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LEGISLATIVE RESEARCH COMMISSION

State Capitol 700 Capital Avenue Frankfort KY 40601

502-564-8100

Capitol Fax 502-564-2922

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Chad McCoy
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Angie Hatton
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MEMORANDUM

TO: Christopher Harlow, Executive Director, Kentucky Board of Pharmacy

FROM: Emily Caudill, Regulations Compiler

RE: Proposed Amendment or New Regulation – 201 KAR 002:015, 201 KAR 002:020, 201 KAR 050 & 201 KAR 002:225

DATE: April 4, 2022

A copy of each administrative regulation listed above is enclosed for your files. These regulations are tentatively scheduled for review by the Administrative Regulation Review Subcommittee at its **July 2022** meeting. We will notify you of the date and time of this meeting once it has been scheduled.

Pursuant to KRS 13A.280, **if** comments are received during the public comment period, a Statement of Consideration or a one-month extension request for these regulations is due **by noon on July 15, 2022**. Please reference KRS 13A.270 and 13A.280 for other requirements relating to the public hearing and public comment period and Statements of Consideration.

If you have questions, please contact us at RegsCompiler@LRC.ky.gov or (502) 564-8100.

Enclosures

FILED WITH LRC
TIME: *8:30 am*
APR - 5 2022
Emily B Caudill
REGULATIONS COMPILER

1 GENERAL GOVERNMENT CABINET
2 Kentucky Board of Pharmacy
3 (Amendment)
4 201 KAR 2:225. Special limited pharmacy permit – Medical gas.
5 RELATES TO: KRS 217.015(11), 315.010(9), 315.020, 315.035, 315.191(1)(a)
6 STATUTORY AUTHORITY: KRS 315.020, 315.035, 315.191(1)(a)
7 NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) authorizes the
8 board to promulgate administrative regulations to regulate and control all matters set
9 forth in KRS Chapter 315 relating to pharmacists and pharmacies. This
10 administrative regulation establishes, consistent with the requirements of KRS
11 315.191(1)(a), minimum requirements for the permitting of those entities that
12 distribute medical gases.
13 Section 1. Definitions. (1) "Medical gases means gases (including liquefied gases)
14 classified by FDA as drugs or devices that are used for medical applications and
15 which may be stored and administered through the use of Medical Gas Related
16 Equipment, which may or may not be required under Federal or State law for the
17 immediate container to bear the label, "Rx only" or "Caution: Federal or State law
18 prohibits dispensing without a prescription.
19 (2) "Special limited pharmacy permits" means a permit issued to a pharmacy that
20 provides miscellaneous specialized pharmacy service and functions.

1 Section 2. General Requirements. (1)(a) An applicant for a special limited
2 pharmacy permit for medical gases shall comply with the requirements of 201 KAR
3 2:180, except Section 5 and 201 KAR 2:205, except that the pharmacist-in-charge
4 designated on the special permit shall be exempt from the requirements of 201
5 KAR 2:205, Section 2(2).

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

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

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

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

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

18 Section 3. Qualifications for License. (1) The board shall consider the following in
19 reviewing the qualifications of an applicant for a special limited pharmacy permit for
20 medical gases:

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

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

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

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

1 (1.) An initial or renewal application for a special limited pharmacy permit medical
2 gases on either the “Application for Special Limited Pharmacy Permit Medical
3 Gas or the “Application for Special Limited Pharmacy Permit – Medical Gas
4 Renewal”; and

5 (2.) As appropriate, the:

6 (a.) Initial application fee established by 201 KAR 2:050, Section 1(8); or

7 (b.) Renewal fee established by 201 KAR 2:050, Section 1(9).

8 Section 5. Incorporation by Reference. (1) The following material is incorporated by
9 reference:

10 (a.) “Application for Special Limited Pharmacy Permit – Medical Gas”, March 2022
11 ~~May 2020~~ and

12 (b.) “Application for Special Limited Pharmacy Permit – Medical Gas Renewal”,
13 March 2022 ~~May 2020~~.

