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,

- 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
- $\mbox{(2) the legislature, not later than October 1 of each} \\ \mbox{even-numbered year.}$

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.