May 2, 2022

VIA EMAIL – RSD.Rule.Comments@dps.texas.gov

Susan Estringel
Office of General Counsel
Texas Department of Public Safety
P.O. Box 4087
Austin, TX 78773-0140

RE: Comments on Texas Compassionate Use Program

Dear Ms. Estringel:

The International Cannabis Bar Association ("INCBA") is pleased to submit comments to the Texas Department of Public Safety ("DPS") regarding its four-year statutory review of the rules governing the Texas Compassionate Use Program ("TCUP").

INCBA is a global cannabis bar association comprised of over 700 member attorneys representing cannabis industry participants nationwide and across the globe. See www.incba.org. Our breadth and depth of knowledge and experience makes INCBA uniquely situated to provide insight into the regulatory hurdles and legal issues faced by industry stakeholders. Our members assist cannabis industry participants from all facets of the industry, including cultivators, processors, manufacturers, distributors, research facilities, testing laboratories, retailers, and more, both plant-touching and ancillary. Specifically, our members provide necessary advice and counsel for industry stakeholders to understand applicable laws and regulations to ensure the greatest possible success while operating within the confines of local, state, federal, and international legal frameworks.

We understand this review is primarily intended to address obsolescence, alignment with current law and policy considerations, and current Department procedures. The current TCUP rules are a matter of significant interest to the legal community. Texas is one of the largest and most populated states in the nation and will have a significant influence on several other states, even the thirty-eight states that have already adopted comprehensive medical cannabis programs. We recognize the rules that are currently in place are based on several laws that have since been repealed or revised. We also recognize that Texas has one of the most restrictive and limiting medical cannabis programs in the country. As such, Texas lacks a truly comprehensive medical program, resulting in a lack of accessibility and continued suffering for patients. In fact, the most recent State of the States Report compiled by Americans for Safe Access gave Texas an "F" on its medical cannabis program.[1] As attorneys representing various interests across a multitude of state-specific legal regimes, we have great insight into rules that work well, as well as those that do not, and we avail ourselves to DPS to answer any questions or provide additional insight based on our experiences.

Below please find INCBA's comments to the TCUP rules, listed in no particular order, submitted on behalf of INCBA, with significant input from Texas members Andrea Steel of Frost Brown Todd LLC, Chelsie

[1] Americans for Safe Access, 2021 State of the States (February 2022) *available at* https://www.safeaccessnow.org/sos.

Spencer of Ritter Spencer, PLLC, Richard Cheng of Weaver Johnston Nelson, PLLC, Susan Hays of the Law Office of Susan Hays, PC, Shawn Hauser of Vicente Sederberg LLP, and Marc Cavazos, J.D., M.A. As attorneys well-versed in the medical cannabis industry, we appreciate the opportunity to provide meaningful and substantive input on the very important issues presented. We also applaud the clearly thoughtful efforts of DPS in researching and drafting these rules and the consideration you are providing to the public. If you have any questions or comments on the following, please do not hesitate to contact us.

1. **General Comment: Products from Licensed Dispensing Organization should be required to undergo full panel testing by third-party independent laboratories.**

   Compassionate Use Program Rule: Currently, there is no independent laboratory testing requirement for products created by TCUP licensed dispensing organizations. Instead, TCUP licensees test their own products.

