BOARDS AND COMMISSIONS

Board of Pharmacy

(Amendment)

201 KAR 2:340. Special limited pharmacy permit - clinical practice.

RELATES TO: KRS 315.010(9), 315.020, 315.035, 315.191(1)(a)

STATUTORY AUTHORITY: KRS 315.035, 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.035 authorizes the Board of Pharmacy issue a permit to a pharmacy. KRS 315.191(1)(a) authorizes the Board of Pharmacy to promulgate administrative regulations with minimum requirements for the permitting of those entities that provide non-dispensing pharmacy services. This administrative regulation establishes the requirements for the Special limited pharmacy permit - Clinical practice.

Section 1. Definitions.

(1) "Special limited pharmacy permit" means a permit issued to a pharmacy that provides miscellaneous specialized pharmacy service and functions.

(2) "Special limited pharmacy permit - clinical practice" means a permit issued to a pharmacy that maintains patient records and other information for the purpose of engaging in the practice of pharmacy and does not dispense prescription drug orders.

Section 2. General Requirements.

(1) An applicant for a special limited pharmacy permit - clinical practice shall:

(a) Prepare and adopt a policy and procedure manual that is updated annually;

(b) Maintain pharmacy references as outlined in 201 KAR 2:090;

(c) Maintain a physical pharmacy address;

(d) Designate a Pharmacist-in-Charge (PIC) without a required minimum number of hours of physical presence;

(e) Maintain patient records for five (5) years in a manner that shall provide adequate safeguard against improper manipulation or alteration of the records; a computer malfunction or data processing services' negligence is not a defense against the charges of improper recordkeeping; and

(f) Maintain patient records by establishing:

1. A patient record system to be maintained for patients for whom non-dispensing pharmacy services and functions are being performed;

2. A procedure for obtaining, recording, and maintaining information required for a patient record by a pharmacist, pharmacist intern, or pharmacy technician; and

3. A procedure for a patient record to be readily retrievable by manual or electronic means.

(2) An applicant for a special limited pharmacy permit - clinical practice shall be exempt from the following:

(a) Prescription equipment requirements of 201 KAR 2:090, Section 1;

(b) Pharmacy sanitation requirements of 201 KAR 2:180; and

(c) Security and control of drugs and prescriptions requirements of 201 KAR 2:100, Sections 1, 2, 3, and 4.

Section 3. Pharmacy Closure. The permit holder shall provide notification to the board fifteen (15) days prior to permanent pharmacy closure.

Section 4. License Fees; Renewals. An applicant shall submit:

(1) An initial or renewal application for a special limited pharmacy permit - clinical practice on either the Application for Special Limited Pharmacy Permit - Clinical

Practice or the Application for Special Limited Pharmacy Permit - Clinical Practice Renewal; and

(2) As appropriate, the:

(a) Initial application fee established by 201 KAR 2:050, Section 1(9); or

(b) Renewal application fee established by 201 KAR 2:050, Section 1(10).

Section 5. Incorporation by Reference.

(1) The following material is incorporated by reference:

(a) "Application for Special Limited Pharmacy Permit - Clinical Practice", June 2023~~[May 2019]~~;~~[and]~~

(b) "Application for Special Limited Pharmacy Permit - Clinical Practice Renewal", June 2023;~~[May 2019.]~~

(c) "Nonresident Application for Special Limited Pharmacy Permit – Clinical Practice", June 2023; and

(d) "Nonresident Application for Special Limited Pharmacy Permit – Clinical Practice Renewal", June 2023.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky 40601, Monday through Friday, 8:00 a.m. to 4:30 p.m. This material is also available on the board's Web site at https://pharmacy.ky.gov/Businesses/Pages/Pharmacy.aspx.

CHRISTOPHER HARLOW, Pharm.D., Executive Director

APPROVED BY AGENCY: June 7, 2023

FILED WITH LRC: June 7, 2023 at 1:45 p.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall be held on August 30, 2023, at 10:00 a.m. Eastern Time via 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 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 August 31, 2023. 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.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person:Christopher Harlow

(1) Provide a brief summary of:

(a) What this administrative regulation does:
This regulation creates rules for pharmacies that do not possess prescription drugs and that only offer clinical services.

(b) The necessity of this administrative regulation:
KRS 315.191(1)(a) authorizes the Board of Pharmacy to promulgate administrative regulations to control the transfer of prescription drug orders between pharmacists and pharmacies. This administrative regulation establishes consistent with the requirements of KRS 315.191(1)(a) minimum requirements for the permitting of those entities that only perform clinical functions.

(c) How this administrative regulation conforms to the content of the authorizing statutes:
This administrative regulation establishes consistent with the requirements of KRS 315.191(1)(a) minimum requirements for the permitting of those entities that only perform clinical functions.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes:
This regulation allows for a separate regulatory regime for entities that don't possess prescription drugs and that only offer clinical services.

(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 only amendment is to the forms.

(b) The necessity of the amendment to this administrative regulation:
The criteria needed to be updated.

(c) How the amendment conforms to the content of the authorizing statutes:
KRS 315.002 and 315.005 authorize the board to regulate the practice of pharmacy. KRS 315.191 authorizes the board to promulgate administrative regulations pertaining to pharmacists and pharmacies. KRS 315.191(1)(a) directs the Board of Pharmacy to promulgate administrative regulations regarding reference material and equipment suitable for pharmaceutical practice.

(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. The form has been updated with the fee increase of twenty-five (25) dollars and this amendment reflects that in the forms.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation:
The board anticipates pharmacies and pharmacists will be affected minimally by this regulation amendment.

(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:

Pharmacies and pharmacists will have to familiarize themselves with amended language. The board will help to educate pharmacists and pharmacies in these changes.

(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):

This administrative regulation establishes consistent with the requirements of KRS 315.191(1)(a) minimum requirements for the permitting of those entities that perform clinical pharmacy functions only.

(5) 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.

(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 amendment. The fee increase is contained in 201 KAR 2:050.

(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 that desire to offer only clinical services.

FISCAL NOTE

(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. The cost of the permitting of this program is contained in 201 KAR 2:050.

(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.

Revenues (+/-):0

Expenditures (+/-):0

Other Explanation:

The cost of managing the permit issuance is $150 per permit. This fee increase is contained in 201 KAR 2:050.

(4) Estimate the effect of this administrative regulation on the expenditures and cost savings of regulated entities for the first full year the administrative regulation is to be in effect.

(a) How much cost savings will this administrative regulation generate for the regulated entities for the first year?

None

(b) How much cost savings will this administrative regulation generate for the regulated entities for subsequent years?

None.

(c) How much will it cost the regulated entities for the first year?

$150 annually.

(d) How much will it cost the regulated entities for subsequent years?
$150 annually.

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

Cost Savings (+/-):0

Expenditures (+/-):$150

Other Explanation:

(5) Explain whether this administrative regulation will have a major economic impact, as defined below.
"Major economic impact" means an overall negative or adverse economic impact from an administrative regulation of five hundred thousand dollars ($500,000) or more on state or local government or regulated entities, in aggregate, as determined by the promulgating administrative bodies. [KRS 13A.010(13)] This regulation does not have major economic impact.