



**TO:** Health and Human Services Commission  
Executive Council

**DATE:** August 21, 2025

**FROM:** Manda Hall, M.D., Deputy Commissioner,  
Community Health Improvement Division

**AGENDA ITEM: 2.c.i**

**SUBJECT:** Low-THC Cannabis for Compassionate Use

**PLAIN LANGUAGE SUMMARY:** Texas Occupations Code Chapter 169 allows qualified doctors to prescribe low-THC cannabis to patients diagnosed with a medical condition listed in Section 169.003 and who meet other requirements of the Texas Compassionate Use Program. The proposed rules explain how physicians can request to add medical conditions to the list, set standards for pulmonary inhalation medical devices prescribed under the program, and establish a timeline for reviewing and approving such devices.

**BACKGROUND:** ☐ Federal ☒ Legislative ☐ Other: Program Initiative

The proposed rules implement House Bill (H.B.) 46, by King et al, 89th Legislature, Regular Session, 2025, which amends Texas Occupations Code §169.003 to allow the Texas Department of State Health Services (DSHS) to receive physician requests to add medical conditions to the list of qualifying conditions for which physicians may prescribe low-THC cannabis under the Texas Compassionate Use Program (TCUP) at the Texas Department of Public Safety (DPS). H.B. 46 also amends Texas Occupations Code Chapter 169 to add §169.006 allowing physicians to prescribe medical devices for the pulmonary inhalation of an aerosol or vapor to administer low-THC cannabis and establish a timeline for reviewing and approving such devices. In accordance with H.B. 46, the rule must be effective not later than October 1, 2025.

**ISSUES AND ALTERNATIVES:**

There are no known outstanding issues or concerns with implementation of the proposed rules. In accordance with H.B. 46, the rule must be effective not later than October 1, 2025.

**STAKEHOLDER INVOLVEMENT:**

DSHS consulted with the Community Health Improvement Medical Director on the proposed amended rule and DPS to propose the new rule as required by H.B. 46. Additionally, stakeholders will have an opportunity to provide feedback during the formal public comment period.

**FISCAL IMPACT:**

☒ None

**SERVICES IMPACT STATEMENT:**

The public will benefit by giving qualified patients access to additional treatment modalities.

**RULE DEVELOPMENT SCHEDULE:**

August 21, 2025	Present to HHSC Executive Council
August 22, 2025	Publish proposed rules in <i>Texas Register</i>
September 2025	Publish adopted rules in <i>Texas Register</i>
October 1, 2025	Effective date

TITLE 25	HEALTH SERVICES
PART 1	DEPARTMENT OF STATE HEALTH SERVICES
CHAPTER 1	MISCELLANEOUS PROVISIONS
SUBCHAPTER D	LOW-THC CANNABIS FOR COMPASSIONATE USE

### PROPOSAL PREAMBLE

The executive commissioner of the Texas Health and Human Services Commission (HHSC), on behalf of the Texas Department of State Health Services (DSHS), proposes an amendment to §1.61, concerning Incurable Neurodegenerative Diseases, and new §1.63, concerning Pulmonary Inhalation Devices for Low-THC Cannabis.

### BACKGROUND AND PURPOSE

The purpose of the proposal is to implement House Bill (H.B.) 46, by King et al, 89th Legislature, Regular Session, 2025, which amends Texas Occupations Code §169.003 to allow DSHS to receive physician requests to add medical conditions to the list of qualifying conditions for which physicians may prescribe low-THC cannabis under the Texas Compassionate Use Program at the Texas Department of Public Safety. H.B. 46 also amends Texas Occupations Code Chapter 169 to add §169.006 to allow physicians to prescribe medical devices for the pulmonary inhalation of an aerosol or vapor to administer low-THC cannabis and establish a timeline for reviewing and approving such devices. In accordance with H.B. 46, the rule must be effective not later than October 1, 2025.

### SECTION-BY-SECTION SUMMARY

The proposed amendment to §1.61, Incurable Neurodegenerative Diseases, changes the rule title to "Medical Conditions for which a Physician May Prescribe Low-THC Cannabis." The proposed amendment also prescribes the way a physician may request additional medical conditions be added to the list of qualifying conditions.

Proposed new §1.63, Pulmonary Inhalation Devices for Low-THC Cannabis, defines a pulmonary inhalation medical device of an aerosol or vapor a physician may prescribe to a qualified patient and establishes a timeline for reviewing and approving such devices.

