

## BOARDS AND COMMISSIONS

### Board of Pharmacy

#### (Amendment)

#### **201 KAR 2:185. Noncontrolled substance prescription drug refills.**

RELATES TO: KRS ~~[215.191(f), (g),]~~ 315.191(1)(f)

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

CERTIFICATION STATEMENT: This is to certify that this administrative regulation complies with the requirements of 2025 RS HB6, Section 8.

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.010, 315.191 and 217.215(2) require the Board of Pharmacy to promulgate administrative regulations necessary to regulate the practice of pharmacists and the recordkeeping systems associated with prescriptions. This administrative regulation establishes the responsibilities of pharmacists and practitioners relating to prescription drug refills.

#### Section 1.

~~[(1)]~~ A pharmacist shall not refill a prescription for a noncontrolled substance prescription drug unless authorized by the prescribing practitioner or permitted under the emergency pharmacy powers granted pursuant to KRS 315.500.

~~[(2)] [A pharmacist shall record all refills by writing the date of the refill together with his name or initials on the original prescription.]~~

~~[(3)] [If an alternate approved automated data processing system is used, refills and records shall be maintained in compliance with 201 KAR 2:170.]~~

#### Section 2.

(1) The use of the terms "prn" and "ad lib" in relation to authorization for refilling prescriptions shall mean the prescription may be refilled for a maximum period of one (1) year from the date prescribed.

(2) After one (1) year from the date prescribed, ~~a[the]~~ prescribing practitioner shall issue a new prescription.

Section 3. If the authorized refills are expressed solely as a number, the prescription shall be refilled for the authorized limit of refills within one (1) year of the date prescribed.

Section 4. Violation of a provision of this administrative regulation shall constitute unethical or unprofessional conduct in accordance with KRS 315.121(2)(d), (f), (g).

*CHRISTOPHER HARLOW, PharmD, Executive Director*

APPROVED BY AGENCY: December 4, 2025

FILED WITH LRC: December 12, 2025 at 10:45 a.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall be held on February 27, 2026, at 9:00 a.m. EST via a Zoom teleconference. 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 was received by that date, the hearing may be cancelled. 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 February 28, 2026. 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: Christopher Harlow, 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 [Christopher.harlow@ky.gov](mailto:Christopher.harlow@ky.gov).

## REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

**Contact Person:** Christopher Harlow

**Subject Headings:** Pharmacy; Drugs and Medicines; Public Health

**(1) Provide a brief summary of:**

**(a) What this administrative regulation does:**

This administrative regulation governs refills of noncontrolled prescription drugs and requires that a pharmacist obtain authorization from the prescribing practitioner before refilling and limits automatic refills to one year from the date prescribed.

**(b) The necessity of this administrative regulation:**

This regulation is necessary to establish clear, enforceable standards governing prescription refills, ensuring that refills occur only with valid prescriber authorization, are properly documented, and are limited to an appropriate timeframe to safeguard patient health and comply with statutory requirements.

**(c) How this administrative regulation conforms to the content of the authorizing statutes:**

KRS 315.191(1) empowers the Board to promulgate administrative regulations to regulate and control all matters relating to the practice of pharmacy, including prescription dispensing standards and recordkeeping. Because 201 KAR 2:185 defines the conditions under which pharmacists may refill noncontrolled prescriptions and sets documentation requirements, it falls squarely within the statutory mandate to ensure safe and lawful pharmacy practice.

**(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes:**

The regulation assists in the effective administration of the statutes by providing clear, uniform rules for when and how prescriptions may be refilled, enabling the Board to evaluate compliance consistently and ensuring pharmacists dispense medications in accordance with statutory safety requirements.

**(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:**

The amendment clarifies the conditions under which a pharmacist may refill a noncontrolled prescription by explicitly recognizing refill authority during declared emergencies in accordance with KRS 315.500.

**(b) The necessity of the amendment to this administrative regulation:**

The regulation language did not include the emergency powers that have been codified since the regulation was last updated.

**(c) How the amendment conforms to the content of the authorizing statutes:**

The amendment clarifies existing statutory authority that did not exist at the time the regulation was drafted originally.

