# Ohio Administrative Code

## Rule 4729:5-9-02.3 Record keeping at an institutional pharmacy.

Effective: February 1, 2022

(A) An institutional pharmacy shall document, using positive identification, the licensed or registered individuals responsible for performing the following activities authorized under Chapter 4729. of the Revised Code and agency 4729 of the Administrative Code:

(1) Medication order or prescription information entered into the record keeping system. This provision shall take effect one-year from the effective date of this rule.

(2) Verification by the pharmacist of the prescription information entered into the record keeping system.

(3) Drug utilization review in accordance with rule 4729:5-9-02.6 of the Administrative Code, which shall be captured as a standalone action or as part of either:

(a) The pharmacist verification of prescription information as required by paragraph (A)(2) of this rule; or

(b) The dispensing process in paragraph (A)(4) of this rule.

(4) Dispensing, except that a pharmacist shall not be required to perform a check of dangerous drugs prior to distribution if the drug is dispensed in accordance with either:

(a) Paragraph (F)(5) of this rule; or

(b) In accordance with rule 4729:5-3-17 of the Administrative Code.

(5) Compounding in accordance with Chapter 4729:7-2 of the Administrative Code.

(6) Administering immunizations pursuant to section 4729.41 of the Revised Code.

(7) Administering other injectable drugs pursuant to section 4729.44 of the Revised Code.

(8) Prescription information transcribed from an order received by telephone or recording device.

(9) Any changes or annotations made to a prescription or medication order.

(B) An institutional pharmacy shall maintain the following records:

(1) All medication orders issued in accordance with rule 4729:5-9-02.7 of the Administrative Code.

(2) Records of drugs dispensed shall including all the following:

(a) The name, strength, dosage form, route of administration, and quantity of drugs dispensed;

(b) The date of dispensing;

(c) The name of the inpatient to whom, or for whose use, the drug was dispensed; and

(d) The positive identification of the individuals involved in the dispensing process in accordance with paragraph (A)(1) of this rule.

(C) An institutional pharmacy shall maintain records of all drugs dispensed to outpatients pursuant to rule 4729:5-5-04 of the Administrative Code.

(D) An institutional pharmacy shall maintain records of all drugs repackaged pursuant to rule 4729:5-9-02.12 of the Administrative Code.

(E) An institutional pharmacy shall maintain records of all drugs compounded pursuant to Chapter 4729:7-2 of the Administrative Code.

(F) An institutional pharmacy shall maintain records for the distribution of non-patient specific dangerous drugs to other areas of the institutional facility for administration or use, which shall

include all the following:

(1) The name, strength, dosage form, and amount of drug distributed.

(2) The area receiving the drug.

(3) The date distributed.

(4) Except as provided in paragraph (F)(5) of this rule, the positive identification of the pharmacist checking the dangerous drugs prior to distribution. Such documentation shall be maintained for a period of three years in a manner that is readily retrievable.

(5) A pharmacist shall not be required to perform a check of dangerous drugs prior to distribution if all the following apply:

(a) The drugs are distributed in accordance with paragraph (A)(2)(a) of rule 4729:5-3-17 of the Administrative Code.

(b) The drugs are stored or will be stored in an automated drug storage system that utilizes barcode system to track and correctly identify drugs stored within the system.

(c) A pharmacist has conducted an initial check of every barcode to ensure they have been assigned correctly to the appropriate drug. The initial check shall be documented using positive identification and maintained for a period of three years in a manner that is readily retrievable.

(d) The pharmacy develops and implements a policy that includes all the following:

(i) Verification by a pharmacist, documented using positive identification, prior to any changes to barcodes, additions to the formulary, or modification of a drugs national drug code (NDC). Any change shall be documented using positive identification and maintained for a period of three years in a manner that is readily retrievable.

(ii) Requiring a pharmacist to document using positive identification the addition of auxiliary

barcodes to drugs. Such documentation shall be maintained for a period of three years in a manner that is readily retrievable.

(iii) A process to immediately alert the pharmacy of an error resulting from an incorrect barcode or a barcode override to ensure the accuracy of the system.

(iv) Prohibits a pharmacy technician or pharmacy intern from moving or modifying any barcodes inside the system. Any modifications may only be done by a pharmacist and shall be documented using positive identification. Such documentation shall be maintained for a period of three years in a manner that is readily retrievable.

