

4729:5-21-01**Opioid Treatment Programs - Definitions.**

As used in Chapter 4729:5-21 of the Administrative Code:

- (A) "Opioid Treatment Program" or "OTP" means a facility that is licensed as a terminal distributor of dangerous drugs in accordance with 4729.54 of the Revised Code and holds, or is in the process of applying for, a valid certification from the substance abuse and mental health services administration of the United States department of health and human services pursuant to 42 CFR 8.11 (3/19/2001). The facility shall comply with all requirements set forth in this chapter. An OTP does not include an office-based opioid treatment clinic as defined in chapter 4729:5-18 of the Administrative Code.
- (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) "Dosage unit" means any of the following:
- (1) A single pill, capsule, ampule, tablet;
 - (2) In the case of a liquid solution, one (1) milliliter;
 - (3) In the case of a cream, lotion or gel, one (1) gram; or
 - (4) Any other form of administration available as a single unit.
- (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.
- (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 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 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.

(K) "Sample" means a dangerous drug or pharmaceutical preparation that would be hazardous to health or safety if used without the supervision of a licensed health professional authorized to prescribe drugs, or a drug of abuse, and that, at one time, had been placed in a container plainly marked as a sample by a manufacturer.

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Certification

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Date

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