Ohio Administrative Code

Rule 4729:5-16-01 Laboratories - definitions.

Effective: March 12, 2020

As used in Chapter 4729:5-16 of the AdministrativeCode:

(A) "Laboratory" means any facility licensed as a terminal distributor of dangerous drugs in accordance with section 4729.54 of the Revised Code where dangerous drugs and controlled substances are possessed for scientific, clinical or instructional purposes. The facility shall comply with all requirements set forth in this chapter. A laboratory does not include any of the following:

(1) A laboratory licensed under Chapter 3796. of the Revised Code; or

(2) Any other person or facility licensed as a terminal distributor of dangerous drugs that is specifically defined and required to comply with another chapter of this division (EMS organization, veterinary clinic, pain management clinic, animal shelter, etc.).

(B) "Anonymous sample" means an unknown substance submitted to a laboratory for qualitative and or quantitative analysis.

(C) "Controlled substance" has the same meaning as in section 3719.01 of the Revised Code but shall not include exempt chemical preparations as defined in paragraph (E) of this rule.

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

(E) "Exempt chemical preparation" means a chemical or compound approved by the United States drug enforcement administration pursuant to 21 CFR 1308.23 (12/30/2016).

(F) "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.

(G) "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.

(H) "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 laboratory who personally furnishes a dangerous drug shall comply with the requirements of rule 4729:5-19-02 or 4729:5-20-02 of the Administrative Code.

(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 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.

(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 and controlled substances 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 controlled substances and maintaining all drug records otherwise required.