Texas Register Vaporization Comments

September 17, 2025

Dear Health and Human Services Commission and Rules Coordination Office:

Re: Comments on Proposed Rule 25R037

The Marijuana Policy Project was pleased to see the expansion of the Texas Compassionate Use Program (TCUP) through the passage of HB 46 in the regular session of the 89th Texas Legislature. The extremely restrictive nature of the program has limited its effectiveness since TCUP's inception. By expanding medical conditions, dispensary licenses, and locations, and adding non-smoked inhalation devices as a method of delivery, the program is preparing to meet the needs of many more patients. Up until this time, many patients dropped out of the program due to its prohibition on inhalation, high prices, and other restrictions. The faithful implementation of HB 46 is crucial to the viability of the program.

We appreciate the Human Services Commission's timely issuance of the proposed rule, but are extremely concerned that the language includes new restrictions that undermine the gains made by HB 46. We urge the following changes to the proposed rule 25 TAC §1.61 and 1.63:

- providing that the Department of State Health Services (DSHS) itself, and its medical experts, have the authority to add qualifying conditions, as statute provides, rather than requiring new conditions to be added by the legislature.
- modifying the process to allow dispensaries, manufacturers of devices for pulmonary inhalation, and patients to request approval for devices for pulmonary inhalation, rather than limiting the ability to file requests to prescribing physicians.
- removing the requirement, which is not in statute, that physicians are required to prescribe a specific device for pulmonary inhalation.
- including a reasonable and explicit deadline for granting approval for medical devices for pulmonary inhalation — six months — and changing the deadline to consider devices for pulmonary inhalation to every four months.

HB 46 Grants DSHS Authority to Add Conditions, 25 TAC §1.61 Removes It

HB 46 provided that physicians may request the approval of additional qualifying conditions and submit peer-reviewed evidence. It does *not* require DSHS to submit the request to the Legislature for consideration. The Legislature chose to delegate this to DSHS, and the proposed rule rejects the delegation and adds a burden on physicians, patients, and the Legislature itself. It would also delay consideration for up to 1.5 years, given that the legislature meets biannually.

Texas Occupations Code, § 169.003, provides:

(c) The Department of State Health Services may designate medical conditions for which a physician may prescribe low-THC cannabis under this section. The executive commissioner shall adopt rules for

the approval of medical conditions under this section.

(d) If a patient is diagnosed with a medical condition not listed in Subsection (a)(3)(A)(i), a physician may submit to the Department of State Health Services a request for the department to designate the condition as a medical condition for which a physician may prescribe low-THC cannabis under this section. The request must be accompanied by medical evidence such as peer-reviewed published research demonstrating that low-THC cannabis may be beneficial to treat that medical condition. The executive commissioner by rule shall prescribe the manner in which a physician may submit a request under this subsection.

We strenuously urge that proposed rule 25 TAC §1.61 be revised to be consistent with statute. DSHS' medical experts should decide whether to approve petitions to add conditions, as the law provides.

Recommended Revision to Proposed Rule 25 TAC §1.61:

Bold underlined text is our proposed new language.

Bold strike-through text in brackets shows our proposed deletions**.**

- 1.61. Medical Conditions for which a Physician May Prescribe

Low-THC Cannabis [~~Incurable Neurodegenerative Diseases~~].

…

(b) A qualifying physician under Texas Occupations Code, Chapter 169, may prescribe low-THC cannabis to a patient with a documented diagnosis of one or more of the conditions listed under Texas Occupations Code §169.003, **one or more of the conditions added by the Texas Department of State Health Services pursuant to this rule; or** one or more of the following incurable neurodegenerative diseases:

…

(c) A [~~treating~~] physician [~~of a patient suffering from an incurable neurodegenerative disease not listed in subsection (b) of this section~~] may submit a form [~~request~~] to the Texas Department of State Health Services (DSHS) [~~the department~~] to request adding a condition to the list of medical conditions in subsection (b) of this section for which a physician may prescribe low-THC cannabis [~~have a disease added~~].

