Ohio Revised Code

Section 4729.54 Terminal distributor licenses.

Effective: April 6, 2023
Legislation: House Bill 558

(A) As used in this section:

(1) "Category II" means any dangerous drug that is not included in category III.

(2) "Category III" means any controlled substance that is contained in schedule I, II, III, IV, or V.

(3) "Emergency medical service organization" has the same meaning as in section 4765.01 of the Revised Code.

(4) "Emergency medical service organization satellite" means a location where dangerous drugs are stored that is separate from, but associated with, the headquarters of an emergency medical service organization. "Emergency medical service organization satellite" does not include the units under the control of the emergency medical service organization.

(5) "Person" includes an emergency medical service organization or an emergency medical service organization satellite.

(6) "Schedule I," "schedule II," "schedule III," "schedule IV," and "schedule V" have the same meanings as in section 3719.01 of the Revised Code.

(B)(1) A person seeking to be licensed as a terminal distributor of dangerous drugs shall file with the executive director of the state board of pharmacy a verified application. After it is filed, the application may not be withdrawn without approval of the board.

(2) An application shall contain all the following that apply in the applicant's case:

(a) Information that the board requires relative to the qualifications of a terminal distributor of dangerous drugs set forth in section 4729.55 of the Revised Code;

(b) A statement as to whether the person is seeking to be licensed as a category II, category III, limited category II, or limited category III terminal distributor of dangerous drugs;

(c) If the person is seeking to be licensed as a limited category II or limited category III terminal distributor of dangerous drugs, a list of the dangerous drugs that the person is seeking to possess, have custody or control of, and distribute, which list shall also specify the purpose for which those drugs will be used and their source;

(d) If the person is an emergency medical service organization, the information that is specified in divisions (C)(1) and (2) of this section, and if the person is an emergency medical service organization satellite, the information required under division (D) of this section;

(e) Except with respect to the units under the control of an emergency medical service organization, the identity of the one establishment or place at which the person intends to engage in the sale or other distribution of dangerous drugs at retail, and maintain possession, custody, or control of dangerous drugs for purposes other than the person's own use or consumption;

(f) If the application pertains to a pain management clinic, information that demonstrates, to the satisfaction of the board, compliance with division (A) of section 4729.552 of the Revised Code;

(g) If the application pertains to a facility, clinic, or other location described in division (B) of section 4729.553 of the Revised Code that must hold a category III terminal distributor of dangerous drugs license with an office-based opioid treatment classification, information that demonstrates, to the satisfaction of the board, compliance with division (C) of that section.

(C)(1) Each emergency medical service organization that applies for a terminal distributor of dangerous drugs license shall submit with its application all of the following:

(a) A copy of its standing orders or protocol, which orders or protocol shall be signed by a physician;

(b) A list of the dangerous drugs that the units under its control may carry, expressed in standard dose units, which shall be signed by a physician;

(c) A list of the personnel employed or used by the organization to provide emergency medical services in accordance with Chapter 4765. of the Revised Code.

In accordance with Chapter 119. of the Revised Code, the board shall adopt rules specifying when an emergency medical service organization that is licensed as a terminal distributor must notify the board of any changes in its documentation submitted pursuant to division (C)(1) of this section.

(2) An emergency medical service organization seeking to be licensed as a terminal distributor of dangerous drugs shall list in its application for licensure the following additional information:

(a) The units under its control that the organization determines will possess dangerous drugs for the purpose of administering emergency medical services in accordance with Chapter 4765. of the Revised Code;

(b) With respect to each such unit, whether the dangerous drugs that the organization determines the unit will possess are in category II or III.

(3) An emergency medical service organization that is licensed as a terminal distributor of dangerous drugs shall file a new application for such licensure if there is any change in the number or location of any of its units or if there is any change in the category of the dangerous drugs that any unit will possess.

(4) A unit listed in an application for licensure pursuant to division (C)(2) of this section may obtain the dangerous drugs it is authorized to possess from its emergency medical service organization or, on a replacement basis, from a hospital pharmacy. If units will obtain dangerous drugs from a hospital pharmacy, the organization shall file, and maintain in current form, the following items with the pharmacist who is responsible for the hospital's terminal distributor of dangerous drugs license:

(a) A copy of its standing orders or protocol;

(b) A list of the personnel employed or used by the organization to provide emergency medical services in accordance with Chapter 4765. of the Revised Code, who are authorized to possess the

drugs, which list also shall indicate the personnel who are authorized to administer the drugs.

(D) Each emergency medical service organization satellite that applies for a terminal distributor of dangerous drugs license shall submit with its application all of the information that the board requires to be submitted with the application, as specified in rules the board shall adopt in accordance with Chapter 119. of the Revised Code.

(E) There shall be four categories of terminal distributor of dangerous drugs licenses. The categories are as follows:

(1) Category II license. A person who obtains this license may possess, have custody or control of, and distribute only the dangerous drugs described in category II.

(2) Limited category II license. A person who obtains this license may possess, have custody or control of, and distribute only the dangerous drugs described in category II that were listed in the application for licensure.

(3) Category III license, which may include a pain management clinic classification issued under section 4729.552 of the Revised Code. A person who obtains this license may possess, have custody or control of, and distribute the dangerous drugs described in category II and category III. If the license includes a pain management clinic classification, the person may operate a pain management clinic.

