

4729:5-18-01**Office-Based Opioid Treatment Clinics - Definitions.**

As used in Chapter 4729:5-18 of the Administrative Code:

(A) "Office-based opioid treatment clinic" or "OBOT clinic" means a facility, clinic or other location licensed as a terminal distributor of dangerous drugs in accordance with section 4729.553 of the Revised Code. An OBOT clinic shall comply with all requirements set forth in this chapter.

(1) Persons meeting any of the following identifying criteria shall obtain licensure under section 4729.553 of the Revised Code:

- (a) A facility, clinic or other location where any prescriber provides office-based opioid treatment to more than thirty patients;
- (b) A facility, clinic or other location that provides office-based opioid treatment and does not accept public or commercial insurance as a form of payment;
- (c) A facility, clinic or other location that provides office-based opioid treatment to more than sixty patients in a thirty-day period.

(2) Paragraph (A)(1) of this rule does not apply to any of the following:

- (a) A hospital;
- (b) A facility for the treatment of opioid dependence or addiction that is operated by a hospital;
- (c) A physician practice owned or controlled, in whole or in part, by a hospital or by an entity that owns or controls, in whole or in part, one or more hospitals;
- (d) A facility that conducts only clinical research and uses controlled substances in studies approved by a hospital-based institutional review board or an institutional review board that is accredited by the association for the accreditation of human research protection programs, inc.;
- (e) A facility that holds a category III terminal distributor of dangerous drugs license in accordance with section 4729.54 of the Revised Code for the purpose of treating drug dependence or addiction as part of an opioid treatment program and is the subject of a current, 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;

- (f) A program or facility that holds a license or certification issued by the department of mental health and addiction services under Chapter 5119. of the Revised Code if the license or certification is approved by the state board of pharmacy;
 - (g) A federally qualified health center or federally qualified health center look-alike, as defined in section 3701.047 of the Revised Code;
 - (h) A board of health of a city or general health district established by section 3709.01 of the Revised Code, or the authority having the duties of a board of health in any city as authorized by section 3709.05 of the Revised Code;
 - (i) A state or local correctional facility, as defined in section 5163.45 of the Revised Code; or
 - (j) Any other person or facility exempted in section 4729.553 of the Revised 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) "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.
- (E) "Patient limit" means the maximum number of individual patients that a prescriber may personally furnish, administer or prescribe a schedule III, IV, or V controlled substance narcotic for the treatment of opioid dependence or addiction at any one time in accordance with state and federal laws, rules and regulations. A patient counts towards a prescriber's patient limit until either:
 - (1) A controlled substance prescription for the treatment of opioid dependence or addiction has expired or the timeframe in which the medication quantity should have been depleted in accordance with prescription instructions has elapsed; or
 - (2) The minimum number of days between doses of a controlled substance administered for the treatment of opioid dependence or addiction elapses in accordance with the manufacturer's instructions.
- (F) "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 OBOT clinic who personally furnishes a dangerous drug shall comply with the requirements of rule 4729:5-19-02 of the Administrative Code.

(G)

(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.

(H) "Office-based opioid treatment" means the treatment of opioid dependence or addiction using a controlled substance.

(I) "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.

(J) "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.

(K) "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.

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