Texas Medical Marijuana Program Rules Open for Public Comment

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The rules governing the Texas Compassionate Use Program (TCUP) are currently under review, and public comments are being accepted through May 2, 2022. The Department of Public Safety (DPS), which is the state agency that oversees TCUP, is reviewing the rules to determine if they are obsolete, reflect current legal and policy considerations, and reflect current procedures of the department. Any proposed changes will be published for additional review and comment in the future. Though the rules are under review, DPS has stated there are no current plans to open the dispensing organization licensing application process.

TCUP was established by Texas lawmakers in 2015 specifically to help those suffering from intractable epilepsy. At that time, the program was incredibly restrictive, capping THC concentration at 0.5% and requiring two physician recommendations. It has since expanded twice, most recently in 2021, and now includes nine qualifying conditions and an increased THC cap of 1%. There are currently two licensed dispensing organizations operating in Texas, [1] though the number of registered patients and physicians continues to grow significantly.[2] Currently, each of these licensees "does it all" – each licensee cultivates, processes, manufactures, tests and dispenses in-house, medicinal cannabis products. This concept is known as "vertical integration" in the industry. Interestingly, however, there is no specific law that requires vertical integration in Texas, which is one area ripe for comment as discussed below in item 1. Medicinal cannabis is provided to patients throughout Texas via delivery and drop-off locations around the state.

The Texas Compassionate-Use Act under the Texas Health and Safety Code and the Texas Occupations Code are the *laws* which govern TCUP, while *rules* are established by DPS. The laws are passed by the Texas legislature, which meets every two years. The laws governing TCUP are broad in nature without many details, but there are certain pieces of TCUP mandated by statute and not

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subject to this current rule review. Requirements such as the 1% THC cap, the listed qualifying conditions (epilepsy, seizure disorders, multiple sclerosis, spasticity, amyotrophic lateral sclerosis, autism, cancer, incurable neurodegenerative diseases,[3] or PTSD), and the ban on medical cannabis for smoking are all prescribed by law and not subject to this current rule review.

The rules are outlined in Chapter 12, Part 1, Title 37 of the Texas Administrative Code. As required by law, DPS must review its rules as currently written every four years, and this review must include an assessment of whether the reasons for initially adopting the rule continue to exist. As part of the review process, the public is invited to submit commentary on the rules. There are a number of rules eligible for revising that are highlighted below which impact physicians, patients, licensees and ancillary businesses, and we encourage stakeholders to consider submitting comments on any of the rules relevant to their interests.

1. Subchapter A (General Provisions)

This subchapter sets out certain definitions, requirements and standards, criminal history disqualifiers, and record keeping requirements. It also includes rules related to testing, production, packaging, inventory control, sanitation, and waste disposal.

As discussed above, one area ripe for comment is to push back against the idea that Texas is a vertical integration state, as the law does not expressly require that, nor does it prohibit multiple licensing categories. While unlikely to change at this juncture, significant public comment on this concept and the idea that DPS could allow for licenses in various categories (such as cultivation, processing/manufacturing, dispensing, testing, transportation, and/or waste, for example) might compel some sort of reconsideration of this concept, even if at a later date.

Another rule prohibits research and development beyond that necessary to make low-THC cannabis and requires all byproducts be destroyed. This prohibition conflicts with the recent law allowing for TCUP Institutional Review Boards and prevents innovation.

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2. Subchapter B (Application and Renewal)

This subchapter sets out the rules relating to the application to become a licensed dispensing organization, registrations, renewals, fees, and application denials.

The TCUP rules require that applications contain evidence of proposed site(s), including ownership information, maps, and floor plans, but states that these site-specific requirements will be inspected following *conditional approval* of the application's threshold items (such as proof of company existence and good standing, names, criminal histories and registration applications of all key staff and owners, and proof of adequate insurance). However, the application itself is heavily weighted based on these site-specific requirements, meaning the application itself does not allow for a conditional approval process as set out in the rules. This effectively means it is not feasible to submit an application without one or more sites in mind and significant headway made to acquire such property at the time of application, even though the rules indicate there is a concept of a conditional approval whereby an applicant can then have the opportunity to invest in site control. This creates an enormous barrier to entry that may not be reasonable for smaller businesses to achieve, and the rules themselves conflict with the application and scoring process.