(4) Limited category III license. A person who obtains this license may possess, have custody or control of, and distribute only the dangerous drugs described in category II or category III that were listed in the application for licensure.

(F) Except for an application made by a county dog warden or on behalf of an animal shelter, if an applicant for a limited category II license or limited category III license intends to administer dangerous drugs to a person or animal, the applicant shall submit, with the application, a copy of its protocol or standing orders. The protocol or orders shall be signed by a licensed health professional authorized to prescribe drugs, specify the dangerous drugs to be administered, and list personnel who are authorized to administer the dangerous drugs in accordance with federal law or the law of this

state.

An application made by a county dog warden or on behalf of an animal shelter shall include a list of the dangerous drugs to be administered to animals and the personnel who are authorized to administer the drugs to animals in accordance with section 4729.532 of the Revised Code.

In accordance with Chapter 119. of the Revised Code, the board shall adopt rules specifying when a licensee must notify the board of any changes in its documentation submitted pursuant to this division.

(G)(1) Except as provided in division (G)(3) of this section, each applicant for licensure as a terminal distributor of dangerous drugs shall submit, with the application, a license fee. The amount assessed shall not be returned to the applicant if the applicant fails to qualify for the license.

(2) The following fees apply under division (G)(1) of this section:

(a) Except as provided in division (G)(2)(b) of this section:

(i) Three hundred twenty dollars for a category II or limited category II license;

(ii) Four hundred forty dollars for a category III license, including a license with a pain management clinic classification issued under section 4729.552 of the Revised Code, or a limited category III license.

(b) One hundred twenty dollars for all of the following:

(i) A person who is required to hold a license as a terminal distributor of dangerous drugs pursuant to division (D) of section 4729.541 of the Revised Code;

(ii) A professional association, corporation, partnership, or limited liability company organized for the purpose of practicing veterinary medicine that is not included in division (G)(2)(b)(i) of this section;

(iii) An emergency medical service organization satellite.

(3) No fee applies for a license issued to a charitable pharmacy, as defined in section 3719.811 of the Revised Code, if the charitable pharmacy is participating in the drug repository program established under section 3715.87 of the Revised Code.

(H)(1) The board shall issue a terminal distributor of dangerous drugs license to each person who submits an application for such licensure in accordance with this section, pays the required license fee, is determined by the board to meet the requirements set forth in section 4729.55 of the Revised Code, and satisfies any other applicable requirements of this section.

(2) Except for the license of a county dog warden, the license shall describe the one establishment or place at which the licensee may engage in the sale or other distribution of dangerous drugs at retail and maintain possession, custody, or control of dangerous drugs for purposes other than the licensee's own use or consumption. The one establishment or place shall be that which is identified in the application for licensure.

No such license shall authorize or permit the terminal distributor of dangerous drugs named in it to engage in the sale or other distribution of dangerous drugs at retail or to maintain possession, custody, or control of dangerous drugs for any purpose other than the distributor's own use or consumption, at any establishment or place other than that described in the license, except that an agent or employee of an animal shelter or county dog warden may possess and use dangerous drugs in the course of business as provided in section 4729.532 of the Revised Code.

(3) The license of an emergency medical service organization shall cover the organization's headquarters and, in addition, shall cover and describe all the units of the organization listed in its application for licensure.

(I)(1) All licenses issued or renewed pursuant to this section shall be effective for a period specified by the board in rules adopted under section 4729.26 of the Revised Code. The effective period for an initial or renewed license shall not exceed twenty-four months unless the board extends the period in rules to adjust license renewal schedules. A license shall be renewed by the board according to the provisions of this section, the standard renewal procedure of Chapter 4745. of the Revised Code, and

rules adopted by the board under section 4729.26 of the Revised Code. A person seeking to renew a license shall submit an application for renewal and pay the required fee on or before the date specified in the rules adopted by the board. The fee required for the renewal of a license shall be the same as the license fee that applies under division (G)(2) of this section.

(2)(a) Subject to division (I)(2)(b) of this section, a license that has not been renewed by the date specified in rules adopted by the board may be reinstated only upon payment of the required renewal fee and a penalty fee of one hundred ten dollars.

(b) If an application for renewal has not been submitted by the sixty-first day after the renewal date specified in rules adopted by the board, the license is considered void and cannot be renewed, but the license holder may reapply for licensure.

(3) A terminal distributor of dangerous drugs that fails to renew licensure in accordance with this section and rules adopted by the board is prohibited from engaging in the retail sale, possession, or distribution of dangerous drugs until a valid license is issued by the board.

(J)(1) No emergency medical service organization that is licensed as a terminal distributor of dangerous drugs shall fail to comply with division (C)(1), (3), or (4) of this section.

(2) No licensed terminal distributor of dangerous drugs shall possess, have custody or control of, or distribute dangerous drugs that the terminal distributor is not entitled to possess, have custody or control of, or distribute by virtue of its category of licensure.

(3) No licensee that is required by division (F) of this section to notify the board of changes in its protocol or standing orders, or in personnel, shall fail to comply with that division.

(K) The board may enter into agreements with other states, federal agencies, and other entities to exchange information concerning licensing and inspection of terminal distributors of dangerous drugs located within or outside this state and to investigate alleged violations of the laws and rules governing distribution of drugs by terminal distributors. Any information received pursuant to such an agreement is subject to the same confidentiality requirements applicable to the agency or entity from which it was received and shall not be released without prior authorization from that agency or

entity.