

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 permit" 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 ~~applicant~~ 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~~~~gases~~ 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 for 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", ~~June 2023~~~~[March 2022]~~; and
 - (b) "Application for Special Limited Pharmacy Permit – Medical Gas Renewal", ~~June 2023~~~~[March 2022]~~.
- (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 40601-8204, 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>~~[https://pharmacy.ky.gov/Forms/Pages/default.aspx]~~.

CHRISTOPHER HARLOW, Pharm.D., Executive Director

APPROVED BY AGENCY: June 7, 2023

FILED WITH LRC: June 7, 2023 at 1:45 p.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall be held on August 30, 2023, at 10:00 a.m. Eastern Time via zoom teleconference. 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 August 31, 2023. 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.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person: Christopher Harlow

(1) Provide a brief summary of:

(a) What this administrative regulation does:

This administrative regulation establishes the requirements for the special limited pharmacy permit for medical gas.

(b) The necessity of this administrative regulation:

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 medical gas.

(c) How this administrative regulation conforms to the content of the authorizing statutes:

This administrative regulation establishes the requirements for the special limited pharmacy permit medical gas.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes:

This administrative regulation establishes criteria for a permit for medical gas since the regulation of medical gas is different from other prescription drugs.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation:

This amendment only changes the forms incorporated by reference due to a proposed fee change in 201 KAR 2:050.

(b) The necessity of the amendment to this administrative regulation:

The forms needed to be congruent with 201 KAR 2:050.

(c) How the amendment conforms to the content of the authorizing statutes:

KRS 315.191(1)(a) authorizes the board to promulgate administrative regulations pertaining to pharmacists and pharmacies.

(d) How the amendment will assist in the effective administration of the statutes:

The amendment will further promote, preserve, and protect public health through effective regulation of pharmacists and pharmacies by ensuring the forms comply with the provisions in the law.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation:

The board anticipates pharmacies and pharmacists will be affected minimally by this regulation amendment.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment:

Pharmacies and pharmacists will have to familiarize themselves with amended language. The board will help to educate pharmacists and pharmacies in these changes.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3):

The only fee is for the application for the permit and renewal of the permit. This includes a proposed \$150 fee.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3):

Quicker turn-around of applications and questions of the board. (5) Provide an estimate of how much it will cost to implement this administrative Regulation:

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially:

No costs will be incurred.

(b) On a continuing basis:

No costs will be incurred.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation:

Board revenues from pre-existing fees provide the funding to enforce the regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment:

This regulation does not directly increase fees but 201 KAR 2:050 does increase the fee by fifty-dollars.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees:

This administrative regulation does not establish fees directly but 201 KAR 2:050 does increase the fee by \$25.

(9) TIERING: Is tiering applied?

Tiering is not applied because the regulation is applicable to all special limited medical gas permit holders.

FISCAL NOTE

(1) What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation?

The Kentucky Board of Pharmacy will be impacted by this administrative regulation.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation.

KRS 315.191(1)(a).

(3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year?

This administrative regulation will not generate revenue for the board in the first year.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years?

This administrative regulation will not generate revenue for the board in subsequent years.

(c) How much will it cost to administer this program for the first year?

It costs roughly \$35,000 to administer this program.

(d) How much will it cost to administer this program for subsequent years?

Unless we acquire more permit holders, the costs will remain the same.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):+35,400

Expenditures (+/-):-35,400

Other Explanation:

(4) Estimate the effect of this administrative regulation on the expenditures and cost savings of regulated entities for the first full year the administrative regulation is to be in effect.

(a) How much cost savings will this administrative regulation generate for the regulated entities for the first year?

None

(b) How much cost savings will this administrative regulation generate for the regulated entities for subsequent years?

None

(c) How much will it cost the regulated entities for the first year?

\$150 annually.

(d) How much will it cost the regulated entities for subsequent years?

\$150 annually.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Cost Savings (+/-):0

Expenditures (+/-):-150

Other Explanation:

(5) Explain whether this administrative regulation will have a major economic impact, as defined below.

"Major economic impact" means an overall negative or adverse economic impact from an administrative regulation of five hundred thousand dollars (\$500,000) or more on state or local government or regulated entities, in aggregate, as determined by the promulgating administrative bodies. [KRS 13A.010(13)] This regulation does not have major economic impact.