

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.

SECTION 2. Chapter 169, Occupations Code, is amended by adding Section 169.001i and amending Sections 169.002, 169.003, and 169.004 to read as follows:

Sec. 169.001i. PRESCRIPTION FOR MEDICAL USE. A reference in this chapter, Chapter 487, Health and Safety Code, or other law to a prescription for medical use or a prescription for low-THC cannabis means an entry in the compassionate-use registry established under Section 487.054, Health and Safety Code.

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

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

- (1) is licensed under this subtitle;
- (2) is board certified in a medical specialty relevant to the treatment of the patient's particular medical condition by a specialty board approved by the American Board of Medical Specialties or the Bureau of Osteopathic Specialists; and

(3) dedicates a significant portion of clinical practice to the evaluation and treatment of the patient's particular medical condition [epilepsy; and
{3} is certified.

[+A] -- by the American Board of Psychiatry and Neurology in:

- [+i] epilepsy; or
- [+ii] -- neurology or neurology with special qualification in child neurology and is otherwise qualified for the examination for certification in epilepsy; or

[+B] in neurophysiology by:

- [+i] -- the American Board of Psychiatry and Neurology; or

[+ii] -- the American Board of Clinical Neurophysiology].

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

- (1) the patient is a permanent resident of the state;
- (2) the physician complies with the registration requirements of Section 169.004; and
- (3) the physician certifies to the department that:

- (A) the patient is diagnosed with:
 - (i) [intractable] epilepsy;
 - (ii) a seizure disorder;
 - (iii) multiple sclerosis;
 - (iv) spasticity;
 - (v) amyotrophic lateral sclerosis;
 - (vi) autism;
 - (vii) terminal cancer; or
 - (viii) an incurable neurodegenerative disease; and

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

Sec. 169.004. LOW-THC CANNABIS PRESCRIBER REGISTRATION. (a) Before a physician qualified to prescribe low-THC cannabis under Section 169.002 may prescribe or renew a prescription for low-THC cannabis for a patient under this chapter, the physician must register as the prescriber for that patient in the compassionate-use registry maintained by the department under Section 487.054, Health and Safety Code. The physician's registration must indicate:

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

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

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

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

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

OCCUPATIONS CODE
TITLE 3. HEALTH PROFESSIONS
SUBTITLE B. PHYSICIANS
CHAPTER 169. AUTHORITY TO PRESCRIBE LOW-THC CANNABIS TO CERTAIN PATIENTS FOR COMPASSIONATE USE
Sec. 169.001. DEFINITIONS. In this chapter: <div><div>(1) "Department" means the Department of Public Safety.</div><div>(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.</div><div>(2) Repealed by Acts 2019, 86th Leg., R.S., Ch. 1300 (H.B. 3703), Sec. 3, eff. June 14, 2019.</div><div>(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 not more than one percent by weight of tetrahydrocannabinols.</div><div>(4) "Medical use" means the ingestion by a means of administration other than by smoking of a prescribed amount of low-THC cannabis by a person for whom low-THC cannabis is prescribed under this chapter.</div><div>(5) "Smoking" means burning or igniting a substance and inhaling the smoke.</div><div>(6) Repealed by Acts 2021, 87th Leg., R.S., Ch. 660 (H.B. 1535), Sec. 5, eff. September 1, 2021.</div></div>
Added by Acts 2015, 84th Leg., R.S., Ch. 301 (S.B. 339), Sec. 4, eff. June 1, 2015.
Amended by: <div><div>Acts 2019, 86th Leg., R.S., Ch. 1300 (H.B. 3703), Sec. 1, eff. June 14, 2019.</div><div>Acts 2019, 86th Leg., R.S., Ch. 1300 (H.B. 3703), Sec. 3, eff. June 14, 2019.</div><div>Acts 2021, 87th Leg., R.S., Ch. 660 (H.B. 1535), Sec. 2, eff. September 1, 2021.</div><div>Acts 2021, 87th Leg., R.S., Ch. 660 (H.B. 1535), Sec. 5, eff. September 1, 2021.</div></div>
Sec. 169.0011. PRESCRIPTION FOR MEDICAL USE. A reference in this chapter, Chapter 487, Health and Safety Code, or other law to a prescription for medical use or a prescription for low-THC cannabis means an entry in the compassionate-use registry established under Section 487.054, Health and Safety Code.
Added by Acts 2019, 86th Leg., R.S., Ch. 1300 (H.B. 3703), Sec. 2, eff. June 14, 2019.
Sec. 169.002. PHYSICIAN QUALIFIED TO PRESCRIBE LOW-THC CANNABIS TO PATIENTS WITH CERTAIN MEDICAL CONDITIONS. (a) Only a physician qualified with respect to a patient's particular medical condition as provided by this section may prescribe low-THC cannabis in accordance with this chapter to treat the applicable medical condition. <div><div>(b) A physician is qualified to prescribe low-THC cannabis with respect to a patient's particular medical condition if the physician:<div><div>(1) is licensed under this subtitle;</div><div>(2) is board certified in a medical specialty relevant to the treatment of the patient's particular medical condition by a specialty board approved by the American Board of Medical Specialties or the Bureau of Osteopathic Specialists; and</div><div>(3) dedicates a significant portion of clinical practice to the evaluation and treatment of the patient's particular medical condition.</div></div></div><div>(c) A physician is qualified to prescribe low-THC cannabis for the treatment of a patient with a medical condition approved by rule of the executive commissioner of the Health and Human Services Commission for treatment in an approved research program conducted under Subchapter F, Chapter 487, Health and Safety Code, if the physician is:<div><div>(1) licensed under this subtitle; and</div><div>(2) certified by a compassionate-use institutional review board created under Section 487.253, Health and Safety Code, that oversees patient treatment undertaken as part of that approved research program.</div></div></div></div>
Added by Acts 2015, 84th Leg., R.S., Ch. 301 (S.B. 339), Sec. 4, eff. June 1, 2015.
Amended by: <div><div>Acts 2019, 86th Leg., R.S., Ch. 1300 (H.B. 3703), Sec. 2, eff. June 14, 2019.</div><div>Acts 2021, 87th Leg., R.S., Ch. 660 (H.B. 1535), Sec. 3, eff. September 1, 2021.</div></div>
Sec. 169.003. PRESCRIPTION OF LOW-THC CANNABIS. A physician described by Section 169.002 may prescribe low-THC cannabis to a patient if: <div><div>(1) the patient is a permanent resident of the state;</div><div>(2) the physician complies with the registration requirements of Section 169.004; and</div><div>(3) the physician certifies to the department that:<div><div>(A) the patient is diagnosed with:<div><div>(i) epilepsy;</div><div>(ii) a seizure disorder;</div><div>(iii) multiple sclerosis;</div><div>(iv) spasticity;</div><div>(v) amyotrophic lateral sclerosis;</div><div>(vi) autism;</div><div>(vii) cancer;</div><div>(viii) an incurable neurodegenerative disease;</div><div>(ix) post-traumatic stress disorder; or</div><div>(x) a medical condition that is approved for a research program under Subchapter F, Chapter 487, Health and Safety Code, and for which the patient is receiving treatment under that program; and</div></div></div><div>(B) the physician determines the risk of the medical use of low-THC cannabis by the patient is reasonable in light of the potential benefit for the patient.</div></div></div></div>
Added by Acts 2015, 84th Leg., R.S., Ch. 301 (S.B. 339), Sec. 4, eff. June 1, 2015.
Amended by: <div><div>Acts 2019, 86th Leg., R.S., Ch. 1300 (H.B. 3703), Sec. 2, eff. June 14, 2019.</div><div>Acts 2021, 87th Leg., R.S., Ch. 660 (H.B. 1535), Sec. 4, eff. September 1, 2021.</div></div>
Sec. 169.004. LOW-THC CANNABIS PRESCRIBER REGISTRATION. (a) Before a physician qualified to prescribe low-THC cannabis under Section 169.002 may prescribe or renew a prescription for low-THC cannabis for a patient under this chapter, the physician must register as the prescriber for that patient in the compassionate-use registry maintained by the department under Section 487.054, Health and Safety Code. The physician's registration must indicate: <div><div>(1) the physician's name;</div><div>(2) the patient's name and date of birth;</div><div>(3) the dosage prescribed to the patient;</div><div>(4) the means of administration ordered for the patient; and</div><div>(5) the total amount of low-THC cannabis required to fill the patient's prescription.</div></div> <div>(b) The department may not publish the name of a physician registered under this section unless permission is expressly granted by the physician.</div>
Added by Acts 2015, 84th Leg., R.S., Ch. 301 (S.B. 339), Sec. 4, eff. June 1, 2015.
Amended by: <div><div>Acts 2019, 86th Leg., R.S., Ch. 1300 (H.B. 3703), Sec. 2, eff. June 14, 2019.</div></div>
Sec. 169.005. PATIENT TREATMENT PLAN. A physician described by Section 169.002 who prescribes low-THC cannabis for a patient's medical use under this chapter must maintain a patient treatment plan that indicates: <div><div>(1) the dosage, means of administration, and planned duration of treatment for the low-THC cannabis;</div><div>(2) a plan for monitoring the patient's symptoms; and</div><div>(3) a plan for monitoring indicators of tolerance or reaction to low-THC cannabis.</div></div>
Added by Acts 2015, 84th Leg., R.S., Ch. 301 (S.B. 339), Sec. 4, eff. June 1, 2015.

