

BOARDS AND COMMISSIONS

Board of Pharmacy

(Amendment)

201 KAR 2:240. Special limited pharmacy permit – Charitable.

RELATES TO: KRS 315.035

STATUTORY AUTHORITY: KRS 315.020, 315.030, 315.035, 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) authorizes the board to promulgate administrative regulations to prescribe the criteria for obtaining a pharmacy permit to dispense legend drugs and the procedures for the safe dispensing of legend drugs to citizens of the Commonwealth. This administrative regulation identifies the manner and procedure by which a charitable organization may obtain a pharmacy permit and dispense legend drugs in the Commonwealth.

Section 1. Definitions.

- (1) "Charitable organization" means an organization qualified as a charitable organization pursuant to Section 501(c)(3) of the Internal Revenue Code.
- (2) "Legend drug sample" means an unopened package of a manufacturer's legend drug product that has been distributed to either a practitioner or the charitable pharmacy in accordance with the provisions of the Prescription Drug Marketing Act of 1987.
- (3) "Qualified indigent patient" means a patient of the charitable pharmacy that has been screened and approved by the charitable organization as meeting the organization's mission of providing pharmaceutical care to those who are without sufficient funds to obtain needed legend drugs.
- (4) "Special limited pharmacy permit" means a permit issued to a pharmacy that provides specialized pharmacy services, such as dispensing legend drugs, and counseling patients.

Section 2.

- (1) A charitable pharmacy:
 - (a) Shall comply with all pharmacy permit requirements except those specifically exempted by the board pursuant to paragraph (b) of this subsection; and
 - (b) May petition the board in writing to be exempted from those pharmacy permit requirements that do not pertain to the operation of that charitable pharmacy.
- (2) The charitable pharmacy only shall dispense prescription legend drug samples or prescription legend drugs to qualified indigent patients of the pharmacy.
- (3) The charitable pharmacy shall not charge any fee for the dispensing of prescription legend drug samples or prescription legend drugs to qualified indigent patients of the pharmacy.
- (4) A charitable pharmacy may accept prescription legend drugs in their unbroken original packaging from pharmacies, wholesalers, or manufacturers, provided appropriate records of receipt and dispensing are maintained.
- (5) A charitable pharmacy shall not:
 - (a) Accept controlled substances from pharmacies, wholesalers, or manufacturers; or
 - (b) Dispense controlled substances.
- (6) A pharmacy that requests a special limited pharmacy permit - charitable shall submit to the board for prior approval, a plan describing the method by which the charitable pharmacy and the pharmacy shall maintain a separate and distinct prescription drug stock. The failure of either pharmacy to follow the plan shall result in revocation of the special limited pharmacy permit - charitable and the pharmacy permit.

Section 3. License Fees; Renewals. An applicant shall submit:

- (1) An initial or renewal application for a special limited pharmacy permit - charitable pharmacy on either the Application for Special Limited Pharmacy Permit – Charitable Pharmacy or the Application for Special Limited Pharmacy Permit – Charitable Pharmacy Renewal; and
- (2) As appropriate, the:
 - (a) Initial application fee established by 201 KAR 2:050, Section 1(8); or
 - (b) Renewal fee established by 201 KAR 2:050, Section 1(9) and (10).

Section 4. Incorporation By Reference.

- (1) The following material is incorporated by reference:
 - (a) "Application for Special Limited Pharmacy Permit – Charitable Pharmacy", June 2023~~[May 2020]~~~~;~~ ~~and~~
 - (b) "Application for Special Limited Pharmacy Permit – Charitable Pharmacy Renewal", June 2023~~[May 2020]~~.
 - (c) "Application for Non-Resident Special Limited Pharmacy Permit – Charitable Pharmacy", June 2023; and
 - (d) "Application for Non-Resident Special Limited Pharmacy Permit—Charitable Pharmacy", June 2023.
- (2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, 125 Holmes Street, Suite 300, Frankfort, Kentucky 40601, Monday through Friday, 8 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 administrative regulation identifies the manner and procedure by which a charitable organization can be permitted to obtain a pharmacy permit and dispense legend drugs in the Commonwealth.

(b) The necessity of this administrative regulation:

KRS 315.020, 315.030, and 315.191(1)(a) requires the board to promulgate administrative regulations to prescribe the criteria for obtaining a pharmacy permit to dispense legend drugs and the procedures for the safe dispensing of legend drugs to citizens of the Commonwealth. This administrative regulation identifies the manner and procedure by which a charitable organization can be permitted to obtain a pharmacy permit and dispense legend drugs in the Commonwealth.

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

This administrative regulation identifies the manner and procedure by which a charitable organization can be permitted to obtain a pharmacy permit and dispense legend drugs in the Commonwealth

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

This administrative regulation identifies the manner and procedure by which a charitable organization can be permitted to obtain a pharmacy permit and dispense legend drugs in the Commonwealth

(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:

This amendment is only to the applications.

(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 315.020 and 315.030 authorize the board to regulate the practice of pharmacy. KRS 315.191 authorizes the board to promulgate administrative regulations pertaining to pharmacists and pharmacies.

(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.

(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 permitted entities to comply with the amendment.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3):

The ability to function as a permitted pharmacy. (5) Provide an estimate of how much it will cost to implement this administrative Regulation:

(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 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 charitable pharmacies equally.

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?

The costs to operate this program are built into the board's operating costs.

(d) How much will it cost to administer this program for subsequent years?

The costs to operate this program are built into the board's operating costs.

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:

(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:

This is the cost of the permit to operate.

(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.