14 (2) This form may be obtained, inspected, or copied at the Kentucky Board of
15 Pharmacy, 125 Holmes Street Suite 300, Frankfort, Kentucky 40601-8204, 8
16 a.m. to 4:30 p.m., Monday through Friday.



Christopher P. Harlow, Pharm.D.
Executive Director
Kentucky Board of Pharmacy

April 4, 2022

Date

PUBLIC HEARING AND PUBLIC 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.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

201 KAR 2:225. Special limited pharmacy permit-medical gas.
Contact person: Christopher Harlow, Phone 502-564-7910, email
christopher.harlow@ky.gov

(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: Changes the terms utilized on the form from “consultant pharmacist” to “pharmacist in charge” to properly reference the regulation. Moreover, it removed the statement that out of state pharmacies do not need a pharmacist in charge since that is not reflected in the regulation.

(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 to remove “consultant pharmacist” and add “pharmacist in charge.” Moreover, it removed the statement that out of state pharmacies do not need a pharmacist in charge since that is not reflected in the regulation.

(b) The necessity of the amendment to this administrative regulation: The forms needed to be congruent with the regulation.

(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): There are no expected costs for the identities to comply with the amendment.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): This amendment will clarify previous statutory language.

(5) Provide an estimate of how much it will cost 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: No increase in fees or funding will be required because of this new regulation.

(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 or directly or indirectly increase any fees.

(9) TIERING: Is tiering applied? (Explain why tiering was or was not used)
Tiering is not applied because the regulation is applicable to all special limited medical gas permit holders.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Regulation No. 201 KAR 2:225. Special Limited Pharmacy Permit—medical gas.

Contact Person: Christopher Harlow, Phone 502-564-7910, email

Christopher.harlow@ky.gov

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? No costs are required to administer this program for the first year.

(d) How much will it cost to administer this program for subsequent years? No costs are required to administer this program for subsequent years.

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

Revenues (+/-): 0

Expenditures (+/-): 0

Other Explanation:

Summary of Material Incorporated by Reference

The “Application for Special Limited Pharmacy Permit – Medical Gas”, March 2022 form is to be utilized by applicants for an initial permit.

The “Application for Special Limited Pharmacy Permit – Medical Gas Renewal”, March 2022 form is to be utilized by applicants for annual permit renewal.

KENTUCKY BOARD OF PHARMACY
State Office Building Annex, Suite 300
125 Holmes Street
Frankfort KY 40601
Phone (502) 564-7910
Fax (502) 696-3806
e-mail: pharmacy.board@ky.gov
<http://pharmacy.ky.gov>

Application for Special Limited Pharmacy Permit - Medical Gas

Please print legibly. Make check or money order payable to 'Kentucky State Treasurer'. Mail to the above address. All applicable entries must be completed. Incomplete applications will be returned. Each permit expires June 30th following the date of issuance.

1. Name of Facility _____

Physical Address of Facility

(Street and Number)

City _____ County _____ State _____ Zip _____

Phone Number _____ Fax Number _____

Email Address _____

Mailing Address of Facility

(Street and Number)

City _____ State _____ Zip _____

Check and complete one of the following and attach proper fee:

New Facility \$125.00

Proposed date of Opening _____

(Filed with Board 30 days in advance of Opening) OR Current Permit No. _____ Expiration Date _____

(In State where presently located)

Change of Ownership \$75.00

Date of Proposed Acquisition _____

Name of Previous Owner(s) _____

(Confirmation statement of previous owner must be attached)

Change of Address/Location \$75.00

Date of Proposed Relocation _____

Previous Address _____

Name Change NO CHARGE

Previous Name _____

2. Ownership:

Sole Proprietor Partnership Unincorporated Business Incorporated Business

Name and title for each owner/officer, including professional designation (e.g. Pres. John Jones, PharmD)

3. Consultant Pharmacist in Charge:

Name

KY License No.

Kentucky Pharmacy Regulation 201 KAR 2:205 requires Consultant the Pharmacist in charge to notify the Board within fourteen (14) calendar days of all pharmacist personnel changes.

