

4729:6-1-01

Definitions - distributors of dangerous drugs.

As used in this division:

(A) "Distributor of dangerous drugs" or "drug distributor" means the following persons licensed in accordance with section 4729.52 of the Revised Code:

(1) Wholesale distributors of dangerous drugs, including:

(a) Brokers; and

(b) Virtual wholesalers.

(2) Manufacturers of dangerous drugs.

(3) Outsourcing facilities.

(4) Third-party logistics providers.

(5) Repackagers of dangerous drugs.

(B) "Abandoned application" means an application submitted for licensure in accordance with this division that meets the criteria in paragraph (B)(1) of this rule. An applicant forfeits all fees associated with an abandoned application. The board shall not be required to act on any abandoned application and the application may be destroyed by board staff. If the application is abandoned, the applicant shall be required to reapply for licensure, submit the required fee, and comply with the licensure requirements in effect at the time of reapplication.

(1) An application shall be deemed abandoned if any of the following apply:

(a) An applicant fails to demonstrate compliance with rule 4729:6-2-01 of the Administrative Code and the applicable licensing rules pursuant to this division within ninety days of receipt of a completed application. The applicant may submit a request to the ~~director of licensing executive~~ director or the director's designee for a one-time, ninety-day extension.

(b) An applicant fails to complete all application requirements within thirty days after being notified of the incomplete application by the board.

(c) An applicant that fails to demonstrate compliance with appropriate security and control rules pursuant to this division of the Administrative Code. The applicant may submit a request to the ~~director of licensing executive~~ director or the director's designee for a one-time, ninety-day extension.

- (2) An application shall not be deemed abandoned if the application is subject to any of the following:
- (a) An administrative proceeding; or
 - (b) If there is discipline pending against the applicant.
- (C) "Access to drug stock" includes not only physical access, but also any influence over the handling of dangerous drugs such as purchases, inventories, issuance of medical orders, etc. It does not include employees or contractors such as maintenance, janitorial, information technology or other staff that may need limited supervised access to areas where dangerous drugs or drug enforcement administration controlled substance order forms are stored.
- (D) "Addicted to or abusing alcohol or drugs" means the chronic and habitual use of alcohol or the use of a drug of abuse as defined in section 3719.011 of the Revised Code by an individual to the extent that the individual no longer can control the individual's use of alcohol or drugs, the individual is physically or psychologically dependent on alcohol or drugs, or the individual's use or abuse of alcohol or drugs endangers the health, safety, or welfare of the individual or others.
- (E) "Adulterated drug" includes a dangerous drug to which any of the following applies:
- (1) A compounded dangerous drug if it exceeds the assigned beyond-use date.
 - (2) Meets any of the requirements described in section 3715.63 of the Revised Code.
 - (3) Is beyond the expiration date as stated by the manufacturer, repackager, or distributor in its labeling. This does not apply to expired drugs that are donated pursuant to sections 3715.88 to 3715.92 of the Revised Code.
 - (4) Is not stored, dispensed or personally furnished according to the requirement of the federal act as indicated in the product labeling.
- (F) "Board of pharmacy" or "board" means the state board of pharmacy established under Chapter 4729. of the Revised Code.
- (G) "Broker" means any person engaged in the marketing, offering, or contracting for wholesale distribution and sale of dangerous drugs in or into Ohio who does not take physical possession of the dangerous drugs. A broker shall be licensed as a wholesale distributor pursuant to section 4729.52 of the Revised Code with a broker classification.

- (H) "Business day" means any day other than Saturday, Sunday or a holiday recognized by the state of Ohio on which the offices of the board of pharmacy are not open for business.
- (I) "Dangerous drug" has the same meaning as in section 4729.01 of the Revised Code.
- (J) "Disciplinary action," unless otherwise stated in this division, means any of the following by the drug enforcement administration or licensing agency of any state or jurisdiction, regardless of whether the action occurred by formal proceeding, consent, settlement, or other agreement:
- (1) An action to revoke, suspend, restrict, limit, or refuse to grant or renew a license, registration, or certification;
 - (2) A summary or emergency suspension of a license, registration or certification, of any length, and any subsequent revision to the action;
 - (3) An administrative fine or money penalty, taken as a result of a formal proceeding, to include any fine or money penalty connected to the delivery of health care services or taken in conjunction with other adverse licensure, registration or certification actions, such as revocation, suspension, censure, reprimand or probation;
 - (4) An action to reprimand or place the license, registration, or certification holder on probation;
 - (5) The issuance of a corrective action plan only if such issuance is in conjunction with other adverse licensure, registration or certification actions, such as revocation, suspension, reprimand, probation or surrender;
 - (6) The withdrawal of a renewal application for licensure, registration or certification while under investigation;
 - (7) The non-renewal of a license, registration or certification while under investigation or to avoid an investigation;
 - (8) The surrender or other relinquishment of a license, registration or certification in lieu of a formal sanction against a person's license, registration, or certificate, whether permanent or temporary;
 - (9) In lieu of an adverse licensure, registration or certification action, a licensing agency issues a consent order in which a person agrees not to re-apply for a license, registration, or certification in the future;