(1) **~~For forms that request addition of non-neurodegenerative diseases to the list of medical conditions, DSHS will provide those forms and any submitted peer reviewed evidence to the Department of Public Safety (DPS). DPS will then submit requests to the legislature for consideration.~~**

(2) **~~For forms that request addition of neurodegenerative diseases to the list of medical conditions,~~Within four months of receiving a request to add a condition to the list of medical conditions for which a physician may prescribe low-THC cannabis, DSHS shall solicit public comment and hold a hearing on the request. DSHS shall accept evidence, including testimonials from patients and physicians, case studies, and peer-reviewed published research demonstrating that cannabis or cannabinoids may be beneficial to**

treat that medical condition.

(3) Within six months of receiving a request to add a condition to the list of medical conditions for which a physician may prescribe low-THC cannabis, DSHS shall assess the request and make a decision about whether to approve the condition [~~for any neurodegenerative diseases not currently listed in subsection (b) of this section~~].

(d) A request under subsection (c) of this section must [~~shall~~] be submitted using the form, Request to Add Medical Conditions for Which a Physician May Prescribe Low-THC Cannabis [~~or Add Pulmonary Inhalation Devices for Low-THC Cannabis,~~] located on the DSHS website [~~to the department on a form prescribed by the department, which can be found on the department's website at https://www.dshs.texas.gov/chronic/default.shtm~~].

(e) DSHS [~~After review of the submitted documentation, the department~~] may request additional information after review of the submitted form [~~or make a determination~~].

Background on Non-Smoked Pulmonary Administration

The Commission should have no reservations about implementing the will of the Legislature and allowing this method of delivery for the patients enrolled in TCUP.

Inhalation allows for precise titration of dosage and rapid-onset, which is critical to relief.[1]

Science has been clear for many years that inhalation of cannabinoids is medically sound. A Dutch study published in the *Journal of Pharmaceuticals* found the vaporizer it tested was "a safe and effective cannabinoid delivery system seems to be available to patients. The final pulmonal uptake of THC is comparable to the smoking of cannabis, while avoiding the respiratory disadvantages of smoking."[2]

An American-based clinical trial came to similar conclusions.[3]

25 TAC §1.63 — Revising the Process

We urge the Commission to create fair rules that do not hamstring pulmonary inhalation as a method of delivery. Proposed rule 25 TAC §1.63 would only allow physicians to propose devices for approval. This limitation is not in statute. The rule should be modified so that dispensary organizations, manufacturers of pulmonary inhalation devices, and patients may propose non-smoked inhalation devices.

Dispensing organizations and device manufacturers will have the most knowledge about the products they seek approval for and issues of feasibility, and many patients will have real-world experience with the products when visiting other states or when using hemp products. Many of these products are already being sold for use in other states' medical cannabis programs, and their scientists and teams may not be based in Texas. Requiring a certifying Texas physician to propose devices will have an adverse economic effect on small businesses.

We are also concerned that, while Health and Safety Code Sec.169.006 does not require physicians to prescribe specific devices, the administrative rules appear to add that new requirement, which would have detrimental impacts on the functionality of the program. In addition, most physicians will not have full knowledge about the various devices. To avoid adding to the administrative and physicians'

burden, the drop down menu on Compassionate Use Registry of Texas (CURT) should simply add "pulmonary administration" as an option under "mode of administration."

Also of note, the CEO of the largest dispensary in Texas, Nico Richardson, explained at a hearing on the proposed rule that if the physicians must prescribe a specific device, the dispensing organizations will not be able to fulfill many of those orders. Mr. Richardson testified the devices typically have a 10,000 unit minimum and a 20-week lead time to fill orders.[4] If a device is approved, but not being stocked near the patient, the patient would not be able to fulfill the prescription.

Finally, Health and Safety Code Sec 169.006 requires rules to include "a reasonable timeline for reviewing and granting approval for medical devices for pulmonary inhalation." (emphasis added) Proposed rule §1.63 (f) provides, "The Texas Department of State Health Services must review pulmonary inhalation devices every six months with stakeholders to determine potential changes to this section." Six months is a fairly long wait, especially in the first year. It should be reduced to four. In addition, there is no deadline for device approval, as mandated by HB 46. We urge a timely deadline for approvals — no more than six months.

Recommended Revision to Proposed Rule 25 TAC §1.63:

Underlined text is our proposed new language.