HEALTH AND SAFETY CODE

TITLE 6. FOOD, DRUGS, ALCOHOL, AND HAZARDOUS SUBSTANCES

SUBTITLE C. SUBSTANCE ABUSE REGULATION AND CRIMES

CHAPTER 487. TEXAS COMPASSIONATE-USE ACT

SUBCHAPTER A. GENERAL PROVISIONS

Sec. 487.001. DEFINITIONS. In this chapter:

- (1) "Department" means the Department of Public Safety.
- (2) "Director" means the public safety director of the department.
- (3) "Dispensing organization" means an organization licensed by the department to cultivate, process, and dispense low-THC cannabis to a patient for whom low-THC cannabis is prescribed under Chapter 169, Occupations Code.
- (4) "Low-THC cannabis" has the meaning assigned by Section 169.001, Occupations Code.

Added by Acts 2015, 84th Leg., R.S., Ch. 301 (S.B. 339), Sec. 1, eff. June 1, 2015.

SUBCHAPTER B. DUTIES OF DEPARTMENT

Sec. 487.051. DUTIES OF DEPARTMENT. The department shall administer this chapter.

Added by Acts 2015, 84th Leg., R.S., Ch. 301 (S.B. 339), Sec. 1, eff. June 1, 2015.

Sec. 487.052. RULES. The director shall adopt any rules necessary for the administration and enforcement of this chapter, including rules imposing fees under this chapter in amounts sufficient to cover the cost of administering this chapter.

Added by Acts 2015, 84th Leg., R.S., Ch. 301 (S.B. 339), Sec. 1, eff. June 1, 2015.

Sec. 487.053. LICENSING OF DISPENSING ORGANIZATIONS AND REGISTRATION OF CERTAIN ASSOCIATED INDIVIDUALS. (a) The department shall:

- (1) issue or renew a license to operate as a dispensing organization to each applicant who satisfies the requirements established under this chapter; and
- (2) register directors, managers, and employees of each dispensing organization.

(b) Subject to Section 411.503, Government Code, the department shall enforce compliance of licensees and registrants and shall adopt procedures for suspending or revoking a license or registration issued under this chapter and for renewing a license or registration issued under this chapter.

Added by Acts 2015, 84th Leg., R.S., Ch. 301 (S.B. 339), Sec. 1, eff. June 1, 2015.

Amended by:

Acts 2019, 86th Leg., R.S., Ch. 595 (S.B. 616), Sec. 4.008, eff. September 1, 2019.

Sec. 487.054. COMPASSIONATE-USE REGISTRY. (a) The department shall establish and maintain a secure online compassionate-use registry that contains:

- (1) the name of each physician who registers as the prescriber for a patient under Section 169.004, Occupations Code, the name and date of birth of the patient, the dosage prescribed, the means of administration ordered, and the total amount of low-THC cannabis required to fill the patient's prescription; and
- (2) a record of each amount of low-THC cannabis dispensed by a dispensing organization to a patient under a prescription.

(b) The department shall ensure the registry:

- (1) is designed to prevent more than one qualified physician from registering as the prescriber for a single patient;
- (2) is accessible to law enforcement agencies and dispensing organizations for the purpose of verifying whether a patient is one for whom low-THC cannabis is prescribed and whether the patient's prescriptions have been filled; and
- (3) allows a physician qualified to prescribe low-THC cannabis under Section 169.002, Occupations Code, to input safety and efficacy data derived from the treatment of patients for whom low-THC cannabis is prescribed under Chapter 169, Occupations Code.

Added by Acts 2015, 84th Leg., R.S., Ch. 301 (S.B. 339), Sec. 1, eff. June 1, 2015.

SUBCHAPTER C. LICENSE TO OPERATE AS DISPENSING ORGANIZATION

Sec. 487.101. LICENSE REQUIRED. A license issued by the department under this chapter is required to operate a dispensing organization.

Added by Acts 2015, 84th Leg., R.S., Ch. 301 (S.B. 339), Sec. 1, eff. June 1, 2015.

Sec. 487.102. ELIGIBILITY FOR LICENSE. An applicant for a license to operate as a dispensing organization is eligible for the license if:

- (1) as determined by the department, the applicant possesses:
 - (A) the technical and technological ability to cultivate and produce low-THC cannabis;
 - (B) the ability to secure:
 - (i) the resources and personnel necessary to operate as a dispensing organization; and
 - (ii) premises reasonably located to allow patients listed on the compassionate-use registry access to the organization through existing infrastructure;
 - (C) the ability to maintain accountability for the raw materials, the finished product, and any by-products used or produced in the cultivation or production of low-THC cannabis to prevent unlawful access to or unlawful diversion or possession of those materials, products, or by-products; and
 - (D) the financial ability to maintain operations for not less than two years from the date of application;
- (2) each director, manager, or employee of the applicant is registered under Subchapter D; and
- (3) the applicant satisfies any additional criteria determined by the director to be necessary to safely implement this chapter.

Added by Acts 2015, 84th Leg., R.S., Ch. 301 (S.B. 339), Sec. 1, eff. June 1, 2015.

Sec. 487.103. APPLICATION. (a) A person may apply for an initial or renewal license to operate as a dispensing organization by submitting a form prescribed by the department along with the application fee in an amount set by the director.

(b) The application must include the name and address of the applicant, the name and address of each of the applicant's directors, managers, and employees, and any other information considered necessary by the department to determine the applicant's eligibility for the license.

Added by Acts 2015, 84th Leg., R.S., Ch. 301 (S.B. 339), Sec. 1, eff. June 1, 2015.

Sec. 487.104. ISSUANCE, RENEWAL, OR DENIAL OF LICENSE. (a) The department shall issue or renew a license to operate as a dispensing organization only if:

- (1) the department determines the applicant meets the eligibility requirements described by Section 487.102; and
- (2) issuance or renewal of the license is necessary to ensure reasonable statewide access to, and the availability of, low-THC cannabis for patients registered in the compassionate-use registry and for whom low-THC cannabis is prescribed under Chapter 169, Occupations Code.

(b) If the department denies the issuance or renewal of a license under Subsection (a), the applicant is entitled to a hearing. Chapter 2001, Government Code, applies to a proceeding under this section.

(c) A license issued or renewed under this section expires as determined by the department in accordance with Section 411.511, Government Code.

Added by Acts 2015, 84th Leg., R.S., Ch. 301 (S.B. 339), Sec. 1, eff. June 1, 2015.

Amended by:

Acts 2019, 86th Leg., R.S., Ch. 595 (S.B. 616), Sec. 4.009, eff. September 1, 2019.

Sec. 487.105. CRIMINAL HISTORY BACKGROUND CHECK. (a) An applicant for the issuance or renewal of a license to operate as a dispensing organization shall provide the department with the applicant's name and the name of each of the applicant's directors, managers, and employees.

(b) Before a dispensing organization licensee hires a manager or employee for the organization, the licensee must provide the department with the name of the prospective manager or employee. The licensee may not transfer the license to another person before that prospective applicant and the applicant's directors, managers, and employees pass a criminal history background check and are registered as required by Subchapter D.

(c) The department shall conduct a criminal history background check on each individual whose name is provided to the department under Subsection (a) or (b). The director by rule shall:

- (1) require each individual whose name is provided to the department under Subsection (a) or (b) to submit a complete set of fingerprints to the department on a form prescribed by the department for purposes of a criminal history background check under this section; and
- (2) establish criteria for determining whether an individual passes the criminal history background check for the purposes of this section.

(d) After conducting a criminal history background check under this section, the department shall notify the relevant applicant or organization and the individual who is the subject of the criminal history background check as to whether the individual passed the criminal history background check.

Added by Acts 2015, 84th Leg., R.S., Ch. 301 (S.B. 339), Sec. 1, eff. June 1, 2015.

Amended by:

Acts 2019, 86th Leg., R.S., Ch. 595 (S.B. 616), Sec. 4.010, eff. September 1, 2019.

Sec. 487.106. DUTY TO MAINTAIN ELIGIBILITY. A dispensing organization must maintain compliance at all times with the eligibility requirements described by Section 487.102.

