

## 201 KAR 2:225. Special pharmacy permit.

RELATES TO: KRS 217.015(5)(a), 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: 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 gasses.

Section 1. Definitions. (1) "Special pharmacy permits" means a permit issued to a pharmacy that provides miscellaneous specialized pharmacy service and functions.

(2) "Medical gasses" means oxygen United States Pharmacopoeia and nitrous oxide.

Section 2. General Requirements. (1)(a) An applicant for a special pharmacy permit for medical gasses shall comply with the requirements of 201 KAR 2:180 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 of the special pharmacy permit for medical gasses not less than once each quarter.

(2) An applicant for a special pharmacy permit for medical gasses 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 gasses remain secure and comply with applicable compendial monographs of official pharmacopoeias specified by KRS 217.015(5)(a).

(3) An applicant for a special pharmacy permit for medical gasses 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 permit for medicinal gasses:

(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 permit for medical gasses; 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 permit for medical gasses, 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 permit for medical gasses;

(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 medicinal gasses; 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 permit for medicinal gasses on "Application for Permit to Operate A Pharmacy In Kentucky"; and

(2) As appropriate, the:

(a) Initial application fee established by Section 1(10), 201 KAR 2:050; or

(b) Renewal fee established by Section 1(11), 201 KAR 2:050.

Section 5. Incorporation by Reference. (1) "Application for Permit to Operate A Pharmacy In Kentucky (11/92)" is incorporated by reference.

(2) This form may be obtained, inspected, or copied at the Kentucky Board of Pharmacy, 1024 Capital Center Drive, Suite 210, Frankfort, Kentucky 40601-8204, 8 a.m. to 4:30 p.m., Monday through Friday. (23 Ky.R. 4021; Am. 24 Ky.R. 329; eff. 7-16-97.)