   Issue Presented: We applaud the DPS's action to streamline the testing of processed low-THC cannabis products and defer to the "applicable provisions" of the Texas Agriculture Code as well as federal consumer product safety regulations. See 37 T.A.C. § 12.7. However, the rules as currently drafted warrant clarification, as there are inherent conflicts and no clarity on which provisions would be deemed "applicable." In deferring to the Texas Agriculture Code, the Texas hemp program gets pulled in, which requires independent testing laboratories be utilized to test hemp crops. However, "hemp" and "low-THC cannabis" — although very similar — have distinctive legal definitions,[2] and in practice the two operating TCUP licensees are not required to test their raw materials or final products by any third-party labs under any sort of standardization. It is unclear whether independent testing laboratories have any pathway to participate in the TCUP program, and we believe they should. Independent testing labs are necessary not only in the consumable cannabis industry, but any industry where manufacturers are creating finished products for consumption. Independent third-party labs serve to provide objective, analytical data on the quality and safety of a product or process, and can assist in the areas of quality control and failure analysis. Without such independence, TCUP licensees are provided an opportunity to serve themselves, potentially at the risk of consumers, without appropriate checks and balances. It does not appear there is any legal prohibition preventing independent third-party lab testing, and actually DPS has been given broad authority and mandated to "adopt any rules necessary for the administration and enforcement" of TCUP. Tex. Health & Safety Code § 487.052. Further, licensure of independent third-party laboratories would also provide an additional assurance of quality and safety control within TCUP to ensure safe, quality medicine for patients, and would reduce burdens on dispensing organizations. Almost all medical cannabis programs in the country require independent third-party testing laboratories, to ensure consumer safety and competent and unbiased testing of medical cannabis.

   Proposed Solution: We recommend DPS revise its rules to provide for mandatory product testing by independent third-party testing laboratories, allowing for a new tier of licensing within TCUP and providing for certain standards of accreditation and methodology. The Texas hemp program can be a source of regulatory reference as a program already functioning within the state.

[2] Tex. Agric. Code §121.001; Tex. Occupations Code §169.001.

2. General Comment & Rule §12.11: DPS should revise TCUP rules to allow for a tiered licensing structure and/or provide for licensees to have multiple facilities.

Compassionate Use Program Rule: TCUP rules provide for licensing to dispensing organizations that cultivate, process and dispense medical cannabis, though there is no statutory requirement for licensees to be vertically integrated in this manner in practice, and the rules already contemplate multiple facilities or locations for various portions of the supply chain process.[3]

Issue Presented: Vertical integration requirements stifle competition and prevent smaller business from participating, all of which end up negatively impacting patients due to limited product options, product availability and lack of standard supply/demand markets setting efficient pricing. We have seen these negative effects in state medical cannabis programs that have required vertical integration. Texas has no additional licensing opportunities such as transportation/delivery, waste control, testing laboratories, etc., nor are there opportunities for any of the licensees to excel in only one area of expertise, be it cultivation, processing/manufacturing or dispensing — three very different skill sets. Nor have the current licensees been authorized to operate using multiple locations. As with many other industries, certain businesses become more effective and efficient with certain tasks and specialize, creating cost efficiencies and improving quality. While vertical integration may provide some sense of efficiency, it comes at the expense of heavy startup costs and substantial investment, difficulty developing expertise in all tiers, and keeps ownership and control of the entire supply chain within a small number of operators while simultaneously stifling entrepreneurship and limiting job opportunities.[4] Vertical integration goes against the free-market spirit of Texas, typically known for being friendly for businesses and industries.

In addition, one of the primary goals of TCUP was to serve the needs of the qualified patients in Texas. As those qualifying conditions have expanded via statute over the years since TCUP's inception, without corresponding rule updates addressing the statutory changes, patients end up suffering the most because of the significant restrictions. This is most evident in the fact that there are only two operating licensed dispensing organizations in the entire state, both located in the Austin area. This was not even adequate to provide "reasonable statewide access" to serve the estimated population living with "intractable epilepsy." Since the addition of several more qualifying conditions in 2019 and the addition of PTSD and any stage of cancer in 2021, there has been a significant increase in the number of patients eligible, and, more importantly, the number of registered TCUP patients is exponentially growing. At the current sustained growth rate of approximately 10% per month, we can expect the patient count to hit 50,000 by the end of the year. Two operating facilities to serve the entire state, both based in one metropolitan area of the state, simply cannot adequately service the more than 22,000 registered patients (as of March 2022) across the state. Diversifying licensing types would also allow operators to better serve patients by enhancing product development through increased operational efficiency and allow businesses to specialize in in one aspect of the supply chain, such as cultivation or processing. Given

[3] *See* Rule §12.2(t) (stating that **any** processing facility of a licensee shall have a building key safe, implying a licensee may have multiple processing facilities); Rule §12.9(a)(6) (specifically referencing the cultivation facility, implying that this facility can be separate and apart from the processing and/or dispensing facility(ies); Rule §12.11(b)(7)(C)(i) (requiring applications include the floor plan of **each** facility, expressly contemplating applicants will have multiple facilities); Rule §12.11(d)(1) and (d)(3) (contemplating multiple dispensing facilities for an applicant).