~~Pharmacist Consultants are not required for non-resident medicinal gas permits.~~

4. Schedule of Hours:

Monday . . . _____ AM to _____ PM

Friday . . . _____ AM to _____ PM

Tuesday . . . _____ AM to _____ PM

Saturday . . . _____ AM to _____ PM

Wednesday . . . _____ AM to _____ PM

Sunday . . . _____ AM to _____ PM

Thursday . . . _____ AM to _____ PM

~~Consultant~~The Pharmacist in charge must notify the Board within fourteen (14) days of any changes in scheduled hours.

The Board may refuse to issue or renew a permit, or suspend, temporarily suspend, revoke, fine or reasonably restrict any permit holder for knowingly making or causing to be made, any false, fraudulent or forged statement in connection with an application for a permit. KRS 315.121

I hereby certify that the foregoing is true and correct to the best of my knowledge, that I have read and understand Kentucky Revised Statutes Chapters 217, 218A, and 315 and the regulations of the Kentucky Board of Pharmacy and the Cabinet for Health and Family Services pertaining to the practice of pharmacy and certify that this pharmacy will be conducted in full compliance with all federal and state laws, and that the facility is currently licensed and in good standing in all states of licensure.

(Original Signature of Owner)

(Original Signature of Consultant Pharmacist in Charge)

(Date)

(Date)

KENTUCKY BOARD OF PHARMACY
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Application for Special Limited Pharmacy Permit - Medical Gas

Please print legibly. Make check or money order payable to 'Kentucky State Treasurer'. Mail to the above address. All applicable entries must be completed. Incomplete applications will be returned. Each permit expires June 30th following the date of issuance.

2. Name of Facility _____

Physical Address of Facility

(Street and Number)

City _____ County _____ State _____ Zip _____

Phone Number _____ Fax Number _____

Email Address _____

Mailing Address of Facility

(Street and Number)

City _____ State _____ Zip _____

Check and complete one of the following and attach proper fee:

New Facility \$125.00

Proposed date of Opening _____

(Filed with Board 30 days in advance of Opening) OR Current Permit No. _____ Expiration Date _____

(In State where presently located)

Change of Ownership \$75.00

Date of Proposed Acquisition _____

Name of Previous Owner(s) _____

(Confirmation statement of previous owner must be attached)

Change of Address/Location \$75.00

Date of Proposed Relocation _____

Previous Address _____

Name Change NO CHARGE

Previous Name _____

2. Ownership:

Sole Proprietor Partnership Unincorporated Business Incorporated Business

Name and title for each owner/officer, including professional designation (e.g. Pres. John Jones, PharmD)

3. Pharmacist in Charge:

Name

KY License No.

Kentucky Pharmacy Regulation 201 KAR 2:205 requires the Pharmacist in charge to notify the Board within fourteen (14) calendar days of all pharmacist personnel changes.

4. Schedule of Hours:

Monday . . . _____ AM to _____ PM

Friday . . . _____ AM to _____ PM

Tuesday . . . _____ AM to _____ PM

Saturday . . . _____ AM to _____ PM

Wednesday . . . _____ AM to _____ PM

Sunday . . . _____ AM to _____ PM

Thursday . . . _____ AM to _____ PM

The Pharmacist in charge must notify the Board within fourteen (14) days of any changes in scheduled hours.

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I hereby certify that the foregoing is true and correct to the best of my knowledge, that I have read and understand Kentucky Revised Statutes Chapters 217, 218A, and 315 and the regulations of the Kentucky Board of Pharmacy and the Cabinet for Health and Family Services pertaining to the practice of pharmacy and certify that this pharmacy will be conducted in full compliance with all federal and state laws, and that the facility is currently licensed and in good standing in all states of licensure.

(Original Signature of Owner)

(Original Signature of Pharmacist in Charge)

(Date)

(Date)

Kentucky Permit Number
MG _____

DON'T FORGET!



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APPLICATION FOR SPECIAL LIMITED PHARMACY PERMIT - MEDICAL GAS RENEWAL

Enclose a check or money order for \$125.00, made payable to 'Kentucky State Treasurer'. Please print legibly and complete this application; including the required original signature and return to the Board office no later than June 30th. All renewals received after June 30th will be assessed a delinquent fee of \$100.00 pursuant to 201 KAR 2:050, Section 1(11).

Facility Name _____ Permit No. _____

Address _____

Email Address _____

Telephone No. _____ Fax No. _____

INCOMPLETE OR UNSIGNED APPLICATIONS WILL BE RETURNED.

OWNERSHIP:

____ Sole Proprietor ____ Partnership ____ Corporation ____ LLC ____ Other

Name and title for each owner/officer, including professional designation:

CONSULTANT PHARMACIST IN CHARGE*:

Name _____

KY License No. _____

***Consultant Pharmacists are not required for non-resident medicinal gas permits.**

Kentucky Pharmacy Regulation 201 KAR 2:205 requires Consultant a Pharmacist in charge to notify the Board within fourteen (14) calendar days of all pharmacist personnel changes.

SCHEDULE OF STORE HOURS:

Consultant Pharmacist in charge must notify the Board within fourteen (14) days of any changes in scheduled hours.

Monday _____ to _____ Thursday _____ to _____
Tuesday _____ to _____ Friday _____ to _____
Wednesday _____ to _____ Saturday _____ to _____
Sunday _____ to _____

Have you had a Pharmacy license/permit surrendered to or fined, suspended, probated, or revoked by any Board of Pharmacy which you have not previously reported to this Board? _____ Yes, attach an explanation _____ No

The Board may refuse to issue or renew a permit, or suspend, temporarily suspend, revoke, fine or reasonably restrict any permit holder for knowingly making or causing to be made, any false, fraudulent or forged statement in connection with an application for a permit. KRS 315.121.

I hereby certify that the foregoing is true and correct to the best of my knowledge and that I have read and understand Kentucky Revised Statutes Chapters 217, 218A, and 315 and the Regulations of the Kentucky Board of Pharmacy and the Cabinet for Health and Family Services pertaining to the practice of pharmacy and certify that this pharmacy will be conducted in full compliance with all federal and state laws. [If applicable, this pharmacy is currently licensed and in good standing in all states of licensure].

Kentucky Permit Number
MG _____

DON'T FORGET!



KENTUCKY BOARD OF PHARMACY
State Office Building Annex, Suite 300
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Facility Name _____ Permit No. _____

Address _____

Email Address _____

Telephone No. _____ Fax No. _____

INCOMPLETE OR UNSIGNED APPLICATIONS WILL BE RETURNED.

OWNERSHIP:

____ Sole Proprietor ____ Partnership ____ Corporation ____ LLC ____ Other

Name and title for each owner/officer, including professional designation:

PHARMACIST IN CHARGE:

Name _____

KY License No. _____

Kentucky Pharmacy Regulation 201 KAR 2:205 requires a Pharmacist in charge to notify the Board within fourteen (14) calendar days of all pharmacist personnel changes.

SCHEDULE OF STORE HOURS:

Pharmacist in charge must notify the Board within fourteen (14) days of any changes in scheduled hours.

Monday _____ to _____ Thursday . . . _____ to _____

Tuesday . . . _____ to _____ Friday _____ to _____

Wednesday _____ to _____ Saturday . . _____ to _____

Sunday _____ to _____

Have you had a Pharmacy license/permit surrendered to or fined, suspended, probated, or revoked by any Board of Pharmacy which you have not previously reported to this Board? _____ **Yes, attach an explanation** _____ **No**

The Board may refuse to issue or renew a permit, or suspend, temporarily suspend, revoke, fine or reasonably restrict any permit holder for knowingly making or causing to be made, any false, fraudulent or forged statement in connection with an application for a permit. KRS 315.121.
I hereby certify that the foregoing is true and correct to the best of my knowledge and that I have read and understand Kentucky Revised Statutes Chapters 217, 218A, and 315 and the Regulations of the Kentucky Board of Pharmacy and the Cabinet for Health and Family Services pertaining to the practice of pharmacy and certify that this pharmacy will be conducted in full compliance with all federal and state laws. [If applicable, this pharmacy is currently licensed and in good standing in all states of licensure].

