

August 10, 2017

Department of Public Safety Via upload **** & Certified Return Receipt #****

LICENSING THE COMPASSIONATE USE PROGRAM'S PRESCRIBED DISPENSING ORGANIZATIONS

The <u>Texas Cannabis Industry Association</u> ("TCIA") urges licensing more dispensing organizations amid concerns that the Compassionate Use Program (the "CUP") has been substantially weakened following behind-the-scenes input from Governor Greg Abbott. As the state industry's guild, TCIA's mission is to ensure the favorable social, economic and legal environment necessary for a legitimate and responsible cannabis industry that, above all, serves patients well.

Evidence from both the state itself and private industry strongly suggests that the DPS has violated the Administrative Procedure Act ("APA"), and the CUP has been undermined in its purpose to reach the more than 149,000 patients with intractable-epilepsy by September 2017. This violates legislative intent and results directly from the inadequate number of "provisional" licensees currently awarded.

The CUP's implementing legislation, SB 339, contained clear requirements toward efficient implementation of the CUP program in order to provide relief to those suffering from intractable epilepsy:

- DPS must adopt rules to administer the CUP by December 1, 2015.
- DPS must issue a license to "each applicant who satisfies the requirements under [Chapter 487]" and must "ensure reasonable statewide access" to low-THC cannabis to CUP patients.
- DPS must issue licenses to "at least three" dispensing organizations, provided they have met Chapter 487's requirements by September 1, 2017.1

DPS began its task of implementing the CUP in earnest, publishing proposed rules in September 2015 and adopting them by the end of that year.² DPS Chief Financial Officer Suzy Whittenton evaluated the program's needs to provide reasonable statewide access to patients and concluded that DPS should issue twelve licenses based on an analysis of other states' compassionate-use programs and the number of patients in Texas with intractable epilepsy.³ However, DPS failed to open up the application process for months on end.

Instead, in October 2016, DPS proposed amended regulations apparently prompted by the Governor's privately proposed fundamental changes to the CUP, including reducing in the number of licensees to three — the minimum SB 339 allows — with no explanation to support the abrupt change. DPS simply repeated its previously published reasons for needing at least twelve licensees and simply changed the number to three.

After public input through written comments and public testimony that three licenses would be insufficient, the Public Safety Commission failed to stand up to the Governor's private edict, and again failed to provide a reasoned justification for this arbitrary choice limiting the number of licensees.⁵ The final adopted rules contained no explanation at all for the arbitrary limit to three licensees. This failure, including the failure to summarize a

⁴ See 41 Tex. Reg. 8520, 8527, 8531 (2016).

¹ Act of May 19, 2015, 84th Leg., R.S., ch. 301 §§ 1 (enacting Tex. Health & Safety Code §§ 487.053(a) and 487.104(a)), 6 (dead-lines), 2016 Tex. Gen. Laws 1419 (S.B. 339).

² See 40 Tex. Reg. 6294 (2015); see also 41 Tex. Reg. 490 (2016).

³ See 40 Tex. Reg. 6294 (2015).

⁵ See 42 Tex. Reg. 48 Tex. Reg. 1139 (2017); see also 42 Tex. Reg. 48, 55 (2017).

factual basis for the rule as adopted and a rational connection between that factual basis and the rule, violated the APA.⁶

DPS finally opened the application process in early March giving applicants thirty days to draft and submit their applications. TCIA has documented the multiple substantive changes to the application process itself that the DPS made in the weeks leading up to the March 31 application deadline. DPS provided contradictory information to different applicants that includes changes to the evaluation process, intrastate shipping rules, insurance policy rules, acknowledgements, and vetting, among other core variables. Most pointedly, *after* applications were filed, DPS changed its review process from having multiple reviewers read the entire applications to having reviewers read components of applications, with some parts only reviewed by one person.

DPS announced three provisional licenses on May 1st, after a very short closed-door evaluation process that continues to raise questions. DPS has published in its FAQ that "The review panel members' judgments regarding the applications materials, reflected in their scores, are not subject to review." Moreover, in response to appeals and complaints filed by multiple applicants, DPS is taking the position that it has "not denied or granted a license" and "no notices of denial have been issued to any applicant" thus no applicant is entitled to a hearing. This position appears to thwart DPS's own rules allowing for appeal of license denial. Thus, DPS attempts to put the applicants in a procedural purgatory where no due process for themselves or the patients they wish to serve may be had. However, avoiding review of agency actions by taking actions not encompassed by statute, agency rules, or rulemaking violates the very heart of the APA's purpose of forcing rationality and transparency to agency actions.

For these reasons and to mitigate the damage caused by these actions, TCIA believes the state needs to prepare for an immediate second round of applications and issue at least nine additional provisional licenses to "ensure reasonable statewide access" as SB 339 requires. TCIA suggests that DPS begin the process by:

- publishing clear guidance whether via FAQs or a public memo to applicants on exactly how applications will be reviewed.⁸
- allow applicants to supplement their applications accordingly within 30 days, and
- re-evaluating the applications and allow "each applicant who satisfies the requirements" under Chapter 487 to proceed toward licensing.

This will serve to comply with both SB 339 and the APA, and this will provide Texans suffering from intractable epilepsy with relief in short order. Without doing so, TCIA believes DPS will remain in substantial noncompliance with the APA rendering its CUP regulations voidable.⁹

To avoid unnecessary delay, this second round should be limited to the forty remaining applicants from round one, who can submit updates to their original applications. After an open evaluation process, the additional provisional licenses can be issued with final licensing deadlines set after September. That will allow the first three provisional licensees to remain on-track for their final inspections and provide them the best opportunity to become operational.

In other states, litigation over agencies not following their legal mandates have tied up government resources and appear to always ultimately lead to more licenses being issued. TCIA seeks to help avoid that unnecessary waste for Texas. The patients and their willing physicians have been documented by the many advocacy groups. The industry is in place and engaged, evidenced by the healthy pool of 43 license applicants. The only thing lacking to ease these families' suffering is the state government living up to its responsibility.

Thank you,

TCIA Board

⁶ See Tex. Gov't Code § 2001.033(a).

⁷ Letter of June 16, 2017, Aaron Heath, Staff Attorney, Office of Regulatory Counsel, Texas Department of Public Safety.

⁸ See Tex. Gov't Code § 2001.007.

⁹ See Tex. Gov't Code § 2001.035.

cc: Governor Greg Abbott
Drew DeBerry, Gov. Abbott's Ofc.