[4] *See* MCBA, "National Cannabis Equity Report 2022" *available at* https://minoritycannabis.org/equitymap/; *see also* Vangst, blog post, "The Pros and Cons of Cannabis Vertical Integration" *available at* https://vangst.com/blog/vertical-integration-cannabis; *see also* https://www.ganjapreneur.com/how-vertical-integration-is-ruining-medical-cannabis-in-florida/.

the large size of Texas, diversification of license types will ensure reasonable statewide access throughout Texas.

Proposed Solution: INCBA recommends DPS create a licensing structure which would allow for a tiered licensing system, meaning licenses will be awarded for various industry specialties, such as cultivators, processors/manufacturers, transportation/delivery, sales, testing laboratories, caregivers and waste disposal. Such a system is seen in several other medicinal use jurisdictions, including the medical programs in every state surrounding Texas.[5] Furthermore, each tier could have its own associated fees and regulations to be determined at DPS' discretion. We again respectfully remind DPS it has been given broad authority to establish ***any*** rules needed to administer TCUP, and tiered licensing is critical to a robust medical cannabis program that provides sufficient product quality and patient access.

In the alternative, DPS could create an abbreviated licensing program for specialized sub-contractors of TCUP licenses for cultivation, processing, testing, transportation, or dispensing and any other necessary service. Such specialized sublicenses could only be renewed if a TCUP licensee acknowledges the sub-contractor is performing duties on behalf of a licensee. This system would allow a lower cost of entry, would give TCUP licensees a method to reduce costs, and would generate more licensing fees for DPS. Finally, it would allow businesses to focus on one skill set creating more efficient and effective services, and would increase patient access to the requisite reasonable standard mandated by law.

Another suggestion would be for DPS to allow for an application "team" concept whereby separate applicants could enter into an agreement to form a complete supply chain among them that would collectively operate the cultivation, processing and dispensing activities. This structure could provide for each application team member to cover one of the regulated activities such that it can spend its energy where it excels most and the same for each of the other team members. This structure promotes collaboration, efficiency, quality and increased access.

Additionally, we respectfully request DPS acknowledge and clarify that a licensee may operate multiple facilities under its license, allowing licensees to dispense from various locations across the state. This structure would increase patient access and reduce burdens for licensees, as opposed to the current untenable and inadequate system whereby licensees bring products to pop-ups or other designated drop-off locations for patients to retrieve their medications, but then the licensee must return all remaining products back to their Austin-based facility each day. Many rural areas and areas further away from Austin, especially those along the state's borders, are simply too far to make the long trek and back, so being able to deliver everywhere under the current regime is not practical. Furthermore, because every single state surrounding Texas has either a comprehensive medical program, adult-use retail program, or both,[6] providing sufficient patient access within the state, especially near the borders, will help reduce illicit cross-border purchasing from surrounding states.

[5] Oklahoma provides licensing for commercial growers, dispensaries, processors, transporters, and testing laboratories. Louisiana allows two universities to grow and produce medical cannabis, while allowing separately licensed regional dispensaries throughout the state. Similarly, Arkansas provides for cultivation facilities and dispensaries to be separately licensed. New Mexico separately licenses cultivators, manufacturers and retailers.
[6] Consider New Mexico and Colorado (medical and adult-use cannabis programs) and Oklahoma, Arkansas and Louisiana (comprehensive medical cannabis programs).

