

Final 11-23-2020

SUGGESTED SUBSTITUTE

BOARDS AND COMMISSIONS Board of Pharmacy

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 ~~315.020, 315.030, and~~ 315.191(1)(a) ~~authorizes/requires~~ ~~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~~ ~~can be permitted to~~ ~~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)~~ ~~(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)~~ ~~(3)~~ ~~(4)~~ "Special limited pharmacy permit" means a permit issued to a pharmacy that provides ~~miscellaneous~~ specialized pharmacy ~~services, such as dispensing legend drugs, and counseling patients~~ ~~service~~ ~~and functions~~.

Section 2. (1) A charitable pharmacy: ~~(a)~~ ~~(a)~~ Shall comply with all pharmacy permit requirements except those specifically exempted by the board pursuant to paragraph (b) of this subsection; and

~~(b)~~ ~~(a)~~ ~~(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~~ ~~will~~ 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 ~~3.2.3~~ 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 ~~Section 1(9)~~ 201 KAR 2:050, ~~Section 1(8)~~, ~~Section 1(9)~~; or

(b) Renewal fee established by ~~Section 1(10-11)~~ 201 KAR 2:050, ~~Section 1(9) and (10)~~, ~~Section 1(10) and (11)~~.

Section ~~4.3.4~~ Incorporation By Reference. (1) The following material is incorporated by reference:

(a) ~~Effective January 1, 2020~~ “Application for Special Limited Pharmacy Permit – Charitable Pharmacy”, ~~May 2020~~, ~~May 2019~~; and

(b) ~~Effective January 1, 2020~~ “Application for Special Limited Pharmacy Permit – Charitable Pharmacy Renewal”, ~~May 2020~~, ~~May 2019~~.

(2) This ~~material~~~~form~~ may be ~~inspected, copied, or~~ obtained, ~~subject to applicable copyright law~~, ~~inspected, or copied~~ at the Kentucky Board of Pharmacy, 125 Holmes Street, Suite 300, Frankfort, Kentucky 40601, ~~8 a.m. to 4:30 p.m.~~ Monday through Friday, ~~8 a.m. to 4:30 p.m.~~

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.

MATERIAL INCORPORATED BY REFERENCE

The agency needs to file at the time that it files this staff suggested amendment one (1) clean copy of the “Application for Special Limited Pharmacy Permit-Charitable Pharmacy Renewal” that includes the following changes:

- Includes May 2020 Edition date
- Includes fees updated to \$125 for permit renewal and references delinquent renewal penalty of \$100