(6) For non-controlled dangerous drugs: the identification of the facility personnel receiving the drug or authorized personnel stocking the automated drug storage system.

(7) For controlled substance dangerous drugs: the positive identification of the facility personnel receiving the drug or authorized personnel stocking the automated drug storage system.

(G) Records of receipt of dangerous drugs shall contain the name, strength, dosage form, and quantity of the dangerous drugs received, the name and address of the seller, the name and address of the recipient, and the date of receipt.

(H) Records of temperature control monitoring described in paragraph (D) of rule 4729:5-9-02.2 of the Administrative Code shall include any of the following:

(1) For temperature logs, either:

(a) The date and time of observation, the full name or the initials of the individual performing the check, and the temperature recorded; or

(b) For systems that provide automated temperature monitoring, maintain a report that provides, at a minimum, the date and time of observation and the temperature recorded.

(2) For temperature monitoring systems capable of detecting and alerting staff of a temperature

excursion, maintain reports that provide information on any temperature excursion that includes the date, time, temperature recorded, and length of each excursion.

(I) Records of dangerous drugs disposed from inventory, other than controlled substances, shall contain the name, strength, dosage form, and quantity of the dangerous drug disposed, the date of disposal, the method of disposal, and, if disposal is performed on-site, the positive identification of the licensed health care professional that performed the disposal.

(J) Records of controlled substance drug disposal shall comply with the requirements of rule 4729:5-3-01 of the Administrative Code.

(1) If the disposal of controlled substance drug inventory is performed on-site in an institutional pharmacy, records shall also include the positive identification of two licensed or registered healthcare professionals conducting and witnessing the disposal, one of whom shall be a pharmacist.

(2) If conducting the disposal of an unused portion of a controlled substance resulting from administration to a patient in an institutional pharmacy, records shall also include the positive identification of two licensed or registered healthcare professionals conducting and witnessing the disposal.

(K) Controlled substance inventory records shall be maintained in accordance with rule 4729:5-3-07 of the Administrative Code.

(L) Records of transfers to other terminal distributors of dangerous drugs, including sales conducted in accordance with rule 4729:5-3-09 of the Administrative Code, shall contain the name, strength, dosage form, and quantity of the dangerous drug transferred, the address of the location where the drugs were transferred and the date of transfer.

(M) All institutional pharmacy records required in accordance with this chapter shall be maintained under appropriate supervision and control to restrict unauthorized access.

(N) All institutional pharmacy records maintained in accordance with this chapter shall be uniformly maintained for a period of three years. Except as provided in paragraph (N)(3) of this rule, all

records shall be made readily retrievable.

(1) Computerized drug record keeping systems or subsequent storage of such records, must be retrievable via digital display, hard copy printout, or other mutually agreeable transfer medium.

(2) If a computerized drug record keeping system is being utilized, the method(s) of achieving positive identification must be approved, in a manner determined by the board, prior to implementation or any subsequent modification.

(3) Record keeping systems shall provide immediate retrieval via digital display and hard copy printout or other mutually agreeable transfer medium of information for all prescriptions, or medication orders, dispensed within the previous twelve months, and shall provide in a manner that is readily retrievable information on all prescriptions dispensed beyond the previous twelve months but within the previous three years.

(4) All computerized record keeping systems shall be able to capture records edited by authorized personnel and maintain an audit trail as defined in rule 4729:5-9-01 of the Administrative Code.

(5) All paper records maintained electronically shall be scanned in full color via technology designed to capture information in one form and reproduce it in an electronic medium presentable and usable to an end user.

(6) All computerized record keeping systems, including systems used to store scanned paper records, shall have daily back-up functionality to protect against record loss and security features to prevent unauthorized access.

(O)

(1) Except as provided for in paragraph (O)(2) of this rule, all records maintained in accordance with this chapter shall be maintained on-site.

(2) An institutional pharmacy located in this state intending to maintain records at a location other than the location licensed by the state board of pharmacy shall send a request in a manner determined

by the board. The board will provide written or electronic notification to the institutional pharmacy documenting the approval or denial of the request. A copy of the board's approval shall be maintained at the licensed location. Any such alternate location used to store records shall be secured and accessible only to authorized representatives or contractors of the terminal distributor of dangerous drugs.