October 3, 2025

Re: Comments on Proposed Rule 25R037

Dear Health and Human Services Commissioners,

Thank you for the opportunity to provide feedback on the proposed rules implementing HB 46. The legislation adopted by the 89th Texas Legislature represents the most significant update to the Texas Compassionate Use Program (TCUP) since its creation. Properly implemented, the changes to eligibility, licensing, and modes of administration can improve the program's ability to meet patient needs and operate effectively.

We respectfully submit the following concerns and recommendations:

1. Process for Pulmonary Inhalation Devices (25 TAC §1.63)

HB 46 authorizes pulmonary inhalation as a mode of administration. The proposed rules limit petitions for inhalation device approval to physicians.

Dispensing organizations, not physicians, are best positioned to research and recommend devices for approval because they have direct knowledge of supply chains, manufacturing requirements, and patient demand. Assigning this responsibility to dispensing organizations will help ensure that approved devices are available in sufficient quantities to meet patient needs.

RECOMMENDATION: To support a practical and reliable process, the rules should designate dispensing organizations as the petitioners for device approval.

2. Review Timelines (25 TAC §1.63(f))

HB 46 requires that the rules include a "reasonable timeline" for reviewing and approving inhalation devices. The proposed rule provides for six-month reviews but does not establish a deadline for approving or denying individual petitions.

RECOMMENDATION: To ensure timely consideration, the rules should require that petitions for new devices be *resolved* within six months.

Please revise the proposed rules to create workable processes for pulmonary inhalation, and establish clear and timely review standards. Implementing HB 46 in this manner will strengthen TCUP's effectiveness and improve patient access.

Thank you for your consideration and service administering this important program that brings relief to thousands of sick Texans.

Respectfully,

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