- (10) An enforceable agreement not to practice or to be placed into inactive or other equivalent status while under investigation or in exchange for not conducting an investigation.
- (K) "Manufacturer of dangerous drugs" or "manufacturer" means a person, other than a pharmacist or prescriber, that meets the following criteria:
- (1) Meets the definition of a manufacturer pursuant in section 21 U.S. Code Section 360 eee (11/27/2013); and
 - (2) Manufactures dangerous drugs and who is engaged in the sale or distribution of dangerous drugs in or into Ohio.
- (L) "Outsourcing facility" means a facility that is engaged in the compounding and sale of sterile drugs and is registered as an outsourcing facility with the United States food and drug administration.
- (M) "Person" has the same meaning as in division (S) of section 4729.01 of the Revised Code and includes any individual member, regardless of the percentage of ownership, of any partnership, association, limited liability company or corporation.
- (N) "Place on probation" means to take action against a license, for a period of time determined by the board, which imposes conditions or other requirements, or suspends or otherwise restricts some or all of the activities in which the licensee may engage.
- (O)
- (1) "Positive identification" means a method of identifying a person that does not rely on the use of a private personal identifier such as a password, but must use a secure means of identification that includes any of the following:
 - (a) A manual signature on a hard copy record;
 - (b) A magnetic card reader;
 - (c) A bar code reader;
 - (d) A biometric method;
 - (e) A proximity badge reader;
 - (f) A board approved system of randomly generated personal questions;

- (g) A printout of every transaction that is verified and manually signed within a reasonable period of time by the individual who performed the action requiring positive identification. The printout must be maintained for three years and made readily retrievable; or
 - (h) Other effective methods for identifying individuals that have been approved by the board.
- (2) A method of positive identification relying on a magnetic card reader, a bar code reader, a proximity badge reader, or randomly generated questions for identification must also include a private personal identifier, such as a password, for entry into a secure mechanical or electronic system.
- (P) "Readily retrievable" means that records maintained in accordance with this division shall be kept in such a manner that, upon request, they can be produced for review no later than three business days to an agent, officer, or inspector of the board.
- (Q) "Refuse to grant or renew" means to deny original or continued licensure for a period of at least twenty-four months. After twenty-four months, or such period of time as the individual board order may require, a person licensed by the board or a person seeking to attain such status by licensure, and whose license the state board of pharmacy has refused to grant or renew, may make application to the board for issuance of a new license. A person that seeks to attain such status by licensure, whose license the state board of pharmacy has refused to grant or renew, must meet all requirements established by the board in rule and as may be set forth in the person's board order.
- (R) "Repackager of dangerous drugs" or "repackager" means a person that meets the following:
- (1) Repacks and relabels dangerous drugs for sale or distribution; and
 - (2) Is required to register with the United States food and drug administration to engage in the repackaging or relabeling of dangerous drugs.
- (S) "Reverse distribute" or "reverse distribution" means to acquire dangerous drugs for the purpose of any of the following:
- (1) Return to a manufacturer or entity authorized by the manufacturer to accept returns on the manufacturer's behalf; or
 - (2) Destruction or disposal.

(T) "Revoke" means to take action against a license rendering such license void and such license shall not be reissued. Revoke is an action that is permanent against the licensee.

(U) "Sale" or "sell" includes any transaction made by any person, whether as principal proprietor, agent, or employee, to do or offer to do any of the following: deliver, distribute, broker, exchange, gift or otherwise give away, or transfer, whether the transfer is by passage of title, physical movement, or both.

The shipment of dangerous drugs to a reverse distributor in this state licensed as a wholesale distributor of dangerous drugs in accordance with section 4729.52 of the Revised Code for the sole purpose of destruction or disposal of dangerous drugs, does not constitute a sale and does not require the person, if located outside of the state of Ohio, shipping the dangerous drugs to the reverse distributor to possess an Ohio license in accordance with Chapter 4729. of the Revised Code.

(V) "State" means a state of the United States, the District of Columbia, the Commonwealth of Puerto Rico or a territory or insular possession subject to the jurisdiction of the United States.

(W) "Suspend" means to take action against a license rendering such license without force and effect for a period of time as determined by the state board of pharmacy. The board may require that an individual whose license or registration has been suspended may not be employed by or work in a facility licensed by the state board of pharmacy to possess or distribute dangerous drugs during such period of suspension.

(X) "Summary suspension" means to take immediate action against a license without a prior hearing rendering such license without force and effect for a period of time as indicated in section 4729.561 of the Revised Code. The board may suspend a license issued pursuant to Chapter 4729. of the Revised Code by utilizing a telephone conference call to review the allegations and take a vote.

(Y) "Third-party logistics provider" means a person that provides or coordinates warehousing or other logistics services pertaining to dangerous drugs including distribution, on behalf of a manufacturer, wholesale distributor, or terminal distributor of dangerous drugs, but does not take ownership of the drugs or have responsibility to direct the sale or disposition of the drugs.

(Z) "Virtual wholesaler" or "virtual wholesaler distributor" means any person engaged in wholesale distribution of dangerous drugs in or into Ohio who has title but does not take physical possession of the dangerous drugs. A virtual wholesale distributor shall be licensed as a wholesale distributor pursuant to section 4729.52 of the Revised Code with a virtual wholesale distributor classification.

- (AA) "Wholesale distributor of dangerous drugs" or "wholesale distributor" means a person engaged in the sale of dangerous drugs at wholesale or the reverse distribution of dangerous drugs and includes any agent or employee of such a person authorized by the person to engage in the sale of dangerous drugs at wholesale.
- (BB) "Wholesale sale" and "sale at wholesale" mean any sale in which the purpose of the purchaser is to resell the article purchased or received by the purchaser.

Effective:

Five Year Review (FYR) Dates: 4/25/2027

Certification

Date

Promulgated Under: 119.03
Statutory Authority: 4729.26, 3719.28, 9.79
Rule Amplifies: 4729.52
Prior Effective Dates: 03/01/2019, 07/08/2019, 04/25/2022