### FISCAL NOTE

Christy Havel-Burton, DSHS Chief Financial Officer, has determined for each year of the first five years the rules will be in effect, enforcing or administering the rules does not have foreseeable implications relating to costs or revenues of state or local governments.

## GOVERNMENT GROWTH IMPACT STATEMENT

DSHS has determined during the first five years the rules will be in effect:

- (1) the proposed rules will not create or eliminate a government program;
- (2) implementation of the proposed rules will not affect the number of DSHS employee positions;
- (3) implementation of the proposed rules will result in no assumed change in future legislative appropriations;
- (4) the proposed rules will not affect fees paid to DSHS;
- (5) the proposed rules will create a new regulation;
- (6) the proposed rules will expand existing regulation;
- (7) the proposed rules will increase the number of individuals subject to the rules;  
and
- (8) DSHS has insufficient information to determine the proposed rules' effect on the state's economy.

## SMALL BUSINESS, MICRO-BUSINESS, AND RURAL COMMUNITY IMPACT ANALYSIS

Christy Havel-Burton has also determined there will be no adverse economic effect on small businesses, micro-businesses, or rural communities. The rules do not impose any requirements or costs to small businesses, microbusinesses, or rural communities.

## LOCAL EMPLOYMENT IMPACT

The proposed rules will not affect a local economy.

## COSTS TO REGULATED PERSONS

Texas Government Code §2001.0045 does not apply to these rules because the rules are necessary to implement legislation that does not specifically state that §2001.0045 applies to the rules.

## PUBLIC BENEFIT AND COSTS

Manda Hall, M.D., Deputy Commissioner, Community Health Improvement Division, has determined for each year of the first five years the rules are in effect, the public may benefit from the use of pulmonary inhalation devices for low-THC cannabis treatment through the Texas Compassionate Use Program.

Christy Havel-Burton has also determined for the first five years the rules are in effect, there are no anticipated economic costs to persons who are required to comply with the proposed rules. The rules are intended to provide guidance for low-THC cannabis pulmonary inhalation devices for treatment under the Texas Compassionate Use Program.

#### TAKINGS IMPACT ASSESSMENT

DSHS has determined that the proposal does not restrict or limit an owner's right to the owner's property that would otherwise exist in the absence of government action and, therefore, does not constitute a taking under Texas Government Code §2007.043.

#### PUBLIC COMMENT

Written comments on the proposal may be submitted to Rules Coordination Office, P.O. Box 13247, Mail Code 4102, Austin, Texas 78711-3247, or street address 4601 West Guadalupe Street, Austin, Texas 78751; or emailed to [HHSRulesCoordinationOffice@hhs.texas.gov](mailto:HHSRulesCoordinationOffice@hhs.texas.gov).

To be considered, comments must be submitted no later than 31 days after the date of this issue of the *Texas Register*. Comments must be (1) postmarked or shipped before the last day of the comment period; (2) hand-delivered before 5:00 p.m. on the last working day of the comment period; or (3) emailed before midnight on the last day of the comment period. If the last day to submit comments falls on a holiday, comments must be postmarked, shipped, or emailed before midnight on the following business day to be accepted. When emailing comments, please indicate "Comments on Proposed Rule 25R037" in the subject line.

#### STATUTORY AUTHORITY

The amendment and new section are authorized by Texas Occupations Code Chapter 169 and Texas Government Code §524.0151, which provide that the executive commissioner of HHSC shall adopt rules for the operation and provision of services by the health and human services system, and Texas Health and Safety Code §1001.075 which authorizes the executive commissioner of HHSC to adopt rules necessary for the operation and provision of health and human services by DSHS and for the administration of Texas Occupations Code Chapter 169.

The amendment and new section affect Texas Occupations Code Chapter 169, Texas Government Code §524.0151, and Texas Health and Safety Code Chapter 1001.

This agency hereby certifies that this proposal has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

TITLE 25                      HEALTH SERVICES  
PART 1                        DEPARTMENT OF STATE HEALTH SERVICES  
CHAPTER 1                  MISCELLANEOUS PROVISIONS  
SUBCHAPTER D              LOW-THC CANNABIS FOR COMPASSIONATE USE

**§1.61. Medical Conditions for which a Physician May Prescribe Low-THC Cannabis-Incurable Neurodegenerative Diseases.**

(a) 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.

