

Final, 9-27-2023

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 315.191(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, **26 U.S.C. 501(c)(3)**.
- (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, **21 C.F.R. Part 203**.
- (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;

- (a) 1. Application for **Resident** Special Limited Pharmacy Permit – Charitable Pharmacy; or
2.[the] Application for **Resident** Special Limited Pharmacy Permit – Charitable Pharmacy Renewal;
or
(b) 1. Application for Non-Resident Special Limited Pharmacy Permit – Charitable Pharmacy;
or
2. Application for Non-Resident 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 **Resident** Special Limited Pharmacy Permit – Charitable Pharmacy", June 2023[May 2020];[-and]
 - (b) "Application for **Resident** Special Limited Pharmacy Permit – Charitable Pharmacy Renewal", June 2023[May 2020].
 - (c) "Application for Non-Resident Special Limited Pharmacy Permit – Charitable Pharmacy", September[June] 2023; and
 - (d) "Application for Non-Resident Special Limited Pharmacy Permit—Charitable Pharmacy **Renewal**", September[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>.

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MATERIAL INCORPORATED BY REFERENCE

At the time that the agency files this staff amendment it needs to file one (1) clean copy of the following:

- "Application for Non-Resident Special Limited Pharmacy Permit – Charitable Pharmacy"
- "Application for Non-Resident Special Limited Pharmacy Permit—Charitable Pharmacy Renewal"
 - Each Form includes updated edition date of September 2023
 - Clarifies the Ownership Section Question on Kentucky Secretary of State Registration by adding a not applicable check box for those non-resident pharmacy permit holders not registered with the Kentucky Secretary of State