

## **201 KAR 2:171. Computerized recordkeeping.**

RELATES TO: KRS 217.215, 217.216, 315.191

STATUTORY AUTHORITY: KRS 217.215(2), 315.191(1), (a), (f)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 217.215(2) authorizes the board to establish administrative regulations relating to the storage and retrieval of prescription records in licensed pharmacies, including administrative regulations regarding computerized recordkeeping. This administrative regulation provides standards for licensed pharmacies using computerized recordkeeping.

Section 1. The following information shall be entered into the system:

- (1) All information pertinent to a prescription shall be entered into the system, including items such as each of the following:
  - (a) The prescription number;
  - (b) The patient's name and address;
  - (c) The prescriber's name and address;
  - (d) The prescriber's Federal Drug Enforcement Administration number, if appropriate;
  - (e) Refill authorization;
  - (f) Any prescriber's instructions or patient's preference permitted by KRS Chapters 217, 218A, and 315, or 201 KAR Chapter 2;
  - (g) The name, strength, dosage form, and quantity of the drug dispensed originally and upon each refill; and
  - (h) The date of dispensing of the prescription and the identifying designation of the dispensing pharmacist for the original filling and each refill.
- (2) The entries shall be made into the system when the prescription is first filled and upon each refill, except that the format of the record may be organized so that the data already entered may appear for the prescription or refill without reentering that data. Records that are received or sent electronically may be kept electronically. The dispensing pharmacist shall ensure the completeness and accuracy of the entries.
- (3)
  - (a) The original prescription and a record of each refill, if received written or oral, shall be preserved as a hard copy for a period of three (3) years and thereafter be preserved as a hard copy or electronically for no less than an additional two (2) years.
  - (b) The original prescription and a record of each refill, if received by facsimile, shall be preserved as a hard copy, the original electronic image, or electronically for a period of three (3) years and thereafter be preserved as a hard copy, the original electronic image, or electronically for no less than an additional two (2) years.
  - (c) The original and electronic prescription shall be subject to inspection by authorized agents. An original and electronic prescription shall not be obstructed in any manner.
- (4) The original prescription and a record of each refill, if received as an e-prescription, shall be preserved electronically for a period of no less than five (5) years. The electronic prescription shall be subject to inspection by authorized agents. An original and electronic prescription shall not be obstructed in any manner.
- (5) The required information shall be entered into the system for all prescriptions filled at the pharmacy.
- (6) The system shall provide adequate safeguards against improper manipulation or alteration of the data.
- (7) The system shall have the capability of producing a hard-copy printout of all original and refilled prescription data as required in this section. A hard-copy printout of the required data shall be made available to an authorized agent within forty-eight (48) hours of the receipt of a written request.
- (8) The system shall maintain a record of each day's prescription data as follows:

(a) This record shall be verified, dated, and signed by the pharmacist or pharmacists who filled those prescription orders either:

1. Electronically;
2. Manually; or
3. In a log.

(b) This record shall be maintained for no less than five (5) years; and

(c) This record shall be readily retrievable and shall be subject to inspection by authorized agents.

(9) An auxiliary recordkeeping system shall be established for the documentation of refills if the automated data processing system is inoperative for any reason. The auxiliary system shall ensure that all refills are authorized by the original prescription order and that the maximum number of refills is not exceeded. If the automated data processing system is restored to operation, the information regarding prescriptions filled and refilled during the inoperative period shall be entered into the automated data processing system within seventy-two (72) hours.

(10) Controlled substance data shall be identifiable apart from other items appearing in the record.

(11) The pharmacist shall assure continuity in the maintenance of records throughout any transition in computerized record systems utilized.

Section 2. A computer malfunction or data processing service provider's negligence shall not be a defense against charges of improper recordkeeping.

Section 3. This administrative regulation is not applicable to the recordkeeping for drugs prescribed for and administered to patients confined as inpatients in an acute care facility. (47 Ky.R.2179, 48 Ky.R. 23; eff. 7-21-2021.)