(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, or one or more of the following incurable neurodegenerative diseases:

(1) Incurable Neurodegenerative Diseases with Adult Onset:

(A) Motor Neuron Disease:

(i) Amyotrophic lateral sclerosis;

(ii) Spinal-bulbar muscular atrophy; and

(iii) Spinal Muscular Atrophy.

(B) Muscular Dystrophies:

(i) Duchenne Muscular Dystrophy;

(ii) Central Core; and

(iii) Facioscapulohumeral Muscular Dystrophy.

(C) Freidreich's Ataxia.

(D) Vascular dementia.

(E) Charcot Marie Tooth and related hereditary neuropathies.

(F) Spinocerebellar ataxia.

(G) Familial Spastic Paraplegia.

(H) Progressive dystonias DYT genes 1 through 20.

(I) Progressive Chorea: Huntington's Disease.

(J) Amyloidoses:

(i) Alzheimer's Disease;

(ii) Prion Diseases:

(I) Creutzfeldt-Jakob Disease;

(II) Gerstmann-Straussler-Scheinker Disease;

(III) Familial or Sporadic Fatal Insomnia; and

(IV) Kuru.

(K) Tauopathies.

(i) Chronic Traumatic Encephalopathy;

(ii) Pick Disease;

(iii) Globular Glial Tauopathy;

(iv) Corticobasal Degeneration;

(v) Progressive Supranuclear Palsy;

(vi) Argyrophilic Grain Disease;

(vii) Neurofibrillary Tangle dementia, also known as Primary Age-related Tauopathy; and

(viii) Frontotemporal dementia and parkinsonism linked to chromosome 17 caused by mutations in MAPT gene.

(L) Synucleinopathies:

(i) Lewy Body Disorders:

(I) Dementia with Lewy Bodies; and

(II) Parkinson's Disease; and

(ii) Multiple System Atrophy.

(M) Transactive response DNA-binding protein-43 (TDP-43) Proteinopathies:

- (i) Frontotemporal Lobar Degeneration;
- (ii) Primary Lateral Sclerosis; and
- (iii) Progressive Muscular Atrophy.

(2) Incurable Neurodegenerative Diseases with Pediatric Onset:

(A) Mitochondrial Conditions:

- (i) Kearns Sayers Syndrome;
- (ii) Mitochondrial Encephalopathy Ragged Red Fiber;
- (iii) Mitochondrial Encephalopathy Lactic Acidosis Stroke;
- (iv) Neuropathy, Ataxia, and Retinitis Pigmentosa;
- (v) Mitochondrial neurogastrointestinal encephalopathy;
- (vi) Polymerase G Related Disorders:
  - (I) Alpers-Huttenlocher syndrome;
  - (II) Childhood Myocerebrohepatopathy spectrum;
  - (III) Myoclonic epilepsy myopathy sensory ataxia; and
  - (IV) Ataxia neuropathy spectrum;
- (vii) Subacute necrotizing encephalopathy, also known as Leigh syndrome;
- (viii) Respiratory chain disorders complex 1 through 4 defects: Co Q biosynthesis defects;
- (ix) Thymidine Kinase;
- (x) Mitochondrial Depletion syndromes types 1 through 14:
  - (I) Deoxyguanosine kinase deficiency;
  - (II) SUCLG1-related mitochondrial DNA depletion syndrome, encephalomyopathic form with methylmalonic aciduria; and



(III) RRM2B-related mitochondrial disease.

(B) Creatine Disorders:

- (i) Guanidinoacetate methyltransferase deficiency;
- (ii) L-Arginine/glycine amidinotransferase deficiency; and
- (iii) Creatine Transporter Defect, also known as SLC 6A8.

(C) Neurotransmitter defects:

| Dystonia; (i) Segawa ~~Disease~~Disease, also known as Dopamine Responsive

- (ii) Guanosine triphosphate cyclohydrolase deficiency;
- (iii) Aromatic L-amino acid decarboxylase deficiency;
- (iv) Monoamine oxidase deficiency;

(v) Biopterin Defects:

- (I) Pyruvoyl-tetrahydropterin synthase;
- (II) Sepiapterin reductase;
- (III) Dihydropteridine reductase; and
- (IV) Pterin-4-carbinolamine dehydratase.

(D) Congenital Disorders of Glycosylation.

(E) Lysosomal Storage Diseases:

(i) Mucopolysaccharidosis:

Syndrome or Scheie Syndrome; (I) Mucopolysaccharidosis Type I, also known as Hurler

Syndrome; (II) Mucopolysaccharidosis Type II, also known as Hunter

and B; (III) Mucopolysaccharidosis Type III, also known as Sanfilippo A

Lamy; and (IV) Mucopolysaccharidosis Type IV, also known as Maroteaux-

(V) Mucopolysaccharidosis Type VII, also known as Sly.

(ii) Oligosaccharidoses:

(I) Mannosidosis;

(II) Alpha-fucosidosis;

(III) Galactosialidosis;

(IV) Asparylglucosaminuria;

(V) Schindler; and

(VI) Sialidosis;

(iii) Mucopolidoses:

and (I) Mucopolidoses Type II, also known as Inclusion Cell disease;

polydystrophy; (II) Mucopolidoses Type III, also known as pseudo-Hurler

(iv) Sphingolipidoses:

(I) Gaucher Type 2 and Type 3;

(II) Neimann Pick Type A and B;

(III) Neimann Pick Type C;

(IV) Krabbe;

(V) GM1 gangliosidosis;

Disease; (VI) GM2 gangliosidosis also known as Tay-sachs and Sandhoff

(VII) Metachromatic leukodystrophy;

Disease; and (VIII) Neuronal ceroid lipofuscinosis types 1-10 including Batten

(IX) Farber Disease; and

(v) Glycogen Storage-Lysosomal: Pompe Disease.

(F) Peroxisomal Disorders:

(i) X-linked adrenoleukodystrophy;

(ii) Peroxisomal biosynthesis defects:

(I) Zellweger syndrome:

(II) Neonatal Adrenoleukodystrophy; and

(iii) D Bidirectional enzyme deficiency.

(G) Leukodystrophy:

(i) Canavan disease;

(ii) Pelizaeus-Merzbacher disease;

(iii) Alexander disease;

(iv) Multiple Sulfatase deficiency;

(v) Polyol disorders;

(vi) Glycine encephalopathy, also known as non-ketotic hyperglycinemia;

(vii) Maple Syrup Urine Disease;

(viii) Homocysteine re-methylation defects;

(ix) Methylenetetrahydrofolate reductase deficiency severe variant;

(x) L-2-hydroxyglutaric aciduria;

(xi) Glutaric acidemia type 1;

(xii) 3-hydroxy-3-methylglutaryl-CoA lyase deficiency;

(xiii) Galactosemia;

(xiv) Manosidosis alpha and beta;

- (xv) Salidososis;
- (xvi) Peripheral neuropathy types 1 through 4;
- (xvii) Pyruvate Dehydrogenase Deficiency;
- (xviii) Pyruvate Carboxylase Deficiency;
- (xix) Refsum Disease; and

(xx) Cerebral Autosomal Dominant Arteriopathy with Sub-cortical Infarcts and Leukoencephalopathy.

(H) Fatty Acid Oxidation:

- (i) Trifunctional protein deficiency; and
- (ii) Long-chain L-3 hydroxyacyl-CoA dehydrogenase deficiency.

(I) Metal Metabolism:

- (i) Wilson Disease;
- (ii) Pantothenate Kinase Associated Neurodegeneration; and
- (iii) Neurodegeneration with brain iron accumulation.

(J) Purine and Pyrimidine Defects:

- (i) Adenylosuccinate synthase Deficiency;
- (ii) 5-aminoimidazole-4-carboxamide ribonucleotide transformylase deficiency;
- (iii) Hypoxanthine-guanine phosphoribosyltransferase Deficiency also known as Lesch-Nyhan disease;
- (iv) Dihydropyrimidine dehydrogenase Deficiency; and
- (v) Dihydropyrimidinase Deficiency.

(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, DSHS will assess those requests 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.

**§1.63. Pulmonary Inhalation Devices for Low-THC Cannabis.**

(a) A pulmonary inhalation device is a machine designed, marketed, and commercially sold to allow a user to inhale an aerosolized or vaporized substance.

(b) A pulmonary inhalation device must not burn or ignite a substance for the purpose of inhaling smoke.

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

(d) A qualifying physician under Texas Occupations Code Chapter 169 may submit a form to DSHS to request adding a pulmonary inhalation device to the list from which a physician may choose when prescribing a pulmonary inhalation device 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 website.

(f) The Texas Department of State Health Services must review pulmonary inhalation devices every six months with stakeholders to determine potential changes to this section.