Added by Acts 2015, 84th Leg., R.S., Ch. 301 (S.B. 339), Sec. 1, eff. June 1, 2015.

Sec. 487.107. DUTIES RELATING TO DISPENSING PRESCRIPTION. (a) Before dispensing low-THC cannabis to a person for whom the low-THC cannabis is prescribed under Chapter 169, Occupations Code, the dispensing organization must verify that the prescription presented:

- (1) is for a person listed as a patient in the compassionate-use registry;
- (2) matches the entry in the compassionate-use registry with respect to the total amount of low-THC cannabis required to fill the prescription; and
- (3) has not previously been filled by a dispensing organization as indicated by an entry in the compassionate-use registry.

(b) After dispensing low-THC cannabis to a patient for whom the low-THC cannabis is prescribed under Chapter 169, Occupations Code, the dispensing organization shall record in the compassionate-use registry the form and quantity of low-THC cannabis dispensed and the date and time of dispensation.

Added by Acts 2015, 84th Leg., R.S., Ch. 301 (S.B. 339), Sec. 1, eff. June 1, 2015.

Sec. 487.108. LICENSE SUSPENSION OR REVOCATION. (a) The department may at any time suspend or revoke a license issued under this chapter if the department determines that the licensee has not maintained the eligibility requirements described by Section 487.102 or has failed to comply with a duty imposed under this chapter.

(b) The director shall give written notice to the dispensing organization of a license suspension or revocation under this section and the grounds for the suspension or revocation. The notice must be sent by certified mail, return receipt requested.

(c) After suspending or revoking a license issued under this chapter, the director may seize or place under seal all low-THC cannabis and drug paraphernalia owned or possessed by the dispensing organization. If the director orders the revocation of the license, a disposition may not be made of the seized or sealed low-THC cannabis or drug paraphernalia until the time for administrative appeal of the order has elapsed or until all appeals have been concluded. When a revocation order becomes final, all low-THC cannabis and drug paraphernalia may be forfeited to the state as provided under Subchapter E, Chapter 481.

(d) Chapter 2001, Government Code, applies to a proceeding under this section.

Added by Acts 2015, 84th Leg., R.S., Ch. 301 (S.B. 339), Sec. 1, eff. June 1, 2015.

SUBCHAPTER D. REGISTRATION OF CERTAIN INDIVIDUALS

Sec. 487.151. REGISTRATION REQUIRED. (a) An individual who is a director, manager, or employee of a dispensing organization must apply for and obtain a registration under this section.

(b) An applicant for a registration under this section must:

- (1) be at least 18 years of age;
- (2) submit a complete set of fingerprints to the department in the manner required by department rule; and
- (3) pass a fingerprint-based criminal history background check as required by Section 487.105.

(c) A registration expires on the second anniversary of the date of the registration's issuance, unless suspended or revoked under rules adopted under this chapter.

Added by Acts 2015, 84th Leg., R.S., Ch. 301 (S.B. 339), Sec. 1, eff. June 1, 2015.

SUBCHAPTER E. DUTIES OF COUNTIES AND MUNICIPALITIES

Sec. 487.201. COUNTIES AND MUNICIPALITIES MAY NOT PROHIBIT LOW-THC CANNABIS. A municipality, county, or other political subdivision may not enact, adopt, or enforce a rule, ordinance, order, resolution, or other regulation that prohibits the cultivation, production, dispensing, or possession of low-THC cannabis, as authorized by this chapter.

Added by Acts 2015, 84th Leg., R.S., Ch. 301 (S.B. 339), Sec. 1, eff. June 1, 2015.

SUBCHAPTER F. COMPASSIONATE-USE RESEARCH AND REPORTING

Sec. 487.251. DEFINITIONS. In this subchapter:

- (1) "Executive commissioner" means the executive commissioner of the Health and Human Services Commission.
- (2) "Institutional review board" means a compassionate-use institutional review board established under Section 487.253.

Added by Acts 2021, 87th Leg., R.S., Ch. 660 (H.B. 1535), Sec. 1, eff. September 1, 2021.

Sec. 487.252. RULES. (a) Except as otherwise provided by Subsection (b), the executive commissioner shall adopt all necessary rules to implement this subchapter, including rules designating the medical conditions for which a patient may be treated with low-THC cannabis as part of an approved research program conducted under this subchapter.

(b) The Texas Medical Board may adopt rules regarding the certification of a physician by an institutional review board.

Added by Acts 2021, 87th Leg., R.S., Ch. 660 (H.B. 1535), Sec. 1, eff. September 1, 2021.

Sec. 487.253. COMPASSIONATE-USE INSTITUTIONAL REVIEW BOARDS. (a) One or more compassionate-use institutional review boards may be established to:

- (1) evaluate and approve proposed research programs to study the medical use of low-THC cannabis in treating a medical condition designated by rule of the executive commissioner under Section 487.252(a); and
- (2) oversee patient treatment undertaken as part of an approved research program, including the certification of treating physicians.

(b) An institutional review board must be affiliated with a dispensing organization and meet one of the following conditions:

- (1) be affiliated with a medical school, as defined by Section 61.501, Education Code;
- (2) be affiliated with a hospital licensed under Chapter 241 that has at least 150 beds;
- (3) be accredited by the Association for the Accreditation of Human Research Protection Programs;
- (4) be registered by the United States Department of Health and Human Services, Office for Human Research Protections, in accordance with 21 C.F.R. Part 56; or
- (5) be accredited by a national accreditation organization acceptable to the Texas Medical Board.

Added by Acts 2021, 87th Leg., R.S., Ch. 660 (H.B. 1535), Sec. 1, eff. September 1, 2021.

Sec. 487.254. REPORTS BY INSTITUTIONAL REVIEW BOARDS. Each institutional review board shall submit written reports that describe and assess the research findings of each approved research program to:

- (1) the Health and Human Services Commission, not later than October 1 of each year; and
- (2) the legislature, not later than October 1 of each even-numbered year.

Added by Acts 2021, 87th Leg., R.S., Ch. 660 (H.B. 1535), Sec. 1, eff. September 1, 2021.

Sec. 487.255. PATIENT TREATMENT. (a) Patient treatment provided as part of an approved research program under this subchapter may be administered only by a physician certified by an institutional review board to participate in the program.

(b) A patient participating in a research program under this subchapter must be a permanent resident of this state.

Added by Acts 2021, 87th Leg., R.S., Ch. 660 (H.B. 1535), Sec. 1, eff. September 1, 2021.

Sec. 487.256. INFORMED CONSENT. (a) Before receiving treatment under an approved research program, each patient must sign a written informed consent form.

(b) If the patient is a minor or lacks the mental capacity to provide informed consent, a parent, guardian, or conservator may provide informed consent on the patient's behalf.

(c) An institutional review board overseeing a research program under this subchapter may adopt a form to be used for the informed consent required by this section.

Added by Acts 2021, 87th Leg., R.S., Ch. 660 (H.B. 1535), Sec. 1, eff. September 1, 2021.

Texas Administrative Code

[TITLE 37](#)

[PART 1](#)

[CHAPTER 12](#)

[SUBCHAPTER G](#)

RULE §12.61

PUBLIC SAFETY AND CORRECTIONS

TEXAS DEPARTMENT OF PUBLIC SAFETY

COMPASSIONATE-USE/LOW-THC CANNABIS PROGRAM

PRODUCTION LIMITS

Production Limits

(a) This subchapter limits the amount of annual statewide production by licensees to the estimated demand as calculated under this subchapter but shall not be construed as adopting a standard of care for treatment involving the product. The intent of this subchapter reflects legislative intent to serve a narrow population of patients living with intractable epilepsy, as defined under Occupations Code, Chapter 169. The subchapter includes a provision allowing the department to increase the established production limit. This provision shall be executed if ever necessary to prevent the subchapter from ever being the cause of a patient legally prescribed the product under Occupations Code, Chapter 169, from being unable to access his or her full prescription from a licensee.

(b) On the first of every September or in accordance with subsection (i) of this section, the Department of State Health Services shall provide a report to the department with:

- (1) a current estimate of people living with intractable epilepsy, as defined by Occupations Code, Chapter 169, in Texas; and
- (2) the most current scientifically accepted dosage of product used to treat an average individual living with intractable epilepsy for one (1) year.

(c) Any information reported under subsection (b) of this section:

- (1) may be extrapolated from the number of beneficiaries receiving state public assistance treating individuals with intractable epilepsy;
- (2) is strictly for the purpose of estimating a limit on production under this chapter; and
- (3) shall not be construed as the Department of State Health Services adopting a standard of care for treating intractable epilepsy.

