GENERAL GOVERNMENT CABINET

Kentucky Board of Pharmacy

(Amendment)

201 KAR 2:380. Board authorized protocols.

RELATES TO: KRS 315.010(25), 315.191(1)(a), (f)

STATUTORY AUTHORITY: KRS 315.010(25), 315.191(1)(a), (f)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.010(25) defines a prescription drug order, which includes orders issued through protocols authorized by the board. KRS 315.191(1)(a) authorizes the board to promulgate administrative regulations necessary to regulate and control all matters pertaining to pharmacists, pharmacist interns, pharmacy technicians, and pharmacies. KRS 315.191(1)(f) authorizes the board to promulgate administrative regulations that are necessary to control the dispensing of prescription drug orders. This administrative regulation establishes procedures for board authorized protocols by which pharmacists may initiate the dispensing of noncontrolled medications or other professional services.

Section 1. Definition. "Prescriber" means any individual authorized to prescribe a legend drug.

Section 2. Procedures. A pharmacist may initiate the dispensing of noncontrolled medications, over-the-counter medications, or other professional services under the following conditions:

(1) A prescriber-approved protocol that meets the minimum requirements in Section 3 of this administrative regulation is in place, and is dated and signed by the prescriber and pharmacist authorized to initiate the dispensing of noncontrolled medications, over-the-counter medications, or other professional services;

(2) The protocol directs the care, based on current clinical guidelines, for conditions listed in Section 5 of this administrative regulation;

(3) The protocol has been approved by the board, who provides notice to the prescriber's licensure board within ten (10) business days of approval by the board;

(4) The pharmacist documents the dispensing event in the pharmacy management system, including:

(a) Documentation as required by 201 KAR 2:170 for the dispensing of prescription medication; and

(b) Documentation that the individual receiving the medication or other professional service was provided with education pursuant to Section 4 of this administrative regulation; and

(5) A pharmacist shall request the individual's primary care provider's information, provided one exists, and shall provide notification to the primary care provider within two (2) business days.

Section 3. Minimum Requirements of Protocol. Protocols shall contain the following elements:

(1) Criteria for identifying persons eligible to receive medication therapies or other professional services under the protocol, and referral to an appropriate prescriber if the patient is high-risk or treatment is contraindicated;

(2) A list of the medications, including name, dose, route, frequency of administration, and refills authorized to be dispensed under the protocol;

(3) Procedures for how the medications are to be initiated and monitored, including a care plan implemented in accordance with clinical guidelines;

(4) Education to be provided to the person receiving the dispensed medications, including aftercare instructions, if appropriate;

(5) Procedures for documenting in the pharmacy management system all medications dispensed, including notification of the prescriber signing the protocol, if requested;

(6) Length of time protocol is in effect;

(7) Date and signature of prescriber approving the protocol;

(8) Dates and signatures of pharmacists authorized to initiate dispensing of medications or other professional services under the protocol; and

(9) The date, and education or training of the pharmacist as referenced in Section 4 of this administrative regulation.

Section 4. Pharmacist Education and Training Required. A pharmacist who dispenses medication pursuant to a prescriber-approved protocol shall first receive education and training in the subject matter of the protocol from a provider accredited by the Accreditation Council for Pharmacy Education or by a comparable provider approved by the board. Documentation of education shall be provided to the board upon request. Education shall be obtained prior to initiating care under the protocol.

Section 5. Authorized Conditions. Board-authorized protocols may be established for the following conditions:

(1) Acute influenza ~~infection pursuant to recommendations by the Centers for Disease Control and Prevention (CDC)~~;

(2) Acute streptococcal pharyngitis infection;

(3) Acute, uncomplicated urinary tract infection;

(4) Acute cutaneous/mucocutaneous fungal infection;

(5) Alcohol use disorder [pursuant to recommendations by the American Society of Addiction Medicine];

(6[~~5~~]) Allergic rhinitis;

(7[~~6~~]) Anaphylaxis;

(8) Colorectal cancer prevention and screening;

(9) HCV infection screening

(10) HIV infection prophylaxis, pre- and post-exposure;

