Ohio Administrative Code

Rule 4729-5-27 Record keeping.

Effective: January 20, 2015

The following record keeping requirements do not apply to records relating to the practice of pharmacy for an inpatient as defined in rule 4729-17-01 of the Administrative Code.

(A) There must be positive identification of the pharmacist or pharmacists responsible for performing all activities relating to the practice of pharmacy including, but not limited to:

(1) Prescription information entered into the record keeping system;

(2) Prospective drug utilization review;

(3) Dispensing;

(4) Patient counseling;

(5) Administering adult immunizations;

(6) Prescription information reduced to writing from an order received by telephone, facsimile, or recording device.

(B) Records of dispensing must provide accountability and ensure that patients do not receive more drugs than intended by the prescriber.

(C) All records relating to the practice of pharmacy shall be uniformly maintained for a period of three years, be readily available, and promptly produced upon request for inspection by a state board of pharmacy officer, agent, and/or inspector during regular business hours.

(D) All prescriptions or other records relating to the practice of pharmacy, which are required to be kept for three years according to section 4729.37 of the Revised Code, may be microfilmed or placed

on electronic, magnetic media. The microfilm or electronic, magnetic media used for this purpose must comply with the "International Standards Organization" standards of quality approved for permanent records. Such records are subject to all other paragraphs of this rule.

(E) Any pharmacy intending to maintain records relating to the practice of pharmacy at a location other than the place licensed with the state board of pharmacy must first send written notification to the state board of pharmacy. The request shall contain the terminal distributor of dangerous drug name and license number of the requestor and the name and address of the alternate location. The state board of pharmacy office will send written notification of the approval or denial of the request. A copy of the board's approval shall be maintained with other records relating to the practice of pharmacy. Any such alternate location shall be secured and accessible only to representatives of the terminal distributor of dangerous drugs.

(F) Alternate record keeping systems include, but are not limited to, the following:

(1) A system that utilizes the original hard copy prescription to document the initial dispensing of a prescription, but utilizes a computerized system to dispense refills that does not document the positive identification of the pharmacist responsible for the practice of pharmacy. In order to document positive identification, this system would require the manual signature or initials of a pharmacist on a hard copy record as indicated in paragraph (I) of this rule.

(2) A computerized system that documents the positive identification of the pharmacist responsible for the practice of pharmacy. If this method is used, it must be approved by the board and provide a daily backup.

(3) Any record keeping system approved by the board.

(G) All computerized record keeping systems must be capable of providing immediate retrieval (via digital display and hard copy printout or other mutually agreeable transfer medium) of patient profile information for all prescriptions filled within the previous twelve months and retrieval within three working days, excluding weekends and holidays, of all prescriptions dispensed within the previous three years. This information shall include at least, but is not limited to, the following data:

(1) The original prescription number;

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

(3) Date of dispensing by the pharmacist;

(4) Full name and address of the patient;

(5) Full name and address of the prescriber;

(6) Directions for use;

(7) The name, strength, dosage form, and quantity of the drug prescribed;

(8) The quantity dispensed if different from the quantity prescribed;

(9) If utilizing a board approved system pursuant to paragraph (F)(2) of this rule, there must be positive identification documented within the system of the pharmacist responsible for prescription information entered into the computer system, the pharmacist responsible for prospective drug utilization review as defined in rule 4729-5-20 of the Administrative Code, and the pharmacist responsible for dispensing;

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

(11) The refill history of the prescription as defined in paragraph (H) of this rule.

(H) The refill history of the prescription must include, but is not limited to:

(1) The prescription number;

(2) The name and strength of the drug dispensed;

(3) The date of refill;

(4) The quantity dispensed;

(5) If utilizing a board approved system pursuant to paragraph (F)(2) of this rule, there must be positive identification documented within the system of the pharmacist responsible for prospective drug utilization review as defined in rule 4729-5-20 of the Administrative Code and the pharmacist responsible for dispensing for each refill;

(6) The total number of refills dispensed to date for that prescription order.

(I) Hard copy documentation as required pursuant to paragraph (F)(1) of this rule must be provided by each individual pharmacist who makes use of such system by one of the following methods:

(1) A hard copy printout of each day's prescription refill data that shall include, at a minimum, the following data:

(a) Date of dispensing;

(b) Prescription number;

(c) Patient name;

(d) Name, strength (if applicable), and quantity of drug;

(e) Identification of pharmacy and pharmacist;

(f) Identification of controlled substances.