(d) Upon receipt of the report required under subsection (b), the department shall determine the maximum amount of product allowed to be produced statewide, which shall be limited to:

- (1) an amount required to treat one third of the population described in subsection (b)(1) of this section with each individual receiving the dosage determined by subsection (b)(2) of this section, if prior to September 1, 2018; or
- (2) the amount of product demand from the previous twelve (12) month period grown by a percent equal to the growth over the same previous twelve (12) month period in the population described by subsection (b)(1), if after September 1, 2018.

(e) The department shall determine a maximum amount of cannabis sativa plants needed to produce the amount of product described in subsection (d) and subsection (j) of this section, if applicable.

(f) Except as provided in subsection (j), each licensee shall not annually produce more than an amount of product described by subsection (d) divided by the number of licensees.

(g) In any fiscal year, licensees shall not have more live cannabis sativa plants than an amount authorized by the department in subsection (e) in this section divided by the number of licensees.

(h) Licensees may report a forecasted shortage of product once in any quarter of the fiscal year to the department, which shall forward the report to the Department of State Health Services.

(i) The Department of State Health Services may resend a revised report under subsection (b) at any time upon receipt of reliable information that conflicts with the most recently released report under subsection (b).

(j) The department may increase the amount allowed under subsection (d) upon notice from the Department of State Health Services under subsection (i). An increase under this subsection is limited to meeting the forecasted demand for product in Texas for the remainder of the current twelve (12) month period ending on the last day of August.

(k) After the department makes a determination under subsection (j), each licensee may increase their maximum production allowed under subsection (f) of this section by the amount of the increase divided by the number of licensees or as otherwise determined by the department.

(l) On March 1, 2018, the Department of State Health Services shall release updated population and dosage amounts required under subsection (b) that will determine the maximum amount of product allowed statewide under subsection (d)(1) of this subsection until September 1, 2018.

(m) Subsection (l) expires on September 1, 2018.

Source Note: The provisions of this §12.61 adopted to be effective March 15, 2017, 42 TexReg 1148

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COMPASSIONATE-USE REGISTRY

RULE §12.44

Prescriptions

Prescriptions for low-THC cannabis must be submitted electronically to the Compassionate-Use Registry in compliance with Texas Occupations Code, §169.003, and may be confirmed and dispensed based on the electronic prescription record in accordance with §487.107 of the Act.

Source Note: The provisions of this §12.44 adopted to be effective January 10, 2016, 41 TexReg 495

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COMPASSIONATE-USE REGISTRY

RULE §12.43

Prescriber Registration

(a) In addition to the requirements of Texas Occupations Code, §169.004, for purposes of identification the physician's registration must include the patient's address, the last four digits of the patient's Social Security number, and if applicable, the name of the patient's legal guardian.

(b) Physicians registered as prescribers of low-THC cannabis under Texas Occupations Code, Chapter 169 must immediately inform the department of any change to their qualifications to prescribe under §169.002.

Source Note: The provisions of this §12.43 adopted to be effective January 10, 2016, 41 TexReg 495

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COMPASSIONATE-USE REGISTRY

RULE §12.42

Verification of Patient Prescription

(a) Before dispensing any low-THC cannabis to a registered patient or the patient's legal guardian, the dispensing organization must verify the identity of the patient or guardian, verify the guardian's status, if applicable, and otherwise comply with the requirements of §487.107 of the Act.

(b) Upon dispensing the low-THC cannabis, the dispensing organization shall immediately enter into the registry the form and quantity of low-THC cannabis dispensed, the amount charged for the low-THC cannabis dispensed, and the date and time of dispensation.

Source Note: The provisions of this §12.42 adopted to be effective January 10, 2016, 41 TexReg 495; amended to be effective March 15, 2017, 42 TexReg 1147

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COMPASSIONATE-USE REGISTRY

RULE §12.41

Access to Compassionate-Use Registry

(a) Qualified physicians registered as prescribers of low-THC cannabis under Texas Occupations Code, Chapter 169 may access the Compassionate-Use Registry using the department's secure web portal.

(b) Dispensing organizations and law enforcement agencies may request access to the Compassionate-Use Registry for purposes of the Act and this chapter, including verifying whether a patient is one for whom low-THC cannabis is prescribed and whether the patient's prescriptions have been filled.

Source Note: The provisions of this §12.41 adopted to be effective January 10, 2016, 41 TexReg 495; amended to be effective March 15, 2017, 42 TexReg 1147

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APPLICATION AND RENEWAL

RULE §12.16

Denial of Application for Registration

The department may deny the application for registration of a director, manager, or employee of a dispensing organization if the applicant is disqualified pursuant to §12.3 of this title (relating to Criminal History Disqualifiers). The applicant may request a hearing by submitting a request through the department's website within thirty (30) days of the date of the denial notice.

Source Note: The provisions of this §12.16 adopted to be effective January 10, 2016, 41 TexReg 492

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APPLICATION AND RENEWAL

RULE §12.15

Denial of Application for License

-
- (a) The department may deny the application for a license as a dispensing organization if the applicant fails to pass the initial review of the application materials or the onsite inspection, based on the failure to satisfy the requirements reflected in subsection (b)(7) of §12.11 of this title (relating to Application for License), and has either failed to address the basis for the failure within sixty (60) days of notice of the failure, or has failed to request an additional thirty (30) days to address the basis for the failure.
- (b) The department may deny the application for a license if the applicant is found to have violated any provision of the Act or this chapter, or §§481.120, 481.121, 481.122, or 481.125 of the Texas Health and Safety Code prior to licensure or renewal.
- (c) The department may also deny the application for a license from an otherwise qualified applicant if the department determines issuance of the license is not necessary to ensure reasonable statewide access to, and the availability of low-THC cannabis for patients registered in the compassionate-use registry and for whom low-THC cannabis is prescribed under Chapter 169, Occupations Code.
- (d) Following the notice of denial the applicant will be provided thirty (30) days to request a hearing by submitting a request through the department's website.
-

Source Note: The provisions of this §12.15 adopted to be effective January 10, 2016, 41 TexReg 492; amended to be effective March 15, 2017, 42 TexReg 1145

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APPLICATION AND RENEWAL

RULE §12.14

Application Fees and Method of Payment

-
- (a) The application fee for a dispensing organization license is \$7,356. The license fee for a dispensing organization is \$488,520 for a two (2) year period.
- (b) The fee for the biennial renewal of the dispensing organization license is \$318,511.
- (c) The registration fee is \$530 for both the original registration and renewals.
- (d) Payment of all fees must be made electronically in the manner determined by the department.
- (e) If payment is dishonored or reversed prior to issuance of the license or registration, the application will be rejected as incomplete. If the license or registration has been issued prior to the payment being dishonored or reversed, revocation proceedings will be initiated pursuant to §12.23 of this title (relating to Revocation). The department may dismiss a pending revocation proceeding upon receipt of payment of the full amount due, including any additional processing fees.
-

Source Note: The provisions of this §12.14 adopted to be effective January 10, 2016, 41 TexReg 492; amended to be effective March 15, 2017, 42 TexReg 1145

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RULE §12.13

Renewal

-
- (a) A license or registration may be renewed at any time during the six (6) months prior to expiration.
- (b) A renewal applicant must pass department inspection prior to approval of the application. This requirement is satisfied by an inspection within ninety (90) days prior to the submission of the renewal application.
- (c) An expired license or registration may be renewed for up to six (6) months after the expiration date. If the license has been expired for more than six (6) months, the former license holder must submit an original license application to receive a license in the future.
-

Source Note: The provisions of this §12.13 adopted to be effective January 10, 2016, 41 TexReg 492

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APPLICATION AND RENEWAL

RULE §12.12

Application for Registration

(a) In conjunction with the dispensing organization's application for license, or prior to employment with a currently licensed dispensing organization, directors, managers, and employees must submit:

(1) Identifiers, including the individual's full name, date of birth, telephone number, electronic mail address, residential address, and driver license or state-issued identification number; and

(2) Fingerprints submitted in the manner approved by the department.

(b) If the applicant does not have a digital photograph on file with the department or the department is unable to access the photograph on file, the registration card will be issued without a photograph. When presenting such a card to a peace officer or to a representative of the department, the registrant shall also present a valid government issued identification card or driver license.

(c) Failure of an applicant to comply with the requirements of this section will result in notification of the deficiency. Applicant will have ninety (90) days from the date of notice to address the deficiency. Upon request of the applicant, the department may extend the period to address the deficiency for one additional ninety (90) day period. If an applicant fails to provide all required application materials, or fails to respond to a request by the department for additional information necessary to process the application, the application will be terminated. Following the termination of an application, a new application, including a new application fee, must be submitted.