3. **General Comment: More protections are needed for patients, attorneys, physicians, and other industry professional service providers.**

Issue Presented: INCBA congratulates DPS on providing access for patients to cannabis in treating specified conditions under state law. Nevertheless, there is no indication TCUP provides many statutory protections for patients or service providers, such as qualified physicians, attorneys, accountants, etc. Without these protection in place, patients and service professionals are at risk for criminal prosecution and loss of employment, housing and a range of other basic necessities, as well as the threat of facing revocation of professional licenses and discrimination in/from the workplace. These unintended consequences result despite these professionals and patients servicing and/or participating in a lawful state program. For example, INCBA members recently assisted a health care worker who is a retired, highly decorated law enforcement officer who was fired for being a TCUP patient and consuming cannabis to treat the very PTSD he developed while protecting the public. Failure to provide these sorts of protections may hamper the purpose of TCUP and encourage the thriving illicit cannabis market within the state due to fear of openly participating in the state-legal program.

Per the State of the States 2021 ASA report, "[t]he most important marker of a well-designed state program is that all patients who would benefit from medical cannabis have safe and legal access to their medicine without fear of losing any of the civil rights and protections afforded to them as residents of that state." While there are currently a limited number of statutory protections in Texas in place for some patients relating to arrests and parental protections, something significantly lacking is employee protections for those legally using medical cannabis in accordance with TCUP. Patients deserve legal protections pertaining to employment, housing, education and family legal matters in order to access their medical cannabis without fear of monetary fines, arrest, prosecution and imprisonment. Additionally, professionals that provide services to patients and operators in TCUP also deserve protections to be able to not only perform their work without fear of reprisal, but also be able to participate as patients without fear of losing their professional licensure. By not providing statutory protection to service providers, TCUP's purpose of serving patients may be stifled, and may perversely keep the most qualified individuals out of a program where they are most needed.

Proposed Solution: INCBA recommends TCUP provide regulatory protections for patients and professional service providers to be exempt from applicable state and ethical violations, similar to other jurisdictions with medicinal cannabis programs.[7] Such patient protections may include: allowing minor cannabis patients to dose on school grounds under qualified supervision; protection of patient's right to housing, employment, child custody, government assistance and organ transplants; protections against unfair discrimination in a roadside sobriety test based on their status as a patient. Professional service provider protections should include the ability to provide such services to industry participants despite complex federal illegality to the extent advising on compliance with state regulations and allowing professionals to provide services within their respective fields free from state and local prosecution. By providing service providers and patients with regulatory protection, it will facilitate TCUP's public policy to provide adequate access to patients. Toward this end, DPS might consider

[7] Oklahoma provides professional protections for physicians. Per the ASA State of the States 2021 report, "Delaware, Illinois, Maine, Minnesota, South Dakota, and the U.S. Virgin Islands all received top marks in [the Patient Rights & Civil Protections] category by providing full arrest protections and providing for an affirmative defense in court, employment protections for medical cannabis patients and caregivers, and explicit privacy standards. With the exception of Illinois, each of these states also provide full parental rights protections, barring evidence of medical cannabis use from being offered as evidence against a parent during custody proceedings."

establishing formal lines of communication, perhaps through an advisory committee, to relevant licensing boards with some representation from the licensed professions and other experts.[8]

4. General Comment: Revise licensing process to expand reasonable statewide access.

Compassionate Use Program Rule: Current TCUP rules provide for licensing based on a scoring matrix to address various operational and compliance standards. While there is no statutory limitation to the number of licenses allowed, only three have been issued to date and five years later only two licensees are functioning.

Issue Presented: As DPS is well aware, the original intent of TCUP was to provide "reasonable statewide access" to patients. DPS itself estimated that twelve dispensing organizations would be required to provide such access when only one condition was included in the program. 40 Tex. Reg. 6294 (Sept. 18, 2015). While we are supportive of an objective system that removes opportunity for bias and corruption, there is room for improvement. In addition, limited licensing also goes against the free-market, competitive nature of the Texas.