(11) HIV infection screening [~~HIV infection prevention through pre-exposure prophylaxis pursuant to recommendations by the CDC~~];

(12[~~8~~]) Nutritional supplementation with vitamins and minerals;

(13[~~9~~]) Opioid use disorder pursuant to recommendations by the American Society of Addiction Medicine;

(14[~~10~~]) Tobacco use disorder;

(15[~~11~~]) Traveler's health pursuant to recommendations by the CDC;

(16[~~12~~]) Tuberculosis prevention and control through skin testing, and referral as necessary, pursuant to recommendations by the CDC; and

(17[~~13~~]) Self-care conditions appropriately treated with over-the-counter medications and products.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD

A public hearing on this administrative regulation shall be held on February 23, 2021 at 9:00 a.m. Eastern Time 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 February 28, 2021. 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: Larry Hadley, 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 Larry.Hadley@ky.gov.

December 11, 2020

Larry A. Hadley, R.Ph.
Executive Director
Kentucky Board of Pharmacy

Date

1

REGULATORY IMPACT ANALYSIS
AND TIERING STATEMENT

201 KAR 2:380.
Contact person: Larry Hadley
Contact Phone No.: 502-564-7910
Contact email: larry.hadley@ky.gov

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes procedures for board authorized protocols by which pharmacists may initiate the dispensing of noncontrolled medications or offer other professional services.

(b)The necessity of this administrative regulation: This administrative regulation is necessary for pharmacists to provide a high level of care to their patients, in accordance with protocols that have been provided from the prescriber and approved by the Board of Pharmacy. This will expand the scope of board authorized conditions which allow for prescriber approved protocols to include protocols for alcohol use disorder, colorectal cancer prevention and screening, HCV infection screening, HIV infection prophylaxis, pre and post exposure and HIV infection screening.

(c) How this administrative regulation conforms to the content of the authorizing statues: KRS 315.191(1)(a) authorizes the Board of Pharmacy to promulgate administrative regulations to regulate and control all matters pertaining to pharmacists and pharmacies. KRS 315.191(1)(f) authorizes the Board to promulgate administrative regulations pertaining to prescription drug orders. KRS 315.010(25) defines a prescription drug order to include protocols authorized by the Board. This administrative regulation establishes criteria for protocols to be authorized by the Board.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: Prescribers, pharmacists, pharmacies, patients and the public will be able to ascertain what is required for pharmacist dispensing of medications pursuant to prescriber approved protocols.

(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 will expand the scope of board-authorized conditions allowing prescriber approved protocols to include protocols for alcohol use disorder, colorectal cancer prevention and screening, HCV infection screening, HIV infection prophylaxis, pre and post exposure and HIV infection screening.

(b) The necessity of the amendment to this administrative regulation: To allow pharmacists to play a more critical clinical role in public health by expanding the scope to include four more authorized conditions for prescriber-approved protocols.

(c) How the amendment conforms to the content of the authorizing statutes: KRS 315.002 and 315.005 authorize the board to regulate the practice of pharmacy. KRS 315.191 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 providing an increased board approved conditions for potential prescriber approved protocols to include alcohol use disorder, colorectal cancer prevention and screening, HCV infection screening, HIV infection prophylaxis, pre and post exposure and HIV infection screening .

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: The board anticipates pharmacists will be impacted, as their potential scope of practice could be increased. Individuals that wish to be treated for alcohol use disorder will have the ability to be treated in a pharmacy. Individuals wishing to be screened for colorectal cancer, HCV infection or HIV infection can now do so in a pharmacy, pursuant to prescriber approved protocol. Moreover, individuals wishing to obtain pre and post HIV infection prophylaxis can do so in a pharmacy that has a prescriber-approved protocol.

(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 new amended language in the regulation. 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): Pharmacists and the public can refer to the correct information for accreditation questions.

(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 pharmacists.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Regulation No. 201 KAR 2:380. Board authorized protocols.
Contact Person: Larry Hadley
Contact Phone No.: 502-564-7910
Contact email: larry.hadley@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(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: