Ohio Administrative Code

Rule 4729:5-5-04 Record keeping.

Effective: December 1, 2020

(A) There shall be positive identification of 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) 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) Prospective drug utilization review, which shall be captured as a standalone action or as part of either:

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

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

(4) Dispensing.

(5) Compounding.

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

(7) Administering injectable drugs pursuant to section 4729.45 of the Revised Code.

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

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

(B) All records maintained in accordance with this rule shall be uniformly maintained for a period of three years.

(C) 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 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. This information shall include, at a minimum, the following data:

(1) The original prescription number;

(2) Date of issuance of the original prescription order by the prescriber;

(3) Full name of the patient for whom the drug is intended; or, if the patient is an animal, the last name of the owner, name of animal (if applicable), and species of the animal or animals;

(4) Residential address, including the physical street address and telephone number of the patient or owner;

(5) Full name and address of the prescriber, including the physical address of the prescriber's practice location;

(6) The prescriber's credential (MD, DDS, DVM, etc.), if indicated on the prescription;

(7) Directions for use;

(8) The brand name, if any, or the generic name and the name of the manufacturer or distributor or national drug code of the drug or device dispensed;

(9) The strength, dosage form, and quantity of the drug or device dispensed;

(10) The prescriber's federal drug enforcement administration number, if applicable;

(11) The positive identification of the persons performing specific actions pursuant to paragraph (A) of this rule;

(12) The total number of refills authorized by the prescriber;

(13) The date of dispensing;

(14) The refill history of the prescription, including all of the following:

(a) The prescription number;

(b) The brand name, if any, or the generic name and the name of the manufacturer or distributor or national drug code of the drug or device dispensed;

(c) The date(s) of dispensing; and

(d) The quantity dispensed.

(D) A pharmacy that utilizes a computerized system to dispense dangerous drugs that is unable to electronically document positive identification in accordance with paragraph (A) of this rule shall be required to maintain hard copy documentation. Hard copy documentation shall be provided by each registered or licensed individual who makes use of such system by one of the following methods:

(1) A hard copy printout of each day's prescription data.

(a) The printout shall include, at a minimum, the following data:

(i) Date of dispensing;

(ii) Prescription number;

(iii) Patient name;

(iv) Name, strength, and quantity of drug dispensed;

(v) Identification of the pharmacist or pharmacy personnel responsible for any activity described in paragraph (A) of this rule;

(vi) Identification of the pharmacy; and

(vii) Identification of controlled substances.

(b) The printout must be verified, dated, and signed by each individual responsible for any activity described in paragraph (A) of this rule. The printout must be verified and manually signed by the individual within a reasonable timeframe to ensure the accuracy of the record.

(c) If the printout is prepared at a location other than where the drug was dispensed, the printout must be provided to the licensed location within three business days of the date on which the drugs were dispensed. Such printouts must be verified and signed by each individual responsible for any activity described in paragraph (A) of this rule within twenty-four hours of the date the printout is received by the individual.

(d) The printout must be readily retrievable and maintained in chronological order in a separate file at the licensed location where the drug was dispensed for a period of three years from the date of dispensing.

(e) The signed printout may be stored electronically in accordance with paragraph (E) of this rule.

(2) A tamper evident log book.

(a) Each individual pharmacist involved in dispensing drugs must enter into a tamper evident log book the following data for each prescription dispensed:

(i) Date of dispensing;

(ii) Prescription number;

(iii) Patient name;

(iv) Name, strength and quantity of drug dispensed;

(v) Identification of the pharmacist and pharmacy personnel responsible for any activity described in paragraph (A) of this rule;

(vi) Identification of controlled substances.

(b) Each individual responsible for any activity described in paragraph (A) of this rule shall review this information at the end of each day, or at the end of the individual's shift, and must either:

(i) Manually sign a statement in the log book attesting to the fact that the prescription information entered into the computer that day and recorded in the log book has been reviewed by the individual and is correct as shown; or

(ii) Manually initial each entry of the log book to indicate that the prescription information entered into the computer that day and recorded in the log book has been reviewed by the individual and is correct as shown.

(c) The log book must be readily retrievable and maintained at the licensed location where the drug was dispensed for a period of three years from the date of dispensing.

(E) A signed printout that is maintained in accordance with paragraph (D) of this rule may be electronically created and maintained, provided the system creates and maintains the printout in accordance with the following:

(1) All information in the printout shall be scanned in full color (i.e. retains color information and/or color graphics in the document) via technology designed to capture information in one form and reproduce it in an electronic medium presentable and usable to an end user;

(2) A record or image once created shall be unalterable but may be annotated as necessary so long as the original record or image is still available for review and the individual that made the annotation is noted;

(3) Contains security features to prevent unauthorized access to the records;

(4) Contains daily back-up functionality to protect against record loss.

(F) In addition to the immediate retrieval and production of prescription information required by paragraph (C) of this rule, an outpatient pharmacy that utilizes a computerized record keeping system shall comply with the following:

(1) Make readily retrievable the following information:

(a) An electronic record in a character-delimited or fixed-width ASCII text file or other mutually acceptable format that contains any requested data fields the pharmacy is responsible for maintaining pursuant to all federal and state laws, rules and regulations; and

(b) A hard copy printout sorted by any requested data fields that the pharmacy is responsible for maintaining pursuant to all federal and state laws, rules, and regulations.

(2) Make readily available upon request by an individual authorized by law to access such records any of the following:

(a) A printout; or

(b) An electronic record and a definition file describing the file layout and column width, if applicable.

(3) All computerized record keeping systems shall be able to capture records edited by authorized personnel and maintain an audit trail.

(G) In the event that a pharmacy utilizes a computerized record keeping system that experiences an outage, the pharmacy must have an auxiliary procedure which will be used for documentation of refills of prescription orders. This auxiliary procedure must ensure that refills are authorized by the original prescription order, that the maximum number of refills has not been exceeded, and that all of the appropriate data is recorded and retained. Nothing in this paragraph shall preclude a pharmacist from dispensing a refill if, in the exercise of the pharmacist's professional judgement, failure to dispense or sell the drug to the patient could result in harm to the health of the patient.

(H) Prescriptions entered into a computer system that are not dispensed shall meet all of the following requirements:

(1) The complete prescription information must be entered in the computer system;

(2) The information must appear in the patient's profile;

(3) There is positive identification of the person who is responsible for entering the prescription information into the system and the pharmacist responsible for verifying the prescription information in accordance with paragraph (A) of this rule;

(4) The prescription must be assigned a prescription number; and

(5) The original prescription is filed according to rule 4729:5-5-03 of the Administrative Code.

(I) Records shall be maintained for three years and made readily retrievable for all immunizations administered in accordance with section 4729.41 of the Revised Code and rules 4729:1-3-02 and 4729:2-3-03 of the Administrative Code and shall include the following information:

(1) Full name and address of the patient;

(2) Patient's date of birth or age;

(3) Patient's applicable allergy information;

(4) Date of administration;

(5) Name, strength, and dose of the immunization administered;

(6) Lot number and expiration date of the immunization;

(7) Route of administration;

(8) Location of the injection site;

(9) Positive identification of the administering pharmacist or the administering pharmacy intern and supervising pharmacist;

(10) Identification of the patient, parent, or legal guardian of the patient who gives informed consent to administer the immunization.

(J) Immunization records may be electronically created and maintained if done so in accordance with the standards set forth in paragraph (E) of this rule.

(K) A pharmacist may document the pharmacist's own administration of an immunization or an immunization administered by a pharmacy intern the pharmacist is personally supervising on a prescription form, which may be assigned a number for record keeping purposes.

(L) Records shall be maintained for three years and made readily retrievable for all dangerous drugs administered in accordance with section 4729.45 of the Revised Code and rule 4729:1-3-03 of the Administrative Code and shall include the following information:

(1) Full name and address of the patient;

(2) Patient's date of birth or age;

(3) Patient's applicable allergy information;

(4) Date of administration;

(5) Name, strength, and dose of the drug administered;

(6) Lot number and expiration date of the drug;

(7) Route of administration;

(8) Location of the injection site;

(9) Documentation of test results required prior to the administration of an opioid antagonist in accordance with rule 4729:1-3-03 of the Administrative Code;

(10) Required physician notification pursuant to rule 4729:1-3-03 of the Administrative Code;

(11) Positive identification of the administering pharmacist; and

(12) Identification of the person who provides permission to administer the dangerous drug pursuant to rule 4729:1-3-03 of the Administrative Code.

(M) Dangerous drug administration records may be electronically created and maintained if done so in accordance with the standards set forth in paragraph (E) of this rule.