Source Note: The provisions of this §12.12 adopted to be effective January 10, 2016, 41 TexReg 492

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RULE §12.11	Application for License

- (a) Application for license as a dispensing organization may only be made in the manner determined by the department.
- (b) A complete application must include the items detailed in this subsection, in a manner determined by the department:

(1) Proof of ownership and current status in the manner required by the department, including but not limited to a current Certificate of Existence or Certificate of Authority from the Texas Office of the Secretary of State and a Certificate of Good Standing from the Texas Comptroller of Public Accounts;

(2) All application fees required under §12.14 of this title (relating to Application and Licensing Fees and Method of Payment);

(3) Names, dates of birth, addresses, and all other information required by the department necessary to verify the identity of all directors, managers, and employees of the applicant;

(4) Criminal history disclosure of all convictions and deferred adjudications for each individual listed on the application as directors, managers, and employees of the dispensing organization;

(5) Complete registration applications for all directors, managers and employees submitted in the manner approved by the department and in compliance with §12.12 of this title (relating to Application for Registration);

(6) Proof of commercial general liability insurance coverage against claims of liability for damage to property of third parties and for personal injuries to third parties, including bodily injury, property damage, and product liability, with limits of:

(A) \$1,000,000 each occurrence;

(B) \$2,000,000 General Aggregate limit; and

(C) \$1,000,000 Product Liability.

(7) Evidence of the qualifications detailed in this paragraph as determined at the time of the required onsite inspection, in the manner determined by the department:

(A) The technical and technological ability to cultivate, process, and/or dispense low-THC cannabis, evidenced by experience in the areas of:

(i) Cultivation, analytical organic chemistry and micro-biology; and analytical laboratory methods; and

(ii) Patient education and interaction, and the handling of confidential information including familiarity with the requirements of the Health Insurance Portability and Accountability Act (HIPAA).

(B) The ability to secure the premises, resources, and employees necessary to operate as a dispensing organization, evidenced by:

(i) Descriptions of all properties applicant proposes to utilize to cultivate, process, and dispense low-THC cannabis, including ownership information for the properties;

(ii) Descriptions of the methods proposed for the cultivation, processing, and dispensing of low-THC cannabis;

(iii) Descriptions of the types and locations of worker safety equipment and plans and procedures for complying with federal Occupational Safety and Health Administration (OSHA) regulations for workplace safety;

(iv) A list of current and proposed staff, including, position, duties and responsibilities, and an organizational chart illustrating the supervisory structure of the dispensing organization;

(v) Description of the applicant's proposed testing laboratory, and description of the proposed testing protocols and methods;

(vi) A proposal establishing the ability to secure premises reasonably located to allow patient access through existing infrastructure; and

(vii) Department approved acknowledgments executed by the applicant's directors, managers and employees indicating familiarity with the federal laws governing marijuana and its interstate transportation.

(C) The ability to maintain accountability of all raw materials, finished products, and any by-products to prevent diversion or unlawful access to or possession of these substances, evidenced by:

(i) Floor plan of each facility or proposed floor plans for proposed facilities, including:

(I) Locking options for all means of ingress and egress consistent with life safety requirements;

(II) Alarm systems;

(III) Video surveillance;

(IV) Name, layout and function of each room; and

(V) Storage, including safes and vaults.

(ii) Diversion prevention procedures;

(iii) Emergency management plan;

(iv) System for tracking source plant material throughout cultivation, processing, and dispensing;

(v) Inventory control system as required by §12.8 of this title (relating to Inventory Control System);

(vi) Policies and procedures for recordkeeping;

(vii) Electronic vehicle tracking systems;

(viii) Vehicle security systems;

(ix) Methods of screening and monitoring employees;

(x) Employee qualifications and experience with chain of custody or other tracking mechanisms;

(xi) Waste disposal plan;

(xii) Recall procedures for any product that has a reasonable probability of causing adverse health consequences based on a testing result, patient reaction, or other reason; and

(xiii) Access to specialized resources or expertise regarding data collection, security, and tracking.

(D) Infrastructure reasonably located to dispense low-THC cannabis to registered patients, evidenced by:

(i) Map showing the location of the applicant's proposed dispensing facilities with streets; property lines; buildings; parking areas; outdoor areas, if applicable; fences; security features; fire hydrants, if applicable; and access to water and sanitation systems;

(ii) Floor plan of the actual or proposed building or buildings where dispensing activities will occur showing areas designed to protect patient privacy and areas designed for retail sales, with proposed hours of operation;

(iii) HIPAA compliant computer network utilized by all facilities;

(iv) Identifying descriptions of any vehicles to be used to transport product; and

(v) Description of all communication systems.

(E) The financial ability to maintain operations for two (2) years from the date of application, evidenced by:

(i) Applicant's business organization, and corporate structure if applicable;

(ii) List of all owners of any non-corporate applicant, or all shareholders of a corporate applicant;

(iii) All individuals and entities with control over the applicant;

(iv) Projected two (2) year budget; and

(v) Description of available assets sufficient to support the dispensing organization activities.

(c) Subsequent to the submission of all information and documentation required by subsection (b)(1) - (6) of this section and the conditional approval of the application, the department will conduct an onsite inspection to confirm applicant's compliance with the requirements of subsection (b)(7) of this section and of this chapter generally. The applicant must pass the inspection prior to licensure. Failure to pass the inspection will result in notification of the basis for the failure. Failure to address the basis for the failure within sixty (60) days of notice may result in the denial of the application, pursuant to §12.15 of this title (relating to Denial of Application for License). Upon request of the applicant, the department may extend the period to address the basis for the failure for one (1) additional thirty (30) day period.

(d) Failure of an applicant to submit all information and documentation required by subsection (b)(1) - (6) of this section will result in notification of the deficiency. Applicant will have ninety (90) days from the date of notice to address the deficiency. Upon request of the applicant, the department may extend the period to address the deficiency for one (1) additional ninety (90) day period. If an applicant fails to provide all required application materials, or fails to respond to a request by the department for additional information necessary to process the application, the application will be terminated. Following the termination of an application, a new application, including a new application fee, must be submitted.

Source Note: The provisions of this §12.11 adopted to be effective January 10, 2016, 41 TexReg 492; amended to be effective March 15, 2017, 42 TexReg 1145

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RULE §12.9

PUBLIC SAFETY AND CORRECTIONS

TEXAS DEPARTMENT OF PUBLIC SAFETY

COMPASSIONATE-USE/LOW-THC CANNABIS PROGRAM

GENERAL PROVISIONS

Sanitation; Waste Disposal

(a) Licensees must maintain regulated premises in a clean and sanitary condition, and shall take all reasonable measures to ensure:

- (1) Litter and waste are routinely removed and waste disposal systems are routinely inspected in accordance with applicable local, state, or federal law, rule, regulation or ordinance;
- (2) Fixtures, floors, walls, ceilings, buildings or other facilities are kept in good repair;
- (3) Regulated premises are adequately screened and otherwise protected against the entry of pests;
- (4) Refuse disposal is conducted in a manner to minimize the development of odor and the potential for breeding of pests;
- (5) Contact surfaces, including utensils and equipment used for the cultivation, drying, trimming, or storage of product, are cleaned and sanitized in a manner to protect against contamination;
- (6) Potentially toxic chemicals used within the cultivation facility are identified, stored, and disposed of in a manner to protect against contamination of the product, in compliance with all applicable local, state, or federal laws, rules, regulations or ordinances;
- (7) Storage and transportation of product is under conditions that protect against physical, chemical, and microbial contamination;
- (8) Safes, vaults, and storage rooms are in good working order, with climate control systems sufficient to prevent spoilage;
- (9) Processing site is free of contamination and suitable for the safe and sanitary preparation of the product, including ensuring all equipment, counters and surfaces used for processing are food-grade and nonreactive with any solvent being used, with easily cleanable surface areas constructed in a manner to reduce the potential for development of mold or fungus;
- (10) Hand-washing facilities provide effective hand-cleaning and sanitizing materials, with sanitary towel service or hand drying devices, and hot and cold running water;
- (11) All persons working in direct contact with product conform to hygienic practices while on duty, including but not limited to:

(A) Maintaining adequate personal cleanliness, including washing hands thoroughly before handling product and as often as necessary to remove soil and contamination and to prevent cross-contamination when changing tasks;

(B) Refraining from direct contact with product if the person has or may have an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, until such condition is corrected;

(C) Keeping fingernails trimmed and filed so that the edges and surfaces are cleanable;

(D) Unless wearing intact gloves in good repair, having no fingernail polish or artificial fingernails on the employee's fingernails;

(E) Wearing clean clothing appropriate to assigned tasks or protective apparel such as coats, aprons, gowns, or gloves to prevent contamination; and

(F) Reporting to the employer's director or manager any health condition experienced by the employee that may adversely affect the safety or quality of product with which the employee may come into contact;
- (12) Prohibiting any employee with a health condition that may adversely affect the safety or quality of the product from having direct contact with any product or equipment or materials for processing low-THC cannabis, or from performing any task that reasonably might contaminate or adversely affect any product.

(b) Destruction and disposal of waste materials resulting from the cultivation or processing of low-THC cannabis must be conducted in compliance with applicable state and local laws and regulations, and Code of Federal Regulations, Title 21, Part 1317, Subpart C. Any waste materials containing low-THC cannabis or raw materials used in or by-products created by the production or cultivation of low-THC cannabis must be rendered irretrievable, as defined in Code of Federal Regulations, Title 21, Part 1300. Waste water generated during production and processing must be disposed of in compliance with applicable state and local laws.

(c) Licensees are responsible for determining whether specific waste materials or waste water constitute hazardous waste under applicable federal or state regulations and for ensuring disposal of any such waste complies with applicable disposal regulations.

(d) All waste materials must be stored on the licensee's premises prior to destruction and disposal.

Source Note: The provisions of this §12.9 adopted to be effective March 15, 2017, 42 TexReg 1139

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RULE §12.8

PUBLIC SAFETY AND CORRECTIONS

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GENERAL PROVISIONS

Inventory Control System

(a) A licensed dispensing organization shall use a perpetual inventory control system that identifies and tracks the licensee's stock of low-THC cannabis from the time it is propagated from seed or cutting, to the time it is delivered to either another licensee or patient or legal guardian.

(b) The inventory control system shall be capable of tracking low-THC cannabis from a patient back to the source of the low-THC cannabis in the event of a serious adverse event.

(c) The inventory control system shall be designed to promptly identify a discrepancy and interact with the department's centralized registry system.

(d) Upon receipt of raw material for cultivation, a licensee shall record in the inventory control system:

- (1) The date delivered; and
- (2) The number of clones or seeds delivered or the weight of the seeds for each variety in the shipment.

(e) For each plant, including any clippings to be used for propagation, a licensee shall:

- (1) Create a unique identifier;
- (2) Assign a batch number;
- (3) Enter appropriate plant identifying information into the inventory control system;
- (4) Create an indelible and tamper resistant tag made of temperature and moisture resistance material, with a unique identifier and batch number;
- (5) Securely attach the tag to a container in which a plant is grown until a plant is large enough to securely hold a tag;

(f) Upon curing or drying of each batch, a licensee shall weigh the batch and enter the weight into the inventory control system database.

(g) At least monthly, a licensee shall conduct a physical inventory of the stock and compare the physical inventory of stock with inventory control system data.

(h) If a licensee discerns a discrepancy between the inventory of stock and inventory control system data outside of normal weight loss due to moisture loss and handling, a licensee shall begin an audit of the discrepancy.

(i) Within fifteen (15) business days of discovering a discrepancy, the licensee shall:

- (1) Complete an audit;
- (2) Amend the licensee's standard operating procedures, if necessary; and
- (3) Send an audit report to the department.

(j) If a licensee finds evidence of theft or diversion, the licensee shall report the theft or diversion to the department within two (2) days of the discovery of the theft or diversion.

Source Note: The provisions of this §12.8 adopted to be effective January 10, 2016, 41 TexReg 490; amended to be effective March 15, 2017, 42 TexReg 1139

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SUBCHAPTER A	GENERAL PROVISIONS
RULE §12.7	Testing, Production, and Packaging

- (a) Licensees must comply with all applicable provisions of the Texas Agriculture Code and the Texas Department of Agriculture's administrative rules, Title 4, Part 1.
- (b) Representative samples of all processed products must be tested for the levels of tetrahydrocannabinol and cannabidiol, and for residual solvents, pesticides, fungicides, fertilizers, mold, and heavy metals, in accordance with applicable provisions of the Texas Agriculture Code and Texas Department of Agriculture's administrative rules, Title 4, Part 1, and Code of Federal Regulations, Title 16, Part 1107.
- (c) Only pesticides of minimum risk exempted under the Federal Insecticide, Fungicide, and Rodenticide Act, 7 USC §136, may be used on cannabis. The pesticide's active ingredients may only be those listed in 40 CFR §152.25(f)(1). The pesticide's inert ingredients may only be those that listed in 40 CFR §152.25(f)(2); commonly consumed food commodities, animal feed items, and edible fats and oils as provided in 40 CFR §180.950(a),(b) and (c); and chemical substances listed in 40 CFR §180.950(e). All pesticide ingredients (both active and inert) must be listed on the pesticide container's label. The active ingredient(s) must be listed by label display name and percentage by weight. Each inert ingredient must be listed by label display name. The product may not bear claims to control or mitigate organisms that pose a threat to human health, or insects or rodents carrying specific diseases. The name of the producer or the company for whom the product was produced and the company's contact information must be displayed prominently on the product label. The label cannot include any false or misleading statements. The label must comply with the Texas Department of Agriculture's administrative rule, 4 TAC §7.11, relating to Label Requirements.
- (d) All facilities must be inspected and approved for their use by a local fire code official, or by the state fire marshal or local designee of the state fire marshal, and must meet any required fire, safety, and building code requirements specified in:
- (1) National Fire Protection Association (NFPA) standards;

(2) International Building Code (IBC);

(3) International Fire Code (IFC);

(4) Texas Department of Insurance administrative rules, 28 TAC Chapter 34, concerning State Fire Marshal; and

(5) Other applicable standards including following all applicable fire, safety, and building codes in processing and the handling and storage of the solvent or gas.
- (e) Licensees must provide certification by a Texas licensed professional engineer that the extraction system to be used to produce low-THC cannabis products was commercially manufactured, safe for its intended use, and built to codes of recognized and generally accepted good engineering practices, such as:
- (1) The American Society of Mechanical Engineers (ASME);

(2) American National Standards Institute (ANSI);

(3) Underwriters Laboratories (UL); or

(4) The American Society for Testing and Materials (ASTM).
- (f) The extraction process must be continuously staffed during operations by a registered employee trained in the extraction process, the transfer of LP-gas where applicable, and all emergency procedures. All staff training records shall be maintained on-site and made available upon request by the department or local law enforcement or regulatory official.
- (g) The installation, operation, repair and maintenance of electrical systems, devices, and components shall conform to the National Electrical Code, NFPA 70 as adopted by the Texas Department of Licensing and Regulation. All electrical components within the extraction room shall be interlocked with the hazardous exhaust system and when provided, the gas detection system. When the hazardous exhaust system is not operational, or the gas detection system is activated, light switches and electrical outlets shall be disabled while leaving lights on that are necessary for evacuation. The electrical systems shall include:
- (1) Extraction room lighting;

(2) Extraction room ventilation system;

(3) Solvent gas detection system;

(4) Emergency alarm systems;

(5) Automatic fire extinguishing systems;

(6) Vent failure alarm system; and

(7) Emergency power backup system.
- (h) For extraction processes utilizing gaseous hydrocarbon-based solvents, a continuous gas detection system shall be provided. The gas detection threshold shall be no greater than 10% of the LEL/LFL limit of the materials.
- (i) Signs shall be posted at the entrance to each production area using or storing carbon dioxide, indicating the hazard. Signs shall be durable and permanent in nature and not less than 7 inches wide by 10 inches tall. Signs shall bear the "skull and crossbones" emblem with the warning "DANGER! POTENTIAL OXYGEN DEFICIENT ATMOSPHERE". NFPA 704 signage shall be provided at the building main entry and the rooms where the carbon dioxide is used and stored. The main entrance to the facility and any door to a room where storage, transfer or use of hazardous materials is conducted shall be appropriately posted with markings in accordance with NFPA 704, Standard System for the Identification of the Hazards of Materials for Emergency Response.
- (j) Mechanical ventilation within an extraction or processing facility shall be in accordance with the applicable local ordinances or the appropriate NFPA standard as adopted by the State Fire Marshal's Office if no applicable local ordinance exists, and shall have:
- (1) Mechanical ventilation in the room or area of rate of not less than 1 cubic foot per minute per square foot;