Texas also has some of the highest medical cannabis licensing fees in the country. Under Section 12.14, an application fee for a dispensing organization license is $7,356 and the license fee is $488,520 for a two-year period. Upon the expiration of the two-year period, dispensing organizations have to pay a $318,511 renewal fee. In addition, there is a $530 fee for both original and renewal license registration. As currently set, the fees to hold a license are over half a million dollars, which inevitably minimizes opportunities for dispensing organizations, especially small startup companies, effectively creating a market available only to well-capitalized companies (essentially multi-state operators). Additionally, fees this high get passed down and built into product pricing, which ends up with medicine being cost prohibitive, especially for those that may be on limited fixed incomes such as social security or veteran benefits. Hence, the "compassionate" piece leaves much to

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be desired when products are too expensive for those who need it most. A decrease in fees could spur an increase in access and allow the program to function more widely in accordance with legislative intent to serve the needs of qualified patients. Since fees are set by rule and not statutory, DPS can revise these them to be more reasonable for potential applicants.

Another suggestion worthy of consideration is the notion of incorporating a set-aside or bonus points for Historically Underutilized Businesses (HUBs) as part of the licensing application process, along with a requirement that a certain percentage of licensee-vendor contracts must entered into with certified HUBs. A HUB is a for-profit business (which does not exceed certain federally mandated caps on gross profits or total employees) primarily based in Texas with majority ownership by a person who is: Asian Pacific American, Black American, Hispanic American, Native American, American woman, and/or Service-Disabled Veteran with a service-related disability of at least 20%. The owner of the HUB must be a U.S. Citizen that has at least one year of Texas residency and control over the daily operations of the business. There are countless state agencies that incorporate HUB goals into the regulations in Texas and TCUP could follow suit.[4]

3. Subchapter C (Compliance and Enforcement)

This subchapter sets out rules relating to inspections, license and registration suspension and revocations, default judgments and hearing costs all relating to complying with the rules and the state's authority to enforce them.

4. Subchapter D (Security)

This subchapter details rules relating to security of facilities and vehicles, as well as responses in the event of a security breach and reporting requirements relating to inventory discrepancy, loss and theft.

As a law enforcement agency, DPS regulates the TCUP program from the lens of a criminal justice agency (as opposed to a healthcare agency operating from a patient access and care

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perspective). Some of these security measures might be unnecessary and are certainly ripe for review by those well-versed in cannabis security facilities in other jurisdictions.

5. Subchapter E (Compassionate-Use Registry)

This section of the rules is geared towards healthcare security measures such as access to the Compassionate-Use Registry, patient prescription verifications, prescriber registrations and prescription requirements.

6. Subchapter F (Special Conditions for Military Service Members and Spouses)

This portion of the rules sets forth certain penalty exemptions and license renewal extensions, as well as alternative licensing for service members, veterans and spouses, in addition to certain credits for military experience and training.

While this section may seem odd, Texas law requires all state agencies with authority to issue licenses to adopt rules of this sort for military service members on active duty and their spouses, as well as veterans. Nonetheless, the function of some of these rules as currently written may not make sense considering the program as a whole. Veterans advocating for cannabis reform have been critical to bettering policies regarding patient access, and these rules have the ability to provide an inherent advantage to those to whom we owe our freedom and privileges. This section could certainly stand to be fleshed out with policies that actualize a tangible benefit for our nation's heroes.

7. Subchapter G (Production Limits)

This subchapter lays out clear limitations with respect to the amount of medical cannabis permitted under TCUP, tying such limitations to the "legislative intent to serve a narrow population of patients living with intractable " This entire subchapter is essentially inapplicable under the current law. Such legislative intent no longer exists because lawmakers have twice expanded the list of qualifying conditions the program serves since these rules were adopted, including the 2019 removal of "intractable" forms of epilepsy,

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allowing all forms of epilepsy to qualify, as well as adding several additional qualifying conditions.