**(d) How the amendment will assist in the effective administration of the statutes:**

The amendment will further promote, preserve, and protect public health through effective regulation of pharmacists and pharmacies by providing the most accurate and up to date information regarding when a pharmacist may refill a noncontrolled substance prescription.

**(3) Does this administrative regulation or amendment implement legislation from the previous five years? No.**

**(4) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation:**

The board anticipates no one will be affected by the administrative regulation amendment as it is just an update but reflects existing practices.

**(5) Provide an analysis of how the entities identified in question (4) 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 (4) will have to take to comply with this administrative regulation or amendment:**

Pharmacies and pharmacists will have to familiarize themselves with new amended language in the regulation. However, there has been no significant changes.

**(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (4):**

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 (4):**

Compliance will give pharmacists definitive, legally supported guidance for dispensing noncontrolled refills during declared emergencies, enabling uninterrupted patient access to essential medications while ensuring adherence to statutory requirements and promoting public health. (6) Provide an estimate of how much it will cost to implement this administrative regulation:

**(6) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:**

**(a) Initially:**

No costs will be incurred.

**(b) On a continuing basis:**

No costs will be incurred.

**(7) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation or this amendment:**

Board revenues from pre-existing fees provide the funding to enforce the regulation.

**(8) 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.

**(9) 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.

**(10) TIERING: Is tiering applied?**

Tiering is not applied because the regulation is applicable to all pharmacists and pharmacies.

## **FISCAL IMPACT STATEMENT**

**(1) Identify each state statute, federal statute, or federal regulation that requires or authorizes the action taken by the administrative regulation:**

KRS 315.191(1) empowers the Board to promulgate administrative regulations to regulate and control all matters relating to the practice of pharmacy, including prescription dispensing standards and recordkeeping. Because 201 KAR 2:185 defines the conditions under which pharmacists may refill noncontrolled prescriptions and sets documentation requirements, it falls squarely within the statutory mandate to ensure safe and lawful pharmacy practice.

**(2) State whether this administrative regulation is expressly authorized by an act of the General Assembly, and if so, identify the act:**

Yes, KRS 315.500.

**(3)(a) Identify the promulgating agency and any other affected state units, parts, or divisions:**

The Kentucky Board of Pharmacy will be impacted by this administrative regulation.

**(b) Estimate the following for each affected state unit, part, or division identified in (3)(a):**

**1. Expenditures:**

**For the first year:\$0**

**For subsequent years:\$0**

**2. Revenues:**

**For the first year:\$0**

**For subsequent years:\$0**

**3. Cost Savings:**

**For the first year:\$0**

**For subsequent years:\$0**

**(4)(a) Identify affected local entities (for example: cities, counties, fire departments, school districts):**

Only the Kentucky Board of Pharmacy will be impacted by this administrative regulation.

**(b) Estimate the following for each affected local entity identified in (4)(a):**

**1. Expenditures:**

**For the first year:\$0**

**For subsequent years:\$0**

**2. Revenues:**

**For the first year:\$0**

**For subsequent years:\$0**

**3. Cost Savings:**

**For the first year:\$0**

**For subsequent years:\$0**

**(5)(a) Identify any affected regulated entities not listed in (3)(a) or (4)(a):**  
None.

**(b) Estimate the following for each regulated entity identified in (5)(a):**

**1. Expenditures:**

**For the first year:\$0**

**For subsequent years:\$0**

**2. Revenues:**

**For the first year:\$0**

**For subsequent years:\$0**

**3. Cost Savings:**

**For the first year:\$0**

**For subsequent years:\$0**

**(6) Provide a narrative to explain the following for each entity identified in (3)(a), (4)(a), and (5)(a)**

**(a) Fiscal impact of this administrative regulation:**

The regulation does not cost anything for regulated parties to implement nor does it have a cost to the Board to oversee.

**(b) Methodology and resources used to reach this conclusion:**

None.

**(7) Explain, as it relates to the entities identified in (3)(a), (4)(a), and (5)(a):**

**(a) Whether this administrative regulation will have a "major economic impact", as defined by KRS 13A.010(14):**

No, this administrative regulation does not have an overall negative or adverse major economic impact to regulated entities, or those entities identified in questions (2)-(4).

**(b) The methodology and resources used to reach this conclusion:**

Analysis of the Board's expenditures as well as an assessment regarding cost of compliance for regulated entities.