Proposed Solution: We encourage DPS to consider investing in a more substantive licensing process by reviewing applicant capabilities with site-visits, interviews, and other research for those applicants who demonstrate the eligibility requirements of Section 487.102 and applicable regulations. See Tex. Health & Safety Code § 487.104. Further, impose a requirement that upon an award of a conditional license, a reasonable timeline to secure funding, property, equipment and other items needed to meet the more detailed site-specific requirements, and become operational within a specified time period, if the applicant fails to do so, it will lose the conditional license. We recommend there be no arbitrary license caps, and DPS should allow qualified applicants the opportunity to freely compete within an open market. Perhaps there could be an annual or biennial application cycle whereby the number of licenses to be awarded is determined each period, and where qualifications or specializations can be revised as needed to address certain deficiencies in the program such as a lack of dispensing locations in certain areas.

We would also request consideration of incorporating either a 50% set-aside or 25 bonus points for licensee applicants certified as Historically Underutilized Businesses (HUBs), along with a requirement that at least 35% of licensee-vendor contracts must be 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 their regulations and TCUP could follow suit.[9]

[8] We can look to state regulations in New Mexico, Oklahoma, Pennsylvania, Florida, Massachusetts, Ohio, North Dakota, New York, California, Colorado, and West Virginia (and others), all of which have medical cannabis advisory councils.

[9] For example, the highly competitive low-income housing tax credit allocation process awarded through the Texas Department of Housing and Community Affairs 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.

5. **Rule §12.11(b)(7): This rule regarding evidence of qualifications appears to conflict with the current application requirements.**

Compassionate Use Program Rule: Rule §12.11(b)(7) sets forth certain qualifications that must be evidenced by a license applicant "at the time of the required onsite inspection."

Issue Presented: While many of the qualifications set forth in this rule are important for operating a compliant and successful medical cannabis facility, the rule explicitly states these qualifications must be present "at the time of the required onsite inspection." However, the application form itself requires this evidence be submitted at the time of application, completely negating the rule's opportunity to essentially have sufficient time to meet the detailed qualifications once the threshold items set forth in sections (1)-(6) are met. A major implication of the current rule and application is that, due to the requirement to provide floor plans, maps and other site-specific details, they effectively require site control of an adequate facility/property long before an applicant even knows whether the license might be granted, creating a very difficult and expensive feat to achieve so far in advance, which establishes a significant barrier to entry.

Proposed Solution: Clarify the rule such that an adequate timeline is provided to applicants who meet the threshold criteria and have a solid indication of being selected to receive a license to allow for appropriate site selection and planning without having to make such a significant investment too early in the process. Clarify that site control is not required at the time of application.

6. **Rule §12.14: Excessive licensing fees.**

Compassionate Use Program Rule: The following are required fees under TCUP: (1) application fee for dispensing organization: $7,356.00; (2) license fee for dispensing organization for two years: $488,520.00; (3) fee for biennial renewal of the dispensing organization license: $318,511.00; (4) registration fee for both the original registration and renewals: $530.00. (37 Tex. Admin. Code §12.14(a)-(c)).

Issue Presented: INCBA commends DPS in their use of licensing fees to help shoulder the burden of operating a newer program within the Department. However, the current fee structure is excessive — among the highest in the nation. These exorbitant expenses then get passed down to the patients where access to low-THC cannabis is already highly restrictive, making the products cost-prohibitive and preventing many from participating, either driving them to the local illicit market or to Oklahoma, Colorado, or New Mexico to obtain medicine, or worst of all by denying them access to medicine that would alleviate their condition. Medical cannabis is not covered by health insurance, so keeping costs affordable is all the more important. The excessive fees also make it infeasible for all but the most capitalized companies to obtain licenses, eliminating healthy market competition. In the states surrounding Texas, all of which have at least a comprehensive medical cannabis program, licensing fees are significantly less than those for TCUP. For example, New Mexico allows both medical and adult-use cannabis, with fees for a vertically integrated medical facility being less than $10,000 (though there are also options for various non-vertical licenses that are less than $3,000). In Oklahoma, each commercial license for a grow, processing facility or dispensary is $2,500. In Arkansas, cultivation facility licenses are $100,000 while dispensary licenses are $15,000. In Louisiana, grow facility licenses are $100,000 and dispensary license fees are $5,000. Texas licensing fees are more than five times the amount of the highest fees available in surrounding states. We understand the law requires the application fee be sufficient to cover the costs associated with administering the program. (Tex. Health

& Safety Code § 487.052). However, if license fees were lowered and more licenses issued, revenue from fees would likely increase dramatically.