Strike-through text in brackets shows proposed deletions**.**

(c) A qualifying physician under Texas Occupations Code Chapter 169 may prescribe [~~a~~] pulmonary inhalation [~~device for low-THC cannabis~~] as a mode of administration to a patient who is qualified to receive a low-THC cannabis prescription.

(d) A qualifying physician under Texas Occupations Code Chapter 169, dispensing organization, manufacturer of a pulmonary inhalation device, or a patient may submit a form to DSHS to request adding a pulmonary inhalation device to the list of approved [~~from which a physician may choose when prescribing a~~] pulmonary inhalation devices for low-THC cannabis.

(e) A request under subsection (d) of this section must be submitted using the form, Request to [~~Add Medical Conditions for Which a Physician May Prescribe Low-THC Cannabis or~~] Add Pulmonary Inhalation Devices for Low-THC Cannabis, located on the DSHS web-site.

(f) The Texas Department of State Health Services must review pulmonary inhalation devices every four [~~six~~]months with stakeholders to determine potential changes to this section. Each request to approve a pulmonary inhalation device must be approved or rejected within six months of its submission.

Other Jurisdictions

In other states with comprehensive medical cannabis programs, raw botanical cannabis is the most common method used by patients. This is followed by inhalation via vaporization and edibles.[5] The legislature has not authorized botanical cannabis, so we believe the long-term viability of TCUP lies in the Commission being willing to work with patients where they are. History has proven that if TCUP does not allow patients access to products they want (and have gotten relief from), they will turn to the underregulated hemp industry or the illicit market. The intent of HB 46, we believe, is to help guide patients to TCUP from both the illicit and hemp markets. We believe that overregulating this

method of delivery will depress participation and thwart the goals of HB 46.

To that end, we strongly urge the Commission to reject any efforts to impose restrictions on devices authorized, which are not found in HB 46. Some may advocate that approved devices be limited to "tightly metered inhalation devices." In neighboring Louisiana, the Legislature initially limited inhalation in this way, but found it drove up costs to patients and depressed participation. The Louisiana Legislature promptly revised the law to allow all types of inhalation and vaporization.

In 2018, the state of Israel became the first nation to approve the vaporization of cannabis for its medical program.[6] In 2021, the use of vaporized cannabis is even permitted in some hospitals[7] as a method of treatment. Israel has been at the forefront of medical cannabis research for decades.

The Commission has the ability to implement rules for these devices that will meet the parameters the legislature implemented. They also have the opportunity to rebuild trust in the TCUP program and its longer-term viability. No one in Texas benefits from a program that is hamstrung from meeting the needs of its patients.

We hope the Commission takes our input into consideration when implementing the final regulations in October. Tens of thousands of Texans' healthcare options will be affected by the decision of the Commission on how to implement this critical aspect of HB 46. We hope the Commission will take into consideration that inhalation via vaporization has been effectively and safely implemented in 38 other state programs.[8] Texas does need to become an outlier in this regard.

Respectfully,

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[1] MacCallum CA, Russo EB. Practical considerations in medical cannabis administration and dosing. Eur J Intern Med. 2018 Mar;49:12-19. doi: 10.1016/j.ejim.2018.01.004. Epub 2018 Jan 4. PMID: 29307505.

[2] Journal of Pharmaceutical Sciences, Vol. 95, 1308–1317 (2006) 2006 Wiley-Liss, Inc. and the American Pharmacists Association

[3] Benowitz NL. (2007). Vaporization as a Smokeless Cannabis Delivery System: A Pilot Study. Clin Pharmacol Ther. 2007 Nov;82(5):572-8. Epub 2007 Apr 11.

[4] https://texashhsc.v3.swagit.com/videos/353323?ts=1305 starting at 25:00

[5] https://pmc.ncbi.nlm.nih.gov/articles/PMC6708744/

[6] https://israel21c.org/israel-first-country-to-approve-medical-cannabis-vaporizer/

[7] https://www.prnewswire.com/il/news-releases/the-israeli-medical-establishment-voices-its-faith-in-tik

un-olam-cannbits---partnership-agreements-with-hmos-and-one-of-israels-largest-hospitals-301327809.html

[8] Those states are Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Hawaii, Illinois, Iowa, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Utah, Vermont, Virginia, Washington, and West Virginia. Kentucky also allows vaporization, but its law is new and sales have not begun yet.