

4729:5-23-01**Limited Facilities - Definitions.**

As used in Chapter 4729:5-23 of the Administrative Code:

(A) "Limited facility" means a facility licensed as a limited category II or limited category III terminal distributor of dangerous drugs in accordance with 4729.54 of the Revised Code where drugs are possessed on-site for administration, dispensing, or personally furnishing. The facility shall comply with all requirements set forth in this chapter.

(1) A limited facility includes any of the following:

- (a) Dog trainers affiliated with an Ohio law enforcement agency;
- (b) Home health care providers, including those offering in-home services;
- (c) Hospice care providers of in-home services;
- (d) Physical therapy providers;
- (e) Teaching institutions; and
- (f) Any other facility as determined by the board.

(2) A limited facility does not include any of the following:

- (a) Non-limited facilities as defined in chapter 4729:22 of the Administrative Code; or
- (b) Any other person or facility licensed as a terminal distributor of dangerous that is specifically defined and required to comply with security, control and record keeping requirements of another chapter of this division (EMS organization, pain management clinic, animal shelter, etc.).

(3) A limited facility shall submit an application for licensure that includes all the following:

- (a) A completed application;
- (b) A list of the controlled substances and dangerous drugs, known as a drug list, that may be possessed and administered by a limited facility, expressed in standard dose units, signed by the responsible person; and
- (c) The fee for the appropriate category of licensure.

(4) A limited facility may only possess those controlled substances and dangerous drugs that are on the drug list submitted to the board pursuant to paragraph

(A)(3)(b) of this rule and only at locations licensed by the state board of pharmacy. The responsible person may modify the drugs that may be possessed and administered by the limited facility by submitting a new drug list to the state board of pharmacy in a manner determined by the board.

(B) "Controlled substance" has the same meaning as in section 3719.01 of the Revised Code.

(C) "Dangerous drug" has the same meaning as in section 4729.01 of the Revised Code.

(D) "Law enforcement officer" has the same meaning as 21 CFR 1300.05 (10/09/2014).

(E) "Licensed health professional authorized to prescribe drugs" or "prescriber" has the same meaning as in rule 4729:5-1-02 of the Administrative Code but shall be limited to a prescriber practicing within the prescriber's applicable scope of practice.

(F) "Personal supervision" means the person specified in rule shall be physically present at the licensed location to deter and detect the diversion of dangerous drugs.

(G) "Personally furnish" or "personally furnishing" means the final association of a drug with a patient by a prescriber prior to the distribution to a patient for use outside the prescriber's practice setting. A prescriber at a limited facility who personally furnishes a dangerous drug shall comply with the requirements of rule 4729:5-19-02 of the Administrative Code.

(H)

(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 such as 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 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.

(I) "Readily retrievable" means that records maintained in accordance with this chapter 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.

(J) "Responsible person" has the same meaning as defined in rule 4729:5-2-01 of the Administrative Code and is responsible for the supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, adequate safeguards as required in division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs and maintaining all drug records otherwise required.

Effective: 3/1/2020

Five Year Review (FYR) Dates: 03/01/2025

CERTIFIED ELECTRONICALLY

Certification

12/06/2019

Date

Promulgated Under: 119.03
Statutory Authority: 4729.26, 3719.28
Rule Amplifies: 4729.54