

BOARDS AND COMMISSIONS
Board of Pharmacy
(New Administrative Regulation)

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) provides for the board to establish administrative regulations relating to the storage and retrieval of prescriptions records, including computerized recordkeeping. This administrative regulation provides standards for those 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, but not limited to, 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 law or administrative regulation;

(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 at the time the prescription is first filled and at the time of 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 be responsible for the completeness and accuracy of the entries.

(3) 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. 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 years. The original and electronic prescription shall be subject to inspection by authorized agents. An original 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 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 Section 1 of this administrative regulation. A hard-copy printout of the required data shall be made available to an authorized agent within forty-eight 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(s) 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 insure 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 be responsible to assure continuity in the maintenance of records throughout any transition in computerized record systems utilized.

Section 2. A computer malfunction or data processing services 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.

LARRY A. HADLEY, R.PH., Executive Director

APPROVED BY AGENCY: March 11, 2021

FILED WITH LRC: March 11, 2021 at 9:51 a.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall be held on May 25, 2021, at 9:00 a.m. Eastern Time at the Kentucky Board of Pharmacy, 125 Holmes Street, Suite 300, State Office Building Annex, Frankfort, Kentucky 40601. Individuals interested in being heard at this hearing shall notify this agency in writing by five workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who wishes to be heard will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted through May 31, 2021. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person.

CONTACT PERSON: Larry Hadley, Executive Director, Kentucky Board of Pharmacy, 125 Holmes Street, Suite 300, State Office Building Annex, Frankfort, Kentucky 40601, phone (502) 564-7910, fax (502) 696-3806, email Larry.Hadley@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact person: Larry Hadley

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes standards for computerized recordkeeping.

(b) The necessity of this administrative regulation: KRS 315.191(1)(a) requires the board to promulgate administrative regulations necessary to regulate and control the practice of pharmacy.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation establishes the standards in which pharmacies and those practicing pharmacy must adhere if they utilize computerized recordkeeping. KRS 315.191(1)(a) allows for the Board to promulgate administrative regulations necessary to regulate and control the practice of pharmacy.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation ensures that there are uniform standards of computerized recordkeeping across the Commonwealth to ensure that patients and patient information are safe.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: n/a

(b) The necessity of the amendment to this administrative regulation: n/a

(c) How the amendment conforms to the content of the authorizing statutes: n/a

(d) How the amendment will assist in the effective administration of the statutes: n/a

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: The board anticipates pharmacies, pharmacists, pharmacist interns and pharmacist technicians that are utilizing computerized recordkeeping to be impacted by this regulation.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: These are the same requirements that existed in 201 KAR 2:170 (expired). Pharmacists, technicians and interns will have to familiarize themselves with the language of the regulation.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There are no expected costs for the identities to comply with the amendment.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Pharmacies, pharmacists, technicians and interns can ensure that they are utilizing safe practices in regards to computerized recordkeeping.

(5) Provide an estimate of how much it will cost to implement this administrative Regulation:

(a) Initially: No costs will be incurred.

(b) On a continuing basis: No costs will be incurred.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: Board revenues from pre-existing fees provide the funding to enforce the regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to

implement this administrative regulation, if new, or by the change if it is an amendment: No increase in fees or funding will be required because of this new regulation.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This administrative regulation does not establish fees or directly or indirectly increase any fees.

(9) TIERING: Is tiering applied? Tiering is not applied because the regulation is applicable to all pharmacies and pharmacists equally.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Kentucky Board of Pharmacy will be impacted by this administrative regulation.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 315.191(1)(a).

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This administrative regulation will not generate revenue for the board in the first year.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation will not generate revenue for the board in subsequent years.

(c) How much will it cost to administer this program for the first year? No costs are required to administer this program for the first year.

(d) How much will it cost to administer this program for subsequent years? No costs are required to administer this program for subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation. N/A

Revenues (+/-): 0

Expenditures (+/-): 0

Other Explanation: