Ohio Administrative Code

Rule 4729:5-3-17 Automated pharmacy systems.

Effective: June 4, 2021

(A) As used in this rule:

(1) "Automated pharmacy system" means a mechanical system that performs operations or activities, other than administration, relative to storage, packaging, compounding, dispensing, or distribution of dangerous drugs that collects, controls, and maintains transaction information and records.

"Automated pharmacy system" does not include an "automated drug storage system" utilized by institutional facilities pursuant to Chapter 4729:5-9 of the Administrative Code or other locations licensed as terminal distributors of dangerous drugs.

(2) "Dispense" means the final association of a drug with a particular patient pursuant to a prescription, drug 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.

(a) In the case of an automated pharmacy system that dispenses dangerous drugs without the final association by a pharmacist, the system shall capture the positive identification of the pharmacist authorizing the patient specific prescription in the system prior to its dispensation.

(b) Nothing in this paragraph shall prohibit an automated pharmacy system from being utilized to restock an automated drug storage system utilized by institutional facilities pursuant to Chapter 4729:5-9 of the Administrative Code or other locations licensed as terminal distributors of dangerous drugs.

(3) "Positive identification" has the same meaning as in rule 4729:5-5-01 of the Administrative Code.

(4) "Tamper evident" means a package, storage container or other physical barrier that 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.

(B) An automated pharmacy system shall be approved by the board prior to its implementation by the terminal distributor of dangerous drugs.

(1) Prior to the approval of an automated pharmacy system, the board shall receive a request from the responsible person on the terminal distributor of dangerous drugs license. Upon notification, the board shall conduct an inspection of the system to determine if it meets the requirements of this rule.

(2) For automated pharmacy systems that dispense dangerous drugs in accordance with paragraph (A)(2)(a) of this rule, the responsible person of the licensed terminal distributor of dangerous drugs shall be required to have a pharmacist verify for accuracy all dangerous drugs dispensed by the system for a continuous forty-five-day period. The responsible person shall compile metrics, using a form developed by the board, documenting the performance of the system during this period. Unless otherwise approved by the board, the accuracy metrics during the forty-five day pharmacy review period shall be no less than ninety-nine and nine hundred eighty-five thousandths (99.985) per cent.

(3) Approval of all automated pharmacy systems shall be site-specific.

(C) An automated pharmacy system shall be located on the premises of a licensed terminal distributor of dangerous drugs.

(D) A terminal distributor of dangerous drugs operating an automated pharmacy system shall maintain the following documentation on-site in a readily retrievable manner:

(1) The manufacturer's name and model;

(2) A description of how the automated pharmacy system is used; and

(3) Policies and procedures for system operation, safety, security, accuracy, patient confidentiality, access, and malfunction.

(E) All records maintained in accordance with this rule, including documentation of quality

assurance metrics, shall be readily retrievable and maintained for period of three years.

(F) For automated pharmacy systems that dispense dangerous drugs in accordance with paragraph (A)(2)(a) of this rule, the terminal distributor of dangerous drugs shall implement a quality assurance program to determine continued appropriate use of the automated pharmacy system. The quality assurance program shall monitor the performance of the automated pharmacy system, ensure the system is in good working order and accurately prepares the correct strength, dosage form, and quantity of the drug prescribed or ordered. At a minimum, the quality assurance program shall consist of a review of at least five per cent of all dispensed prescriptions over the daily operational hours of the automated pharmacy system.

(G) If an automated pharmacy system that dispenses dangerous drugs in accordance with paragraph (A)(2)(a) of this rule selects an incorrect drug, the terminal distributor shall immediately institute a one hundred per cent pharmacist verification of all drugs dispensed. The one hundred per cent verification procedure shall continue until such time as the terminal distributor can document that the cause of the error has been determined and addressed and that the system is no longer making errors.

(H) A registered or certified pharmacy technician, pharmacy technician trainee, pharmacy intern, or nurse licensed in accordance with Chapter 4723. of the Revised Code may stock an automated pharmacy system provided that:

(1) Except as provided in paragraph (H)(2) of this rule, the container, canister, or other dangerous drug storage device being stocked by the technician, trainee, intern, or nurse is tamper-evident and is verified by a pharmacist and documented using positive identification.

(2) Pharmacist verification requirements in paragraph (H)(1) of this rule do not apply if all the following are met:

(a) Verification is being conducted by a registered or certified pharmacy technician, pharmacy intern, or nurse; and

(b) The container, canister, or other dangerous drug storage device being stocked is properly

identified by bar code or other such secondary information system, which has been verified by a pharmacist to ensure the proper drug is being placed into and recognized as the correct drug by the system.

(3) The utilization of a bar code, electronic verification, or similar verification process shall require an initial quality assurance validation by a pharmacist and shall be followed by a quarterly quality assurance review by a pharmacist.

(4) The positive identification of the individual stocking the system is documented.

(5) A pharmacist is fully responsible for all activities conducted by the technician, trainee, intern, or nurse.

(6) A pharmacist must be immediately available to answer questions or discuss the stocking of an automated pharmacy system.

(7) A registered pharmacy technician or pharmacy technician trainee shall be acting under the personal supervision of a pharmacist.

(I) Except for an automated pharmacy system in a long-term care facility, a pharmacist shall be physically present at the terminal distributor of dangerous drugs to provide supervision of the automated pharmacy system.

(J) The automated pharmacy system shall have security to prevent unauthorized individuals from accessing or obtaining dangerous drugs and include safeguards to detect the diversion of dangerous drugs. This shall include the use of tamper-evident containers, canisters, or other storage devices for use in long-term care facilities.

(K) The records kept by the automated pharmacy system shall comply with the applicable record keeping requirements of division 4729:5 of the Administrative Code and shall also capture all events involving the contents of the automated pharmacy system.

(L) If applicable, an automated pharmacy system shall comply with the requirements set forth in 21

CFR 1301.27 (5/13/2005) for automated systems in long term care facilities.