

## Ohio Administrative Code Rule 4729-17-01 Definitions; institutional facility.

Effective: November 1, 2017

As used in Chapter 4729-17 of the Administrative Code:

(A) "Institutional facility" means a hospital as defined in section 3727.01 of the Revised Code, or a facility licensed by the state board of pharmacy and the Ohio department of health, the Ohio department of rehabilitation and correction, the Ohio department of developmental disabilities, or the Ohio department of mental health and addiction services at which medical care is provided on site and a medical record documenting episodes of care, including medications ordered and administered, is maintained, including the following:

(1) Convalescent homes;

- (2) Developmental facilities;
- (3) Long term care facilities;
- (4) Nursing homes;
- (5) Psychiatric facilities;
- (6) Rehabilitation facilities;
- (7) Developmental disability facilities;

(8) Level III sub-acute detoxification facilities certified by the Ohio department of mental health and addiction services;

(9) State or local correctional facilities, as defined in section 5163.45 of the Revised Code;



(10) Any other facility as determined by the board.

(B) "Inpatient" means any person who receives drugs for use while within the institutional facility.

(C) "Inpatient prescription" means a written, electronic, or oral order for a drug to be dispensed for use in treating an inpatient.

(D) "Dispensing of a drug pursuant to an inpatient prescription" means the professional review by a pharmacist required to place a specific drug in final association with the name of a particular inpatient pursuant to the lawful order of a prescriber. In the case of an automated drug delivery system meeting the requirements of rule 4729-5-35 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.

(E) "Contingency drugs" are those drugs which may be required to meet the therapeutic needs of inpatients when a licensed pharmacist is not available and personally in full and actual charge of the institutional pharmacy.

(F) "Emergency drugs" are those drugs which are required to meet the immediate therapeutic needs of inpatients in order to sustain life in an emergency situation.

(G) "Outpatient" means any person who receives drugs for use outside of the institutional facility.

(H) "Electronic drug record keeping system" means a system of storing drug records electronically and capturing the positive identification of the person responsible for a specific drug transaction including, but not limited to, the prescribing, administering, or dispensing of a drug.

(I) "Positive identification" has the same meaning as paragraph (N) of rule 4729-5-01 of the Administrative Code except that a specific hospital having a closed electronic drug record keeping system may be permitted to use identifiers utilizing both a password combined with a personal identifier to document the positive identification of each user for, but not limited to, the prescribing and administration of a drug if approved by the board of pharmacy.



(1) At a minimum, the following items will be considered during the approval process:

(a) Audit controls are in place to detect and deter drug diversion;

(b) Access controls are in place to ensure the identity of a user and to assign accountability of the user for any drug transaction;

(c) Safeguards are in place to prevent and detect the unauthorized use of an individual's password and personal identifier;

(d) An ongoing quality assurance program is in place to ensure that paragraphs (I)(1)(a) to (I)(1)(c) of this rule are being fulfilled and reviewed; and

(e) Policies and procedures are in place to address all of the items in paragraphs (I)(1)(a) to (I)(1)(d) of this rule.

(2) Positive identification pursuant to paragraph (N) of rule 4729-5-01 of the Administrative Code shall always be used to document the:

(a) Dispensing, compounding, or repackaging of a drug;

(b) Removal and possession of a controlled substance to administer to a patient;

(c) Waste of a controlled substance.

(J) "Password" means a private identification that is created by a user to obtain access to an electronic drug record keeping system.

(K) "Personal identifier" means a unique user name or number for identifying and tracking a specific user's access to an electronic drug record keeping system such as social security number, user identification number, or employee number.

(L) "Point of care location" means a location within an institutional facility that stores dangerous



drugs and all of 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.

(M) "Outpatient institutional pharmacy" means a pharmacy located within or on the campus of an institutional facility that provides outpatient pharmacy services which is physically separate from, and not contiguous to, the area in which inpatient pharmacy services are provided. An outpatient institutional pharmacy shall have a separate terminal distributor of dangerous drugs license in addition to the license for the institutional facility.