



Ohio Revised Code

Section 4729.52 Licenses for wholesale distributors and manufacturers of dangerous drugs, outsourcing facilities, third-party logistics providers, and repackagers; application; issuance; renewal; fees.

Effective: September 29, 2017

Legislation: House Bill 49 - 132nd General Assembly

(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) "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) The state board of pharmacy shall license the following persons:

- (i) Wholesale distributors of dangerous drugs;
- (ii) Manufacturers of dangerous drugs;
- (iii) Outsourcing facilities;
- (iv) Third-party logistics providers;
- (v) Repackagers of dangerous drugs.

(b) There shall be two categories for the licenses identified in division (B)(1)(a) of this section. The categories are as follows:

- (i) 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.

(ii) Category III license. 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.

(c) The board may adopt rules under section 4729.26 of the Revised Code to create classification types of any license issued pursuant to this section. Persons who meet the definitions of the classification types shall comply with all requirements for the specific license classification specified in rule.

(C) A person seeking a license identified in division (B)(1)(a) of this section shall file with the executive director of the board a verified application containing such information as the board requires of the applicant relative to the licensure qualifications set forth in section 4729.53 of the Revised Code and the rules adopted under that section.

The board shall license as a category II or category III manufacturer, outsourcing facility, third-party logistics provider, repackager, or wholesale distributor each applicant who has paid the required license fee, if the board determines that the applicant meets the licensure qualifications set forth in section 4729.53 of the Revised Code and the rules adopted under that section.

(D) The board may issue to a person who does not reside in this state a license identified in division (B)(1)(a) of this section if the person pays the required licensure fee and meets either of the following:

(1) Possesses a current and valid manufacturer, outsourcing facility, third-party logistics provider, repackager, or wholesale distributor license, or its equivalent, issued by another state in which that person is physically located, but only if that state has qualifications for licensure comparable to the licensure requirements in this state;

(2) Meets the requirements set forth by the board for issuance of a license identified in division (B)(1)(a) of this section, as verified by a state, federal, or other entity recognized by the board to perform such verification.



(E) All licenses issued or renewed pursuant to this section are 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 pursuant to 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 renewal fee before the date specified in the rules adopted by the board.

(F) Each license issued under this section shall describe not more than one establishment or place where the license holder may engage in the activities authorized by the license. No license shall authorize or permit the person named therein to engage in the sale or distribution of drugs at wholesale or to maintain possession, custody, or control of dangerous drugs for any purpose other than for the licensee's own use and consumption at any establishment or place other than that described in the license.

(G)(1)(a) The category II license fee is one thousand nine hundred dollars and shall accompany each application for licensure. The license renewal fee is one thousand nine hundred dollars and shall accompany each renewal application.

(b) The category III license fee is two thousand dollars and shall accompany each application for licensure. The license renewal fee is two thousand dollars and shall accompany each renewal application.

(c)(i) Subject to division (G)(1)(c)(ii) of this section, a license issued pursuant to this section that has not been renewed by the date specified in rules adopted by the board may be reinstated upon payment of the renewal fee and a penalty of three hundred dollars.

(ii) If a complete 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.

(2) Renewal fees and penalties assessed under division (G)(1) of this section shall not be returned if



the applicant fails to qualify for renewal.

(3) A person licensed pursuant to this section that fails to renew licensure in accordance with this section and rules adopted by the board is prohibited from engaging in manufacturing, repackaging, compounding, or distributing as a third-party logistics provider or wholesale distributor until a valid license is issued by the board.

(H) Holding a license issued pursuant to this section subjects the holder and the holder's agents and employees to the jurisdiction of the board and to the laws of this state for the purpose of the enforcement of this chapter and the rules of the board. However, the filing of an application for licensure under this section by or on behalf of any person, or the issuance of a license pursuant to this section to or on behalf of any person, shall not of itself constitute evidence that the person is doing business within this state.

(I) The board may enter into agreements with other states, federal agencies, and other entities to exchange information concerning licensing and inspection of any manufacturer, outsourcing facility, third-party logistics provider, repackager, or wholesale distributor located within or outside this state and to investigate alleged violations of the laws and rules governing distribution of drugs by such persons. 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. Any information received is also subject to section 4729.23 of the Revised Code.