



Ohio Revised Code

Section 4729.54 Terminal distributor licenses.

Effective: April 6, 2017

Legislation: Senate Bill 319 - 131st General Assembly

(A) As used in this section:

(1) "Category I" means single-dose injections of intravenous fluids, including saline, Ringer's lactate, five per cent dextrose and distilled water, and other intravenous fluids or parenteral solutions included in this category by rule of the state board of pharmacy, that have a volume of one hundred milliliters or more and that contain no added substances, or single-dose injections of epinephrine to be administered pursuant to sections 4765.38 and 4765.39 of the Revised Code.

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

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

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

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

(6) "Schedule I, schedule II, schedule III, schedule IV, and schedule V" mean controlled substance schedules I, II, III, IV, and V, respectively, as established pursuant to section 3719.41 of the Revised Code and as amended.

(B)(1) A person who desires 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 After it is filed, the application may not be withdrawn without approval of the board.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 that the person wishes to be licensed as a category I, category II, category III, limited category I, limited category II, or limited category III terminal distributor of dangerous drugs;

(c) If the person wishes to be licensed as a limited category I, limited category II, or limited category III terminal distributor of dangerous drugs, a notarized list of the dangerous drugs that the person wishes 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 division (C)(1) of this section;

(e) Except for 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) An emergency medical service organization that wishes 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 I, II, or III.

(2) 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 any change in the category of the dangerous drugs that any unit will possess.

(3) A unit listed in an application for licensure pursuant to division (C)(1) 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 that applies for a terminal distributor of dangerous drugs license shall submit with its application the following:

(1) A notarized copy of its standing orders or protocol, which orders or protocol shall be signed by a physician and specify the dangerous drugs that its units may carry, expressed in standard dose units;

(2) 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.

An emergency medical service organization that is licensed as a terminal distributor shall notify the board immediately of any changes in its standing orders or protocol.

(E) There shall be six categories of terminal distributor of dangerous drugs licenses, which categories



shall be as follows:

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

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

(3) 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 I and category II.

(4) 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 I or category II that were listed in the application for licensure.

(5) 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 I, category II, and category III. If the license includes a pain management clinic classification, the person may operate a pain management clinic.

(6) 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 I, category II, or category III that were listed in the application for licensure.

(F) Except for an application made on behalf of an animal shelter, if an applicant for licensure as a limited category I, II, or III terminal distributor of dangerous drugs intends to administer dangerous drugs to a person or animal, the applicant shall submit, with the application, a notarized copy of its protocol or standing orders, which 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 on behalf of an animal shelter shall include a notarized 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. After obtaining a terminal distributor license, a licensee shall notify the board immediately of any changes in its protocol or standing orders, or in such personnel.

(G)(1) Except as provided in division (G)(2) of this section, each applicant for licensure as a terminal distributor of dangerous drugs shall submit, with the application, a license fee determined as follows:

(a) For a category I or limited category I license, forty-five dollars;

(b) For a category II or limited category II license, one hundred twelve dollars and fifty cents;

(c) 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, one hundred fifty dollars.

(2) (a) Except as provided in division (G)(2)(b) of this section, for 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, the fee shall be sixty dollars.

(b) For a professional association, corporation, partnership, or limited liability company organized for the purpose of practicing veterinary medicine, the fee shall be forty dollars.

(3) Fees assessed under divisions (G)(1) and (2) of this section shall not be returned if the applicant fails to qualify for registration.

(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) The license of a person other than an emergency medical service organization 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 described 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 may possess and use dangerous drugs in the course of business as provided in division (D) of section 4729.532 of the Revised Code.

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

(4) The license of every terminal distributor of dangerous drugs shall indicate, on its face, the category of licensure. If the license is a limited category I, II, or III license, it shall specify, and shall authorize the licensee to possess, have custody or control of, and distribute only, the dangerous drugs that were listed in the application for licensure.

(I) All licenses issued pursuant to this section shall be effective for a period of twelve months from the first day of April of each year. A license shall be renewed by the board for a like period, annually, according to the provisions of this section, and the standard renewal procedure of Chapter 4745. of the Revised Code. A person who desires to renew a license shall submit an application for renewal and pay the required fee on or before the thirty-first day of March each year. The fee required for the renewal of a license shall be the same as the fee paid for the license being renewed, and shall accompany the application for renewal.

A license that has not been renewed during March in any year and by the first day of May of the same year may be reinstated only upon payment of the required renewal fee and a penalty fee of fifty-five dollars.

(J)(1) No emergency medical service organization that is licensed as a terminal distributor of dangerous drugs shall fail to comply with division (C)(2) or (3) of this section.



(2) No emergency medical service organization that is licensed as a terminal distributor of dangerous drugs shall fail to comply with division (D) of this section.

(3) 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.

(4) 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.