpful to understand the recently passed law concerning CIRBs.

Under the new law, which went into effect September 1, 2021, *one or more* CIRBs may be established. The proposed rule establishes *one*. This is reminiscent of the initial TCUP bill, which required *at least* three dispensaries to be licensed under the program, but subsequent rules and procedures resulted in *only* three licensees. This seems to indicate that Texas will continue to operate its programs very restrictively.

The CIRBs serve the purposes of not only evaluating medical use, but also overseeing patient treatment and, interestingly, certifications of treating physicians. A physician treating a patient under a CIRB-authorized research program is required to be certified by that CIRB.

Under current law and regardless of CIRB status, in order for a physician to be able to prescribe^[3] low-THC cannabis through TCUP, the physician must be properly licensed, board-certified in a relevant medical specialty, and essentially specialize in the patient's particular medical condition. The physician must also register with the state's [Compassionate Use Registry](#) as the patient's prescriber (but the physician's name cannot be published unless the physician expressly consents). The physician is also required to maintain a patient treatment plan that includes dosage, means of administration, anticipated duration of treatment, and a plan to monitor symptoms and indications of tolerance or reactions to low-THC cannabis.

Patients in the TCUP program, whether part of a CIRB or not, must be permanent residents of Texas, and CIRB patients must also sign a

written consent to receive the research treatment (or a parent/guardian/conservator must consent on behalf of a minor or incapacitated patient).

CIRBs must submit written annual reports on their findings to HHSC by October 1 each year, and every other year to the legislature (i.e., even-numbered years).

CIRBs must be affiliated with one of the licensed TCUP dispensing organizations (recall there are currently only three in the state) and meet *one* of the following criteria:

- (1) be affiliated with a medical school;[\[4\]](#)
- (2) be affiliated with a hospital licensed under [Chapter 241](#) that has at least 150 beds;
- (3) be accredited by the [Association for the Accreditation of Human Research Protection Programs](#);
- (4) be registered by the [United States Department of Health and Human Services, Office for Human Research Protections](#), in accordance with [21 C.F.R. Part 56](#); or
- (5) be accredited by a national accreditation organization acceptable to the [Texas Medical Board](#).

What Does the Proposed Rule Say?

Under the law, HHSC was granted the authority to adopt all rules necessary to implement the CIRB program.

The proposed rule implies a CIRB approval process whereby the principal investigator of a proposed research program must clearly identify the medical condition to be treated and shall study only that medical condition identified in the CIRB-approved application. An end date of any CIRB-approved study must be established, but the actual end date may be earlier if either the principal investigator chooses or if the CIRB suspends or terminates the program due to violations or because the treatment is associated with unexpected serious harm to subjects. Note that suspension/termination can be authorized for mere association and not necessarily causation.

The proposed rule also states that CIRB-approved research programs are non-transferable.

The rule includes a few other subsections that reiterate the law regarding patient and physician qualifications and written report deadlines but adds nothing else of substance.

There are no other requirements or timelines and no details about applications. In some respects, this broadness is preferable because the lack of details and restrictions allows for more flexibility and creativity, but, on the other hand, the lack of specificity provides minimal guidance for interested stakeholders.

What Should the Proposed Rule Include?

More details! Rules relating to research and institutional review boards for other programs in Texas exist and are more fleshed out. It seems this rule was proposed simply to have *some progress* before the September 1 effective date, but this attempt is not very informative. At the very least, specifics with respect to timelines, reporting hierarchy, and application guidelines, as well as details regarding the applicability of other Department of State Health Services IRB policies, are important factors that should be included.

While the state's health agencies have much more important issues to deal with right now (ahem, COVID-19), it would be incredibly beneficial for a task force or advisory council to be established to focus specifically on the future of the state's medical marijuana program. The expansion of the TCUP program (and legality of cannabis generally) is inevitable, and Houston is home to the world's largest medical center. The best and the brightest are right here and can and should be utilized to provide another innovation pathway for Texas's ascent as a medical breakthrough leader.

Written comments to the proposed rule are being accepted through September 20, 2021. Please contact me, [Andrea Steel](#) (asteel@fbtlaw.com; 713-590-9346), or anyone on our [Health Care Innovation Team](#) if you would like additional information.

[1] Chapter 487, Texas Health and Safety Code, Subchapter F, as authorized by [HB 1535](#).

[2] To otherwise qualify for TCUP, a patient must be diagnosed with epilepsy, a seizure disorder, MS, spasticity, ALS, autism, cancer, an incurable neurodegenerative disease, or PTSD.

[3] Because marijuana remains illegal under federal law, doctors cannot actually “prescribe” it, but a 2019 change to the TCUP law expressly states that any reference to a prescription for low-THC cannabis in any law means an entry in the TCUP registry.

[4] as defined under [Section 61.501, Texas Education Code](#). Medical schools meeting this definition are: The University of Texas Health Science Center at Houston, the medical school at The University of Texas Southwestern Medical Center, the medical school at The University of Texas Health Science Center at San Antonio, The University of Texas Medical Branch at Galveston, the medical school at The University of Texas at Austin, the medical school at The University of Texas Rio Grande Valley, the medical education program of The University of Texas Health Science Center at Tyler, the medical school at the Texas Tech University Health Sciences Center, the medical school at the Texas Tech University Health Sciences Center at El Paso, the Sam Houston State University College of Osteopathic Medicine, the University of Houston College of Medicine, the Baylor College of Medicine, the college of osteopathic medicine at the University of North Texas Health Science Center at Fort Worth, or the medical school at the Texas A&M University Health Science Center.

© 2026 FBT Gibbons LLP. May be considered attorney advertising in some jurisdictions.