Commentors should consider whether this subchapter should be removed entirely or modified to be applicable under current law. For example, Section 12.61(d) restricts medical cannabis production to a fraction of the population estimated to be living with intractable epilepsy. It is unclear what benefit there is to any TCUP stakeholder, most importantly patients, to have patient access restricted in this manner. Under Section 12.61(f), each licensee is restricted from producing medical cannabis in a disproportionate amount compared to the other licensees, and does so without considering any functional realities such as facility capability or operational status of other licensees. For example, there are currently three licensees, but only two operating. This rule limits the amount of the two operating licensees due solely to the fact the third holds a license with no operations, unduly limiting patient access.

Tips & Strategies for Submitting Comments

For those wishing to submit comments, here are some suggested tips:

- Focus on the rules that are under review. DPS is unable to make changes to statutory requirements made by lawmakers, such as the 1% cap and the list of qualifying conditions.
- Let DPS know which rules you like and want to see remain – if there is silence on a rule, DPS could interpret that as it being unnecessary.
- Point out the specific rule you want to comment on, including the section number and/or topic. Per DPS's notice, "comments must clearly specify the particular section of the rule to which they apply."
- If your comment is general in nature, make that clear too.
- Explain how the regulation impacts you or could impact you, and include real-life situations and data to back up your ideas.

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- Phrase comments in the form of a statement rather than a question. For instance, instead of asking "Why is this here?" in your comment, explain that "This section is not relevant to the program's purpose and is unclear with respect to actual expectations."
- Provide proposals of what you want to see, including specific language if possible. Explaining why your proposed language is better than the current rule helps DPS better understand the need and what is presently missing.
- There is no need to submit comments multiple times – once is enough. Quality over quantity.
- Public comments are part of the public record, so don't reveal private information you would prefer others not have access to.
- Do not miss the comment deadline and submit the comments per the instructions in the notice. Comments should be postmarked on or before May 2, 2022, and mailed to: Susan Estringel, Office of General Counsel, Texas Department of Public Safety, P.O. Box 4087, Austin, Texas 78773-0140. Ms. Estringel has notified us comments will also be accepted via email to RSD.Rule.Comments@dps.texas.gov if received no later than 5:00 p.m. on Monday, May 2, 2022.

Suggested Letter Format

- Begin with an introduction of who you are and why your knowledge, experience, skills and other credentials qualify you to provide thoughtful comments based on reality.
- Provide comments on what you find helpful about the rules and how you or someone you know has benefitted.
- If you have general comments for changes, discuss them separately before diving into specific rule comments.
- For comments specific to a particular rule, cite the rule, explain your comments, and provide proposed language or an idea that resolves the concern.
- Close out respectfully and provide your contact information in the event of desired follow-up.

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While significant rule changes may not be on the immediate horizon, it is important lawmakers and regulators have a written record of public response to TCUP and the needs of patients, physicians, license applicants and licensees. Typically, comments will be summarized and responded to publicly by DPS. This opportunity does not come around often and is critical for effecting change through transparent, public processes and grassroots advocacy.

If you would like a full copy of the current rules or help crafting comments, please contact Andrea Steel (713.590.9346; asteel@fbtlaw.com) or Hannah Johannes (713.590.9312; hjohannes@fbtlaw.com) of Frost Brown Todd's Health Care Innovation Team.

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[1] The two operating licensees are Surterra Texas LLC (d/b/a goodblend) and Compassionate Cultivation. A third organization – Fluent (formerly Cansortium Texas) – holds a license, but does not actively operate within Texas.

[2] Annual reports, including year-to-date statistics of patient counts, physician counts and prescription amounts are maintained by DPS and are available at Reports & Statistics | Department of Public Safety (texas.gov).

[3] An incurable neurodegenerative disease is a condition, injury, or illness: (1) that occurs when nerve cells in the brain or peripheral nervous system lose function over time; and (2) for which there is no known cure. The Texas Department of State Health Services (DSHS) maintains a list of dozens of conditions that qualify as incurable neurodegenerative diseases, which are proscribed by rule and can be added to upon approval by DSHS. That list can be found in Title 25 of the Texas Administrative Code, Part 1, Chapter 1, Subchapter D, Rule § 1.61.

[4] For example, the highly competitive low-income housing tax credit allocation process gives points for applicants that incorporate a HUB in the ownership structure and requires the HUB to have a specified combination of ownership interest, cash flow and fees.

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