(2) Exhaust system intake from a point within 12 inches of the floor; and

(3) Ventilation operating at a negative pressure in relation to the surrounding area.
- (k) Any liquid extraction process using flammable and combustible liquids in which the liquid is boiled, distilled, or evaporated must operate in compliance with this section and NFPA 30 as adopted by the State Fire Marshal's Office.
- (l) Any processing equipment using a flammable or combustible vapor or liquid must meet the requirements of NFPA 30 and NRPA 70. Such equipment shall be located within a hazardous exhaust fume hood, rated for exhausting flammable vapors. Electrical equipment used within the hazardous exhaust fume hood shall be rated for use in flammable atmospheres. Heating of flammable or combustible liquids over an open flame is prohibited, with the exception that the use of a heating element not rated for flammable atmospheres may be used where documentation from the manufacturer or a nationally recognized testing laboratory indicates it is rated for heating of flammable liquids.
- (m) Product extraction processes may use only potable water in compliance with Code of Federal Regulations, Title 40, Part 141.
- (n) All regulated premises shall be located at least 1000 feet from any private or public school or day care center that existed prior to the date of initial license application, measured from the closest points on the respective property lines.
- (o) All final packaging for patient consumption must be in child-resistant packaging designed or constructed to be significantly difficult for children under five (5) years of age to open and not difficult for normal adults to use properly as defined by the most current version of the Code of Federal Regulations, Title 16, Part 1700 and Title 40, Part 157.2 and American Society for Testing and Materials (ASTM) D3475-15, Standard Classification of Child-Resistant Packages, ASTM International, West Conshohocken, PA, 2015.
- (p) All final packaging labels must include:
- (1) Physician's name;

(2) Patient's name;

(3) Dispensing organization's name, state license number, telephone number, and mailing address;

(4) Dosage prescribed and means of administration;

(5) Date the dispensing organization packaged the contents;

(6) Batch number, sequential serial number, and bar code when used, to identify the batch associated with manufacturing and processing;

(7) Potency of the low-THC cannabis product contained in the package, including the levels of tetrahydrocannabinol and cannabidiol;

(8) Statement that the product has been tested for contaminants with specific indications of all findings, and the date of testing in accordance with Code of Federal Regulations, Title 16, Part 1107; and

(9) Statement that the product is for medical use only and is intended for the exclusive use of the patient to whom it is prescribed. This statement should be in bold print.
- (q) The dispensed product may contain no more than 0.5% by weight of tetrahydrocannabinols and not less than 10% by weight of cannabidiol.
- (r) The storage, transfer, and use of LP- Gas shall conform to the regulations of the Texas Railroad Commission, including but not limited to NFPA 58, LP Gas Code (as amended) and the adopted standards of the State Fire Marshal's Office.
- (s) The storage, use and handling of liquid carbon dioxide shall be in accordance with Chapter 13 of NFPA 55.

Source Note: The provisions of this §12.7 adopted to be effective January 10, 2016, 41 TexReg 490; amended to be effective March 15, 2017, 42 TexReg 1139

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GENERAL PROVISIONS

RULE §12.6

Notice

-
- (a) The department is entitled to rely on the physical mailing address, the facsimile number, and the electronic mail address currently on file for all purposes relating to notification. The failure to maintain current addresses with the department is not a defense to any action based on the licensee's, registrant's, or applicant's failure to respond.
- (b) Service of notice is complete and receipt is presumed upon the date the notice is sent, if sent before 5:00 p.m. by facsimile transmission or electronic mail, or three (3) days following the date sent, if notice is sent by regular United States mail or certified mail, return receipt requested.
- (c) Unless otherwise specified by the Act, notifications by the department may be by facsimile transmission, electronic mail, regular U.S. mail, certified mail, return receipt requested, or hand-delivery.
-

Source Note: The provisions of this §12.6 adopted to be effective January 10, 2016, 41 TexReg 490

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RULE §12.5

Address on File

-
- (a) All licensees, registrants, or applicants shall at all times maintain on file with the department a current electronic mail address, physical mailing address, facsimile number, and the physical address of each location at which low-THC cannabis is cultivated, processed, or dispensed.
- (b) All licensees or registrants shall notify the department of any change to their addresses on file in the manner provided on the department's website prior to the effective date of the change of address.
-

Source Note: The provisions of this §12.5 adopted to be effective January 10, 2016, 41 TexReg 490

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GENERAL PROVISIONS

RULE §12.4

Records

(a) Records required under the Act or this chapter must be maintained and made available for inspection or copying for a period of two (2) years. Records may be maintained in digital form so long as a hard copy may be produced upon request of department personnel.

(b) In addition to any records otherwise required to be maintained under the Act or this chapter, licensees must specifically retain:

(1) Copies of all application materials submitted to the department or relied on in making any representation or affirmation in conjunction with the application process;

(2) Purchase, sale, and inventory records;

(3) Shipping invoices, log books, records of duty status if applicable, delivery records and manifests reflecting the recipient's acknowledgment and establishing the chain of custody, relating to the transportation of:

(A) Low-THC cannabis and any cannabis sativa plants intended for use in the processing of low-THC cannabis;

(B) Raw materials used in or by-products created by the production or cultivation of low-THC cannabis;

(C) Drug paraphernalia used in the production, cultivation or delivery of low-THC cannabis; or

(D) Waste material resulting from cultivation, processing, or dispensing of low-THC cannabis.

(4) Security records, including building access and visitor logs, video recordings, and transportation trip plans;

(5) The licensee's drug-free workplace policy;

(6) Records on all registered directors, managers, and employees, including a color photograph of the individual, a copy of the registration issued by the department, records reflecting the individual's position, assigned duties, and work schedule, and a copy of the company's drug-free workplace policy signed by the individual. These records must be maintained for two (2) years from the date employment is terminated;

(7) Records of any disposal or destruction of waste materials resulting from cultivating, processing, or dispensing low-THC cannabis;

(8) Records of any local or state regulatory inspections, including state or local fire marshal inspections; and

(9) Records of all tests conducted in compliance with §12.7 of this title (relating to Testing, Production, and Packaging).

Source Note: The provisions of this §12.4 adopted to be effective January 10, 2016, 41 TexReg 490; amended to be effective March 15, 2017, 42 TexReg 1139

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RULE §12.3

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GENERAL PROVISIONS

Criminal History Disqualifiers

(a) Registration as a director, manager or employee of a licensed dispensing organization provides these individuals access to sensitive medical information, drugs, and the equipment and raw materials needed to produce drugs. Registration provides those predisposed to commit fraud, theft and drug related crimes with greater opportunities to engage in such conduct and escape detection or prosecution. Therefore, the department has determined that offenses of the types detailed in subsection (b) of this section directly relate to the duties and responsibilities of those who are registered under the Act. Such offenses include crimes under the laws of another state or the United States, if the offense contains elements that are substantially similar to the elements of an offense under the laws of this state. Such offenses also include those "aggravated" or otherwise enhanced versions of the listed offenses.

(b) The list of offenses in this subsection is intended to provide guidance only and is not exhaustive of either the offenses that may relate to the regulated occupation or of those independently disqualifying under Texas Occupations Code, §53.021(a)(2) - (4). The listed offenses are general categories that include all specific offenses within the corresponding chapter of the Texas Penal Code and Texas Health and Safety Code. In addition, after due consideration of the circumstances of the criminal act and its relationship to the position of trust involved in the particular licensed occupation, the department may find that an offense not described in this subsection also renders an individual unfit to hold a registration. In particular, an offense that is committed in one's capacity as a registrant under the Act, or an offense that is facilitated by one's registration under the Act, will be considered related to the regulated occupation and may render the individual unfit to hold the registration.

- (1) Bribery--Any offense under the Texas Penal Code, Chapter 36.
- (2) Burglary and criminal trespass--Any offense under the Texas Penal Code, Chapter 30.
- (3) Fraud--Any offense under the Texas Penal Code, Chapter 32.
- (4) Perjury--Any offense under the Texas Penal Code, Chapter 37.
- (5) Robbery--Any offense under the Texas Penal Code, Chapter 29.
- (6) Theft--Any offense under the Texas Penal Code, Chapter 31.
- (7) Organized Crime--Any offense under the Texas Penal Code, Chapter 71.
- (8) Any offense under Texas Health and Safety Code, Chapters 481, 482, or 483.
- (9) In addition:
- (A) An attempt to commit a crime listed in this subsection;
- (B) Aiding and abetting in the commission of a crime listed in this subsection; and
- (C) Being an accessory before or after the fact to a crime listed in this subsection.

(c) A felony conviction for an offense listed in subsection (b) of this section is disqualifying for ten (10) years from the date of the conviction.

(d) A Class A or B misdemeanor conviction for an offense listed in subsection (b) of this section is disqualifying for five (5) years from the date of conviction.

(e) Conviction for a felony or Class A offense that does not relate to the occupation for which registration is sought is disqualifying for five (5) years from the date of commission, pursuant to Texas Occupations Code, §53.021(a)(2).

(f) Independently of whether the offense is otherwise described or listed in subsection (b) of this section, a conviction for an offense listed in Texas Code of Criminal Procedure, Article 42.12, §3g or Article 42A.054, or that is a sexually violent offense as defined by Texas Code of Criminal Procedure, Article 62.001, is permanently disqualifying subject to the requirements of Texas Occupations Code, Chapter 53.

(g) Any unlisted offense that is substantially similar in elements to an offense listed in subsection (b) of this section is disqualifying in the same manner as the corresponding listed offense.