This printout must be verified, dated, and signed by each individual pharmacist who dispensed a prescription that day. The pharmacist must verify that the data on the printout is complete and correct and sign a statement to that effect on the document as he/she would sign a check or legal document (e.g., J. H. Smith or Jane H. Smith). These documents must be 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. If the printout is prepared at a location other than that where the drug was dispensed, the printout must be provided to the licensed location within three working days, excluding holidays and weekends, of the date on which the drugs were dispensed. Such printouts must be verified and signed by each pharmacist who dispensed drugs within twenty-four hours of the date the printout is received;

(2) A tamper evident log book in which shall be entered, at a minimum, the date of dispensing and prescription number. The dispensing pharmacist must manually record his/her name or initials on each log book entry at the time of dispensing each refill; or

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

(a) Date of dispensing;

(b) Prescription number;

(c) Patient name;

(d) Name, strength (if applicable), and quantity of drug;

(e) Identification of the pharmacist;

(f) Identification of controlled substances.

Each individual pharmacist involved in dispensing drugs must review this information at the end of each day and then must 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 him/her and is correct as shown.

(J) In addition to the immediate retrieval and production of patient profile information required by paragraph (G) of this rule, a pharmacy that utilizes a computerized record keeping system must be able to:

(1) Produce:

(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 user pharmacy is responsible for maintaining pursuant to all federal and state laws, rules and regulations; and

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

(2) Provide, within three working days of a request by an individual authorized by law to access such records, any requested:

(a) Printout; or

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

(K) In the event that the computerized record keeping system experiences down time, a record of all refills dispensed during such time must be recorded on the back of the original prescription. The refill information must be entered into the computerized record keeping system as soon as it is available for use. During the time the computerized record keeping system is not available, prescriptions may be refilled only if, in the professional judgment of the pharmacist, the number of refills authorized by the prescriber has not been exceeded.

(L) A pharmacy purging a computerized record keeping system of prescription records must develop a method of record keeping capable of providing retrieval (via digital display, hard copy printout, or other mutually agreeable transfer medium) within three working days, excluding holidays and weekends, of prescription order information for all prescriptions filled or refilled within the previous three years. This information shall include, at a minimum, the following data:

(1) Pharmacy name and address;

(2) Original prescription number;

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

(4) Date of original dispensing by the pharmacist;

(5) Full name and address of the patient;

(6) Full name and address of the prescriber;

(7) Directions for use;

(8) Name, strength, dosage form, and quantity of the drug prescribed;

(9) Quantity dispensed if different from the quantity prescribed;

(10) Total number of refills authorized by the prescriber;

(11) Total number of refills dispensed to date for that prescription order;

(12) Date of each refill;

(13) Name or initials of each individual dispensing pharmacist.

(M) A log must be maintained of all changes made to a prescription record after the prescription has been dispensed. Such log may be accessible to the pharmacist for review, but shall be protected from being altered in any way. The log must contain at least, but is not limited to, the following:

(1) Date and time of change;

(2) Changes made;

(3) Pharmacist making the change.

(N) Prescriptions entered into a computer system but not dispensed must meet all of the following conditions:

(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, in the computer system or on the hard copy prescription, of the pharmacist who is responsible for entering the prescription information into the system; and

(4) The original prescription is filed according to rule 4729-5-09 of the Administrative Code.

(O) Records shall be maintained for three years on all immunizations administered pursuant to section 4729.41 of the Revised Code and rule 4729-5-38 of the Administrative Code and must include at least the following information:

(1) Full name and address of the patient;

(2) Patients date of birth or age;

(3) Patients gender;

(4) Patients applicable allergy information;

(5) Date of administration;

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

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

(8) Route of administration;

(9) Location of the injection site;

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

(11) Positive identification of the patient, parent, or legal guardian of the patient who gives informed consent to administer an immunization.

(P) A pharmacist or pharmacy intern under the direct supervision of a pharmacist who administers an immunization pursuant to section 4729.41 of the Revised Code and rule 4729-5-38 of the Administrative Code shall maintain and immediately make available, upon the request of the state board of pharmacy, the following records:

(1) Documentation of the successful completion of a board approved course in the administration of immunizations;

(2) Documentation of current certification to perform basic life support procedures pursuant to division (B)(2) of section 4729.41 of the Revised Code.