

Final, 9-27-2023

SUGGESTED SUBSTITUTE

**BOARDS AND COMMISSIONS
Board of Pharmacy**

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) 1. Maintain patient records for five (5) years in a manner that shall provide adequate ~~safeguards~~[safeguard] against improper manipulation or alteration of the records; and 2. Abide by the standard that 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:
(a)1. Application for Special Limited Pharmacy Permit - Clinical Practice; or

2.[the] Application for Special Limited Pharmacy Permit - Clinical Practice Renewal; or
(b)1. Non-Resident Application for Special Limited Pharmacy Permit – Clinical Practice; or
2. Non-Resident 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) "~~Non-Resident~~~~[Nonresident]~~ Application for Special Limited Pharmacy Permit – Clinical Practice", ~~September~~~~[June]~~ 2023; and
- (d) "~~Non-Resident~~~~[Nonresident]~~ Application for Special Limited Pharmacy Permit – Clinical Practice Renewal", ~~September~~~~[June]~~ 2023.

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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:

- **“Non-Resident Application for Special Limited Pharmacy Permit – Clinical Practice”**
- **“Non-Resident Application for Special Limited Pharmacy Permit – Clinical Practice 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**