Proposed Solution: DPS should implement a more reasonable licensing fee structure to allow more dispensing organizations to participate. This action would facilitate patient access to low-THC cannabis by lessening the cost-burden for patients, many of which are among our State's most vulnerable, such as veterans, children and the elderly, who are often times on fixed or limited incomes.

As an aside, we applaud Texas for not taxing medical cannabis, and strongly encourage the exemption from sales and other excise taxes be maintained as is the practice in many other states and for all medicine in Texas.

7. Subchapter G, Rule §12.61: Production Limits set out in Rule §12.61 are outdated and largely inapplicable.

Compassionate Use Program Rule: Rule §12.61 focuses on supply limitations based on demand of patients with intractable epilepsy and contemplates reporting requirements that no longer apply.

Issue Presented: Though the Legislature has expanded TCUP over the last few legislative sessions, Subchapter G remained unchanged despite the fact that it is simply no longer applicable. The entire rule centers on the notion that intractable epilepsy patients are limited and that therefore, any production of low-THC cannabis should accordingly be limited based on those patient numbers. The rule is based on several false scientific premises such as that a plant would produce the same amount of THC consistently, a patient would need the same dose consistently, and all patients would need the same dose. The rule further includes a formula based on the number of licenses issued. Beyond the mere fact this rule is outdated, the idea that any formula should be based on the number of licenses issued is problematic. As we know, there have been three licenses issued to dispensing organizations, but only two are operating. If any production limitation is to be imposed on licensees, it should be limited to those actually in operation.

Proposed Solution: We recommend deleting Subchapter G altogether. In keeping with the free market, business-friendly culture of Texas, supply and demand should be determined by the market, and business operators should plan accordingly or otherwise deal with the failure to do so. Arbitrary limitations serve no one, reduce patient access, hinder supply chain functioning and result in unnecessarily cumbersome regulatory issues.

8. Rule 12.2(v): Prohibition on research should be deleted.

Compassionate Use Program Rule: Rule §12.2(v) prohibits research beyond that necessary for cultivation and production.

Issue Presented: This rule conflicts with multiple Texas laws. First, the revisions to TCUP in HB 1535 explicitly provide for research within the TCUP program. Second, the Texas Hemp Program provides for cannabis research. 24 Tex. Reg. §§ 24.49-24.50. Finally, longstanding Texas law allows for medical cannabis research. Tex. Health & Safety Code ch. 481, subch. G. Further, by limiting the research capabilities of operators, this rule effectively stifles important research and product development that could benefit patients. Research is critical to support the safety and efficacy of cannabis products for Texas patients, and the development of intellectual property and research by Texas institutions.

Proposed Solution: We recommend deleting Texas Administrative Code Title 37 Part 1 Chapter 12.2(v) altogether as obsolete. The program should not contain barriers to research and development of intellectual property by operators serving patients with debilitating medical conditions, especially where these operators who are working with some of the top medical institutions in the country.

Conclusion

As part of this statutory rule review period, we encourage DPS to revise the rules accordingly to reflect reality, provide clarity, and generally improve the program. Rules should also provide clarity and not mislead or provide a source of conflict or confusion. As industry stewards, we are hopeful the above points of concern can be adequately resolved through this vast opportunity to update the TCUP rules. As knowledgeable professionals with significant experience in cannabis law and policy across the nation, we would be happy to further assist with any of these points or others in gathering data and resources from our experience with other states.

Thank you for the consideration of these comments and for the continued dedication to the Texas Compassionate Use Program.

Sincerely,

Christopher J. Davis, on behalf of The International Cannabis Bar Association
Executive Director