

4729:5-9-01**Definitions.**

As used in Chapter 4729:5-9 of the Administrative Code:

(A) "Institutional facility" means any of the following:

- (1) A public hospital or hospital as defined in section 3701.01 or 5122.01 of the Revised Code.
- (2) A freestanding emergency department.
- (3) A freestanding inpatient rehabilitation facility or inpatient rehabilitation facility as defined in rule 3701-83-25 of the Administrative Code.
- (4) An ambulatory surgical facility as defined in rule 3701-83-15 of the Administrative Code.
- (5) A nursing home licensed under Chapter 3721. of the Revised Code;
- (6) An inpatient psychiatric service provider as defined in rule 5122-14-01 of the Administrative Code;
- (7) A facility that provides medically supervised detoxification services that meets the following requirements:
 - (a) Patients are administered dangerous drugs to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of drugs or alcohol;
 - (b) Patients are under the care of a licensed prescriber and are provided continuous onsite monitoring by nurses licensed in accordance with Chapter 4723 of the Revised Code;
 - (c) If the period of detoxification is less than twenty-four hours, patients shall be transitioned to an inpatient, residential, or outpatient treatment program; and
 - (d) The facility holds the appropriate license or certification by the Ohio department of mental health and addiction services.
- (8) A residential care facility licensed under Chapter 3721. of the Revised Code that provides skilled nursing care to its residents, including medication administration as authorized in Chapter 3701-16 of the Administrative Code, provided the facility meets the following requirements:

- (a) The administration of medication shall be in compliance with this Chapter and Chapter 3701-16 of the Administrative Code, including the requirement to maintain individual medication records and documentation of medication orders; and
- (b) The residential care facility maintains an executed contract or agreement with an institutional pharmacy for the provision of institutional pharmacy services. The executed contract or agreement shall be maintained in a readily retrievable manner.
- (9) A state or local correctional facility, as defined in section 5163.45 of the Revised Code;
- (10) A juvenile correctional facility that is under the management and control of the department of youth services or a private entity with which the department of youth services has contracted for the institutional care; and
- (11) Any other facility as determined by the board.
- (B) "Institutional pharmacy" means a pharmacy that primarily provides inpatient pharmacy services to an institutional facility in accordance with this chapter.
- (C) "Audit trail" means all materials and documents required for the entire processing of a prescription, which shall be sufficient to document or reconstruct the origin of the prescription order, and authorization of subsequent modifications of that order.
- (D) "Automated drug storage system" means a mechanical system used for the secure storage of dangerous drugs used as floor stock or contingency drugs outside of an institutional pharmacy that collects, controls, and maintains transaction information and records.
- (E) "Contingency drugs" are a supply of non-patient specific dangerous drugs which may be required to meet the therapeutic needs of patients or staff when either apply:
- (1) The institutional facility's on-site pharmacy is closed or otherwise unavailable to provide pharmacy services;
- (2) The institutional facility does not have an on-site pharmacy.
- (F) "Dispense" means the final association of a drug with a particular patient pursuant to a prescription, medication order, or other lawful order of a prescriber and the professional judgment of and the responsibility for interpreting, preparing, compounding, labeling, and packaging a specific drug.

In the case of an automated drug storage system meeting the requirements of rule 4729:5-9-03.4 of the Administrative Code, the final association with the name of a particular inpatient will be deemed to have occurred when the pharmacist has given final approval to the patient specific order in the system.

- (G) "Electronic drug record keeping system" means a system of storing drug records electronically and, when required, capturing positive identification.
- (H) "Inpatient" means any person who receives drugs for use while within an institutional facility.
- (I) "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.
- (J) "Medication order" or "inpatient prescription" means a written, electronic, facsimile, or oral order for a drug to be dispensed or administered in treating an inpatient.
- (K) "OARRS report" means a report of information related to a specific person generated by the drug database established and maintained pursuant to section 4729.75 of the Revised Code.
- (L) "Outpatient" means any person who receives drugs for use outside of an institutional facility.
- (M) "Medications removed on override function" or "override medications" means a dangerous drug that may be removed from floor stock or contingency drugs prior to pharmacist review because the institutional facility's interdisciplinary committee has determined that the clinical status of the patient would be compromised by delay.
- (N) "Personal supervision" or "direct supervision" means a pharmacist shall be physically present in the pharmacy, or in the area where the practice of pharmacy is occurring, and provides personal review and approval of all professional activities.
- (O) "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 an institutional facility. A prescriber at an institutional facility who personally furnishes a dangerous drug shall comply with the requirements of rule 4729:5-19-02 of the Administrative Code.
- (P) "Pharmacist" means an individual who holds a current pharmacist license under Chapter 4729. of the Revised Code.

(Q) "Pharmacy," except when used in a context that refers to the practice of pharmacy, means any area, room, rooms, place of business, department, or portion of any of the foregoing where the practice of pharmacy is conducted.

(R)

(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 for entry into a secure mechanical or electronic system.

(S) "Point of care location" means a location within an institutional facility that stores dangerous drugs and all the following apply:

(1) The point of care location is licensed as a terminal distributor of dangerous drugs;

(2) The dangerous drugs are not owned by the institutional facility where the point of care location is located;

(3) The dangerous drugs stored are owned by another institutional facility licensed as a terminal distributor of dangerous drugs; and

- (4) The location may be used for the administration, personally furnishing, or dispensing of dangerous drugs, including controlled substances.
- (T) "Practice of pharmacy" has the same meaning as in division (B) of section 4729.01 of the Revised Code.
- (U) "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.
- (V) "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.
- (W) "Skilled nursing care" has the same meaning as in section 3721.01 of the Revised Code.
- (X) "Tamper-evident" means a package, storage container or other physical barrier is sealed or secured in such a way that access to the drugs stored within is not possible without leaving visible proof that such access has been attempted or made.

Replaces: 4729-17-01

Effective:

Five Year Review (FYR) Dates:

Certification

Date

Promulgated Under: 119.03
Statutory Authority: 4729.26, 3719.28
Rule Amplifies: 3719.01, 4729.01
Prior Effective Dates: 09/10/1976, 09/01/1985, 07/01/1991, 03/13/1995,
01/10/1996, 03/01/1999, 02/01/2005, 01/01/2006,
04/27/2007, 01/01/2011, 04/28/2016