

TITLE 25 HEALTH SERVICES
PART 1 DEPARTMENT OF STATE HEALTH SERVICES
CHAPTER 1 MISCELLANEOUS PROVISIONS
SUBCHAPTER D DESIGNATING INCURABLE NEURODEGENERATIVE
DISEASES

§1.61. 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 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) Freidrich'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 Choreas: Huntington's Disease.

(J) Amyloidoses:

(i) Alzheimer's Disease;

(ii) Prion Diseases:

(I) Creutzfeldt-Jakob Disease;

(II) Gerstmann-Strausler-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:

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

(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:

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

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

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

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

(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) Mucopolipidoses:

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

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

(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;

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

(VII) Metachromatic leukodystrophy;

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

(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) Sialidosis;

(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 request to the department to have a disease added.

(d) A request under subsection (c) of this section shall be submitted 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) After review of the submitted documentation, the department may request additional information or make a determination.

AN ACT

relating to the prescription of low-THC cannabis for medical use by certain qualified physicians to patients with certain medical conditions.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Section 169.001, Occupations Code, is amended by adding Subdivisions (1-a) and (6) and amending Subdivision (3) to read as follows:

(1-a) "Incurable neurodegenerative disease" means a disease designated as an incurable neurodegenerative disease by rule of the executive commissioner of the Health and Human Services Commission, adopted in consultation with the National Institutes of Health.

(3) "Low-THC cannabis" means the plant *Cannabis sativa* L., and any part of that plant or any compound, manufacture, salt, derivative, mixture, preparation, resin, or oil of that plant that contains[+]

~~[(A)] not more than 0.5 percent by weight of tetrahydrocannabinols[, and~~

~~[(B) not less than 10 percent by weight of cannabidiol].~~

(6) "Terminal cancer" means cancer that meets the criteria for a terminal illness, as defined by Section 1003.051, Health and Safety Code.

1 SECTION 2. Chapter 169, Occupations Code, is amended by
2 adding Section 169.0011 and amending Sections 169.002, 169.003, and
3 169.004 to read as follows:

4 Sec. 169.0011. PRESCRIPTION FOR MEDICAL USE. A reference
5 in this chapter, Chapter 487, Health and Safety Code, or other law
6 to a prescription for medical use or a prescription for low-THC
7 cannabis means an entry in the compassionate-use registry
8 established under Section 487.054, Health and Safety Code.

9 Sec. 169.002. PHYSICIAN QUALIFIED TO PRESCRIBE LOW-THC
10 CANNABIS TO PATIENTS WITH CERTAIN MEDICAL CONDITIONS. (a) Only a
11 physician qualified with respect to a patient's particular medical
12 condition as provided by this section may prescribe low-THC
13 cannabis in accordance with this chapter to treat the applicable
14 medical condition.

15 (b) A physician is qualified to prescribe low-THC cannabis
16 with respect to a patient's particular medical condition [~~to a~~
17 ~~patient with intractable epilepsy~~] if the physician:

18 (1) is licensed under this subtitle;

19 (2) is board certified in a medical specialty relevant
20 to the treatment of the patient's particular medical condition by a
21 specialty board approved by the American Board of Medical
22 Specialties or the Bureau of Osteopathic Specialists; and

23 (3) dedicates a significant portion of clinical
24 practice to the evaluation and treatment of the patient's
25 particular medical condition [~~epilepsy, and~~

26 [~~(3) is certified:~~

27 [~~(A) by the American Board of Psychiatry and~~

1 Neurology in:

2 ~~[(i) epilepsy; or~~

3 ~~[(ii) neurology or neurology with special~~
4 ~~qualification in child neurology and is otherwise qualified for the~~
5 ~~examination for certification in epilepsy; or~~

6 ~~[(B) in neurophysiology by:~~

7 ~~[(i) the American Board of Psychiatry and~~
8 ~~Neurology; or~~

9 ~~[(ii) the American Board of Clinical~~
10 ~~Neurophysiology].~~

11 Sec. 169.003. PRESCRIPTION OF LOW-THC CANNABIS. A
12 physician described by Section 169.002 may prescribe low-THC
13 cannabis to a patient ~~[alleviate a patient's seizures]~~ if:

- 14 (1) the patient is a permanent resident of the state;
15 (2) the physician complies with the registration
16 requirements of Section 169.004; and

- 17 (3) the physician certifies to the department that:
18 (A) the patient is diagnosed with:
19 (i) [intractable] epilepsy;
20 (ii) a seizure disorder;
21 (iii) multiple sclerosis;
22 (iv) spasticity;
23 (v) amyotrophic lateral sclerosis;
24 (vi) autism;
25 (vii) terminal cancer; or
26 (viii) an incurable neurodegenerative

27 disease; and

1 (B) the physician determines the risk of the
2 medical use of low-THC cannabis by the patient is reasonable in
3 light of the potential benefit for the patient[~~, and~~
4 [~~(C) a second physician qualified to prescribe~~
5 ~~low-THC cannabis under Section 169.002 has concurred with the~~
6 ~~determination under Paragraph (B), and the second physician's~~
7 ~~concurrence is recorded in the patient's medical record]~~.

8 Sec. 169.004. LOW-THC CANNABIS PRESCRIBER REGISTRATION.

9 (a) Before a physician qualified to prescribe low-THC cannabis
10 under Section 169.002 may prescribe or renew a prescription for
11 low-THC cannabis for a patient under this chapter, the physician
12 must register as the prescriber for that patient in the
13 compassionate-use registry maintained by the department under
14 Section 487.054, Health and Safety Code. The physician's
15 registration must indicate:

- 16 (1) the physician's name;
17 (2) the patient's name and date of birth;
18 (3) the dosage prescribed to the patient;
19 (4) the means of administration ordered for the
20 patient; and
21 (5) the total amount of low-THC cannabis required to
22 fill the patient's prescription.

23 (b) The department may not publish the name of a physician
24 registered under this section unless permission is expressly
25 granted by the physician.

26 SECTION 3. Section 169.001(2), Occupations Code, is
27 repealed.

1 SECTION 4. Not later than December 1, 2019, the executive
2 commissioner of the Health and Human Services Commission, in
3 consultation with the National Institutes of Health, shall adopt
4 rules designating diseases as incurable neurodegenerative diseases
5 for which patients may be prescribed low-THC cannabis for medical
6 use under Chapter 169, Occupations Code, as amended by this Act.

7 SECTION 5. This Act takes effect immediately if it receives
8 a vote of two-thirds of all the members elected to each house, as
9 provided by Section 39, Article III, Texas Constitution. If this
10 Act does not receive the vote necessary for immediate effect, this
11 Act takes effect September 1, 2019.

President of the Senate

Speaker of the House

I certify that H.B. No. 3703 was passed by the House on May 8, 2019, by the following vote: Yeas 133, Nays 10, 2 present, not voting; and that the House concurred in Senate amendments to H.B. No. 3703 on May 24, 2019, by the following vote: Yeas 136, Nays 5, 1 present, not voting.

Chief Clerk of the House

I certify that H.B. No. 3703 was passed by the Senate, with amendments, on May 22, 2019, by the following vote: Yeas 31, Nays 0.

Secretary of the Senate

APPROVED: _____

Date

Governor