TO: Health and Human Services Commission Executive Council

DATE: November 14, 2019

FROM: Manda Hall, MD, Associate Commissioner, DSHS Community Health Improvement Division

AGENDA ITEM: 2.c

SUBJECT: **Designating Incurable Neurodegenerative Diseases**

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

The proposal is necessary to comply with House Bill (H.B.) 3703, 86th Legislature, Regular Session, 2019, which amended Texas Occupations Code, Chapter 169, and requires the Executive Commissioner of HHSC to adopt a rule designating incurable neurodegenerative diseases. The new rule designates incurable neurodegenerative diseases eligible for prescription of low-THC cannabis pursuant to Texas Occupations Code, Chapter 169. The Executive Commissioner charged rule development for the designation of incurable neurodegenerative diseases to DSHS.

ISSUES AND ALTERNATIVES:

There are no expected issues with adoption of this rule.

STAKEHOLDER INVOLVEMENT:

On June 28, 2019 and July 26, 2019, DSHS reached out to Dr. Johnathan Hollander, Health Scientist Administrator, and Dr. Cindy Lawler, Branch Chief, Genes, Environment, and Health, both with the National Institutes of Environmental Health Sciences (NIEHS) at the National Institutes of Health. Drs. Hollander and Lawler are program leads for NIEHS neurodegenerative disease grant program.

On July 30, 2019, DSHS consulted two neurology colleagues from Baylor College of Medicine/ Texas Children's Hospital and the Director of the University of Washington Neurogenetics Clinic to develop a list of incurable neurodegenerative diseases.

A public hearing was held on September 11, 2019. The proposed rule was published in the *Texas Register* on September 27, 2019, for a 31-day public comment period.

FISCAL IMPACT:

☒ None

SERVICES IMPACT STATEMENT:

The public benefit anticipated through this rule is the implementation of H.B. 3703, which is intended to allow patients with an incurable neurodegenerative disease to have access to more treatment options.

RULE DEVELOPMENT SCHEDULE:

September 27, 2019	*Publish proposed rule in* Texas Register
November 14, 2019	*Present to HHSC Executive Council*
November 2019	Publish adopted rule in *Texas Register*
December 2019	Effective date

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

PROPOSED PREAMBLE

The Executive Commissioner of the Texas Health and Human Services Commission (HHSC), on behalf of the Department of State Health Services (DSHS), proposes new §1.61, concerning designating incurable neurodegenerative diseases.

BACKGROUND AND PURPOSE

The proposal is necessary to comply with House Bill (H.B.) 3703, 86th Legislature, Regular Session, 2019, which amended Texas Occupations Code, Chapter 169, and requires the Executive Commissioner of HHSC to adopt a rule designating incurable neurodegenerative diseases. The new rule designates incurable neurodegenerative diseases eligible for prescription of low-THC cannabis pursuant to Texas Occupations Code, Chapter 169. The Executive Commissioner charged rule development for the designation of incurable neurodegenerative diseases to DSHS.

SECTION-BY-SECTION SUMMARY

The new rule includes a definition for an incurable neurodegenerative disease.

The new rule includes a list of incurable neurodegenerative diseases eligible for prescription of low-THC cannabis pursuant to Texas Occupations Code, Chapter 169.

The new rule provides a method to expand the list to include other incurable neurodegenerative diseases.

FISCAL NOTE

Donna Sheppard, DSHS Chief Financial Officer, has determined that for each year of the first five years that the rule will be in effect, enforcing or administering the rule does not have foreseeable implications relating to costs or revenues of state or local governments.

GOVERNMENT GROWTH IMPACT STATEMENT

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

(1) the proposed rule will not create or eliminate a government program;
(2) implementation of the proposed rule will not affect the number of DSHS employee positions;
(3) implementation of the proposed rule will result in no assumed change in future legislative appropriations;
(4) the proposed rule will not affect fees paid to DSHS;
(5) the proposed rule will create a new rule;
(6) the proposed rule will not expand, limit, or repeal an existing rule; and
(7) the proposed rule will not change the number of individuals subject to the rule.

DSHS has insufficient information to determine the proposed rule's effect on the state's economy.

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

Donna Sheppard has also determined that there will be no adverse economic effect on small businesses, micro-businesses, or rural communities, as the rule does not apply to small or micro-businesses, or rural communities. The rule does not impose any additional costs to small businesses, microbusinesses, or rural communities.

LOCAL EMPLOYMENT IMPACT

The proposed rule will not affect a local economy.

COSTS TO REGULATED PERSONS

Texas Government Code, §2001.0045 does not apply to this rule because the rule is necessary to implement H.B. 3703 that does not state that §2001.0045 applies to the rule.

PUBLIC BENEFIT AND COSTS

Dr. Manda Hall, Associate Commissioner of DSHS Community Health Improvement Division, has determined that for each year of the first five years the rule is in effect, the public benefit anticipated through this rule is the implementation of H.B. 3703, which designates incurable neurodegenerative diseases eligible for prescription of low-THC cannabis pursuant to Texas Occupations Code, Chapter 169.

Donna Sheppard has also determined that for the first five years the rule is in effect, there are no anticipated economic costs to persons who are required to comply with the proposed rule because the rule does not require any additional conduct for compliance.

TAKINGS IMPACT ASSESSMENT

DSHS has determined that the proposal does not restrict or limit an owner's right to his or her 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

Questions about the content of this proposal may be directed to Raiza Ruiz at (512) 776-3829 or at HPCDPS@dshs.texas.gov in the DSHS Heath Promotion and Chronic Disease Prevention Section.

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 4900 North Lamar Boulevard, Austin, Texas 78751; or emailed to HHSRulesCoordinationOffice@hhsc.state.tx.us.

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. When emailing comments, please indicate "Comments on Proposed Rule 19R060" in the subject line.

STATUTORY AUTHORITY

The new section is authorized by Texas Government Code, §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of services by the health and human services agencies; and H.B. 3703, which requires the Executive Commissioner of HHSC, in consultation with the National Institutes of Health, to adopt a rule designating incurable neurodegenerative diseases eligible for prescription of low-THC cannabis pursuant to Texas Occupations Code, Chapter 169.

The new section implements Texas Occupations Code, Chapter 169.

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 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-Strausller-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) Kearn 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-Huttenlodcher 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) Deoxyguanisine kinase deficiency;

(II) SUCLG1-related mitochondrial DNA depletion syndrome, encephalmyopathic form with methylmalonic aciduria; and

(III) RRM2B-related mitochondrial disease.

(B) Creatine Disorders:

(i) Guanidinoacetate methytransferase deficiency;

(ii) L-Arginine/glycine amidinotransferase deficiency; and

(iii) Creatine Transporter Defect, also known as SLC 6A8.

(C) Neurotransmitter defects:

(i) Segawa Diease, 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-tetahydropterin synthase;

(I) Sepiapterin reductase;

(III) Dihydropteridine reductase; and

(IV) Pterin-4-carbinolamine dehydratase.

(D) Congenital Disorders of Glycosylation.

(E) Lysosomal Storage Diseases:

(i) Mucopolysaccaridosis:

(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) Mucolipidoses:

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

(II) Mucolipidoses 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) Salidosis;

(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 phosophoribosyltransferase Deficiency also known as Lesch-Nyhan disease;

(iv) Dihydropyrimidine dehydrogenase Deficiency; and

(v) Dihydropirimidinase 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.