

BOARDS AND COMMISSIONS

Board of Pharmacy

(Amendment)

201 KAR 2:225. Special limited pharmacy permit – Medical gas.

RELATES TO: KRS 217.015(11), 315.010(9), 315.020, 315.035, 315.191(1)(a)

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

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) authorizes the board to promulgate administrative regulations to regulate and control all matters set forth in KRS Chapter 315 relating to 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 distribute medical gases.

Section 1. Definitions.

(1) "Medical gases" means gases (including liquefied gases) classified by FDA as drugs or devices that are used for medical applications and which may be stored and administered through the use of Medical Gas Related Equipment, which may or may not be required under Federal or State law for the immediate container to bear the label, "Rx only" or "Caution: Federal or State law prohibits dispensing without a prescription.

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

Section 2. General Requirements.

(1)

(a) An applicant for a special limited pharmacy permit for medical gases shall comply with the requirements of 201 KAR 2:180, except Section 5 and 201 KAR 2:205, except that the pharmacist-in-charge designated on the special permit shall be exempt from the requirements of 201 KAR 2:205, Section 2(2).

(b) The pharmacist-in-charge shall review the records and do an onsite visit of the special limited pharmacy permit application for medical gases not less than once each quarter.

(2) An applicant for a special limited pharmacy permit for medical gases shall prepare and adopt a policy and procedures manual that sets forth a detailed description of how the:

(a) Operation will comply with applicable federal, state, or local laws or administrative regulations; and

(b) Licensee will maintain the premises so that the medical gas remains secure and complies with applicable compendial monographs of official pharmacopoeias.

(3) An applicant for a special limited pharmacy permit for medical gas shall be inspected by the board prior to the issuance of the license.

Section 3. Qualifications for License.

(1) The board shall consider the following in reviewing the qualifications of an applicant for a special limited pharmacy permit for medical gases:

(a) The applicant's experience in the sale or distribution of prescription drugs, including controlled substances;

(b) A felony conviction of the applicant under federal, state, or local laws;

(c) The furnishing by the applicant of false or fraudulent material in a previous application for:

1. A special limited pharmacy permit for medical gases; or

2. A federal or state medical assistance program;

- (d) Suspension or revocation of an applicant's license or permit by federal, state, or local government; and
- (e) Compliance with requirements under a previously granted license or permit.
- (2) The board shall deny an application for a special limited pharmacy permit for medical gases, if an applicant has:
 - (a) Been convicted for a violation of federal, state, or local laws relating to:
 - 1. The practice of pharmacy;
 - 2. Drugs; or
 - 3. Federal or state medical assistance programs.
 - (b) Furnished false or fraudulent material in the application for a special limited pharmacy permit for medical gases;
 - (c) Failed to maintain or make available required records to the:
 - 1. Board; or
 - 2. Federal, state, or local law enforcement officials;
 - (d) Failed to comply with applicable federal, state, and local laws and regulations relating to medical gas; or
 - (e) Failed to provide appropriate land, buildings, and security necessary to properly carry on the business described in his application.

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

- (1) An initial or renewal application for a special limited pharmacy permit medical gases on either the "Application for Special Limited Pharmacy Permit Medical Gas or the "Application for Special Limited Pharmacy Permit – Medical Gas 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).

Section 5. Incorporation by Reference.

- (1) The following material is incorporated by reference:
 - (a) "Application for Special Limited Pharmacy Permit – Medical Gas", March 2022; and
 - (b) "Application for Special Limited Pharmacy Permit – Medical Gas Renewal", March 2022.
- (2) This form may be obtained, inspected, or copied, at the Kentucky Board of Pharmacy, 125 Holmes Street Suite 300, Frankfort, Kentucky 40601-8204, 8 a.m. to 4:30 p.m., Monday through Friday.

CHRISTOPHER HARLOW, Pharm.D., Executive Director

APPROVED BY AGENCY: April 4, 2022

FILED WITH LRC: April 5, 2022 at 8:30 a.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall be held on June 22, 2022, at 9:00 a.m. Eastern Time via zoom teleconference with the physical location being at the Kentucky Board of Pharmacy, 125 Holmes Street, Suite 300, State Office Building Annex, Frankfort, Kentucky 40601. 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 June 30, 2022. 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.