

Ohio Administrative Code Rule 4729-9-01 Definitions.

Effective: September 15, 2017

(A) "Dangerous drug", as defined in section 4729.01 of the Revised Code, means any drug or drug product whose commercial package bears a label containing the symbol "Rx only", the legend "Caution: Federal Law Prohibits Dispensing Without Prescription" or "Caution: Federal Law Restricts This Drug To Use By Or On The Order Of A Licensed Veterinarian," or any similar restrictive statement.

(B) "Adulterated drug" includes a dangerous drug to which any of the following applies:

(1) A compounded dangerous drug if it exceeds the beyond use date as indicated in United States pharmacopeia chapters 795 and 797, USP 38 - NF 33, or any official supplement thereto (10/16/2016).

(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, packer, or distributor in its labeling or it is not stored, dispensed or personally furnished according to the requirement of the federal act as indicated in the product labeling. This does not apply to expired drugs that are donated pursuant to sections 3715.88 to 3715.92 of the Revised Code.

(C) "Psychiatric outpatient facility" means a facility where psychiatric evaluation and treatment is provided on an outpatient basis.

(D) As used in Chapters 3719. and 4729. of the Revised Code, "registered" and "licensed" mean that an individual or facility has met the initial qualifications for registration or licensure with the state board of pharmacy and have complied with renewal procedures, including payment of applicable fees.

(E) "Revoke", as used in Chapters 3719. and 4729. of the Revised Code, means to take action against



a license or registration rendering such license or registration void and such license or registration may not be reissued. "Revoke" is an action that is permanent against the license/registration and licensee/registrant.

(F) "Suspend", as used in Chapters 3719. and 4729. of the Revised Code, means to take action against a license or registration rendering such license or registration 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.

(G) "Summary suspension", as used in Chapters 3719. and 4729. of the Revised Code, means to take immediate action against a license or registration without a prior hearing rendering such license or registration without force and effect for a period of time as indicated in section 3719.031, 3719.121, 4729.561 or 4729.571 of the Revised Code. The board may suspend a license or registration issued pursuant to Chapters 3719. and 4729. of the Revised Code by utilizing a telephone conference call to review the allegations and take a vote.

(H) "Place on probation", as used in Chapter 4729. of the Revised Code, means to take action against a license or registration suspending some or all of the sanctions imposed by the board against that license or registration. The terms of the probation shall state the period of time covered by the probation and may include other conditions as determined by the state board of pharmacy.

(I) "Refuse to grant or renew", as used in Chapter 4729. of the Revised Code, means to deny original or continued licensure or registration for a period of at least twelve months. After twelve months, or such period of time as the individual board order may require, an individual or facility licensed or registered by the board or an individual or facility seeking to attain such status by licensure or registration, and whose license or registration the state board of pharmacy has refused to grant or renew, may make application to the board for issuance of a new license. A pharmacist, or an individual or facility that seeks to attain such status by licensure or registration, whose license the state board of pharmacy has refused to grant or renew must meet any requirements established by the board or must pass any examination required by the board.



(J) "Campus", as used to describe a type of terminal distributor of dangerous drugs license issued pursuant to section 4729.51 of the Revised Code, means an establishment or place consisting of multiple buildings where dangerous drugs are stored that are located on a contiguous plot of land. All such buildings and stocks of dangerous drugs shall be under common ownership and control.

(K) "Certified diabetes educator," as used in Chapters 3719. and 4729. of the Revised Code, means a person who has been certified to conduct diabetes education by the "National Certification Board for Diabetes Educators (NCBDE)."

(L) "Abandoned application" means an application submitted for licensure or registration that meets the requirements in paragraphs (L)(1) and (L)(2) 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 or registration, submit the required fee and comply with the 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 complete all application requirements within thirty days after being notified of the incomplete application by the board.

(b) An applicant for a terminal distributor of dangerous drugs that fails to demonstrate compliance with rules 4729-5-11, 4729-9-11 and 4729-9-05 of the Administrative Code within ninety days of receipt of a completed application. The applicant may submit a request to the director of licensing for a one-time ninety-day extension.

(c) An applicant for a wholesale distributor of dangerous drugs that fails to demonstrate compliance with rule 4729-5-11 and the applicable licensing rules pursuant to Chapter 4729-9 of the Administrative Code within ninety days of receipt of a completed application. The applicant may submit a request to the director of licensing for a one-time ninety-day extension.

(d) An applicant for a wholesale distributor of dangerous drugs with an outsourcing facility classification that fails to demonstrate compliance with rules 4729-5-11 and 4729-16-02 of the



Administrative Code.

(e) An applicant for licensure as a pharmacist pursuant to rules 4729:1-2-01 and 4729:1-2-02 of the Administrative Code.

(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.