(h) A pending Class B misdemeanor charged by information for an offense listed in subsection (b) of this section is grounds for suspension.

(i) Any pending Class A misdemeanor charged by information or pending felony charged by indictment is grounds for suspension.

(j) In determining the fitness to perform the duties and discharge the responsibilities of the regulated occupation of an individual against whom disqualifying charges have been filed or who has been convicted of a disqualifying offense, the department may consider evidence of:

- (1) The extent and nature of the individual's past criminal activity;
- (2) The age of the individual when the crime was committed;
- (3) The amount of time that has elapsed since the individual's last criminal activity;
- (4) The conduct and work activity of the individual before and after the criminal activity;
- (5) Evidence of the individual's rehabilitation or rehabilitative effort while incarcerated or after release;
- (6) The date the individual will no longer be disqualified under the provisions of this section; and
- (7) Any other evidence of the individual's fitness, including letters of recommendation from:
- (A) Prosecutors or law enforcement and correctional officers who prosecuted, arrested, or had custodial responsibility for the individual; or
- (B) The sheriff or chief of police in the community where the individual resides.

(k) In addition to the documentation listed in subsection (j) of this section, the applicant or registrant shall, in conjunction with any request for hearing on a criminal history based denial, suspension or revocation, furnish proof in the form required by the department that the individual has:

- (1) Maintained a record of steady employment;
- (2) Supported the individual's dependents;
- (3) Maintained a record of good conduct; and
- (4) Paid all outstanding court costs, supervision fees, fines and restitution ordered in any criminal case in which the individual has been charged or convicted.

(l) The information listed in subsection (j) and subsection (k) of this section must be submitted in conjunction with the request for hearing, following notification of the proposed action and prior to the deadline for submission of the request for hearing.

Source Note: The provisions of this §12.3 adopted to be effective January 10, 2016, 41 TexReg 490; amended to be effective March 15, 2017, 42 TexReg 1139

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GENERAL PROVISIONS

RULE §12.2

Requirements and Standards

- (a) A licensee may only perform regulated functions at a department approved location. Any change in location must be approved by the department prior to operation in a regulated capacity.
- (b) Licensees shall notify the department within five (5) business days of a registrant's termination of employment.
- (c) All licensees shall display in a conspicuous location a copy of the department issued license and information on how to submit a complaint to the department.
- (d) Licensees must establish and implement a drug-free workplace policy consistent with the Texas Workforce Commission's "Drug-Free Workplace Policy," and shall maintain in each registrant's file a copy of the company's policy signed or otherwise acknowledged by the registrant.
- (e) Licensees and registrants must cooperate fully with any inspection or investigation conducted by the department, or by a state fire marshal, or local designee of the state fire marshal, including but not limited to the provision of any laboratory test results, employee records, inventory and destruction records, or other records required under the Act or this chapter, and the compliance with any lawfully issued subpoena.
- (f) Licensees and registrants may not cultivate, process, or dispense low-THC cannabis or possess any raw material used in or by-product created by the production or cultivation of low-THC cannabis if the respective license or registration has expired, or has been suspended or revoked.
- (g) Licensees and registrants may not dispense to an individual other than a patient for whom low-THC cannabis is prescribed under Chapter 169, Occupations Code, or the patient's legal guardian.
- (h) Licensees and registrants may not permit or fail to prevent the diversion of any controlled substance.
- (i) Those registered with the department as directors, managers, or employees of a licensed dispensing organization may only perform functions regulated under the Act for the licensee(s) with whom they are registered.
- (j) If arrested, charged, or indicted for a criminal offense above the level of Class C misdemeanor, a registrant shall within seventy-two (72) hours notify the employing licensee. When notified by the registrant or otherwise informed, the licensee shall notify the department in writing (including by email) within seventy-two (72) hours of notification. The notification shall include the name of the arresting agency, the offense, court, and cause number of the charge or indictment. The registrant and licensee must supplement their respective notifications as further information becomes available.
- (k) Registrants must carry on their person or otherwise display their department issued registration card while performing any functions regulated under the Act involving contact with or exposure to patients or the general public, including the dispensing of low-THC cannabis to patients and the transportation of low-THC cannabis on behalf of a licensee.
- (l) All advertisements for functions regulated under the Act must contain the dispensing organization's license number in a font of the same size as the primary text of the advertisement.
- (m) Licensees must comply with all applicable local, state and federal regulations and permitting requirements relating to air and environmental quality, advertising, business and occupancy, building, plumbing, electrical, fire safety, noise, and odor or other nuisances. This subsection does not require compliance with a regulation that conflicts with the Act or this chapter.
- (n) Licensees must use applicable best practices to limit contamination of the product including but not limited to residual solvents, metals, mold, fungus, bacterial diseases, rot, pests, pesticides, mildew, and any other contaminant identified as posing potential harm.
- (o) Licensees must have a plan for establishing a recall of their products in the event a product is shown by testing or other means to be, or potentially to be, defective or have a reasonable probability that their use or exposure to will cause adverse health consequences. At a minimum, the plan should include the method of identification of the products involved; notification to the processing or dispensing organization or others to whom the products were sold or otherwise distributed; and how the products will be disposed of if returned to or retrieved by the licensee.
- (p) Licensees shall retain the registration card of all terminated registrants for two (2) years after termination, unless the card is seized or destroyed by department personnel.
- (q) Licensees shall maintain commercial general liability insurance coverage, as described in §12.11 of this title (relating to Application for License), and maintain current proof of such insurance on file with the department.
- (r) Licensees' regulated premises must annually pass an inspection conducted by the state fire marshal or local designee of the state fire marshal. Proof of the passing inspection must be submitted to the department on a form approved by the department.
- (s) Licensees' regulated premises shall be protected by a fire alarm and sprinkler system that complies with local ordinances and applicable Texas Department of Insurance administrative rules, 28 TAC Chapter 34, concerning State Fire Marshal.
- (t) Licensees shall install an exterior wall-mounted building key safe at the main entrance to any processing facility, to enable emergency access for fire departments and emergency medical services.
- (u) To the extent there is a conflict between the requirements of this chapter, or a conflict between this chapter and the Act, the more restrictive requirement governs. To the extent any requirement of this chapter or the Act conflicts with a regulation incorporated herein, this chapter or the Act shall govern.
- (v) Research or development beyond that which is necessary for the cultivation or production of low-THC cannabis is prohibited.
- (w) Only low-THC cannabis may be dispensed or sold. By-products must be destroyed.
- (x) Registrants must be at least twenty-one (21) years of age at the time of application.

Source Note: The provisions of this §12.2 adopted to be effective January 10, 2016, 41 TexReg 490; amended to be effective March 15, 2017, 42 TexReg 1139

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GENERAL PROVISIONS

RULE §12.1

Definitions

The terms in this section have the following meanings when used in this chapter unless the context clearly indicates otherwise:

- (1) Act--Texas Health and Safety Code, Chapter 487.
- (2) Application--Includes an original application for a registration or license, or an application to renew a registration or license, issued under the Act.
- (3) Department--The Texas Department of Public Safety.
- (4) Director--An individual involved in decisions governing the operation or daily functions of the licensed dispensing organization, and any owner, partner, or shareholder of the business with an ownership interest that exceeds 10 percent.
- (5) Dispensing organization--An organization licensed to perform the regulated functions of cultivation, processing, and dispensing of low-THC cannabis.
- (6) Employee--An individual engaged by or contracting with a licensee to assist with any regulated function, whether or not compensated by salary or wage.
- (7) Licensee--An organization licensed under the Act.
- (8) Manager--An individual employed or otherwise engaged by a dispensing organization to supervise others in any portion of the regulated functions and processes.
- (9) Prescription--An entry in the compassionate-use registry that meets the requirements of Texas Occupations Code, Chapter 169.
- (10) Product--Any form of low-THC cannabis that is cultivated, handled, transported, processed, or dispensed, or raw materials used in or by-products created by the production or cultivation of low-THC cannabis.
- (11) Registrant--An individual registered with the department as a director, manager, or employee of a licensee; this term does not include a physician registered as a prescriber of low-THC cannabis.
- (12) Regulated premises--The physical areas under the control of a licensee, in which low-THC cannabis, or production related raw materials or by-products, are cultivated, handled, transported, processed, or dispensed.
- (13) SOAH--State Office of Administrative Hearings.

Source Note: The provisions of this §12.1 adopted to be effective January 10, 2016, 41 TexReg 490; amended to be effective March 15, 2017, 42 TexReg 1139

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SUBCHAPTER D	LOW-THC CANNABIS FOR COMPASSIONATE USE
RULE §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) 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) 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-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) Biotpterin 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;
- (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) Methylene tetrahydrofolate 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) Saldosis;
- (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;

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