STATEMENT OF EMERGENCY
201 KAR 2:380E.

The Department for Medicaid Services has requested the Board of Pharmacy promulgate this emergency regulation to ensure Medicaid patients have access to Paxlovid, the COVID-19 therapeutic drug, from pharmacies without a prescription drug order. Currently there is no mechanism for Kentucky Medicaid to compensate pharmacists for their prescribing services, despite the PREP Act, 85 Fed. Reg. 51160, allowing for pharmacists to prescribe and administer COVID-19 therapeutics. Without this emergency amendment, Medicaid patients cannot access Paxlovid from a pharmacist without a prescription drug order issued by another prescriber since the Department for Medicaid Services does not recognize pharmacists as providers. This emergency amendment will allow for a prescriber approved protocol to be reviewed for approval by the Board of Pharmacy. Once approved, the physician Director of Medicaid Services can sign a prescriber approved protocol for any pharmacist to initiate the dispensing of Paxlovid for Medicaid patients. An ordinary amendment is not a sufficient way to address this issue since COVID-19 case numbers are rising, and Medicaid patients are in need of Paxlovid now. This emergency amendment provides the Board with discretion to respond to public health emergencies rapidly without the need to go through the rulemaking process to add a specific condition to the protocol. An amendment to the current regulation is being simultaneously filed and will replace the emergency regulation. The emergency amendment is identical to the ordinary amendment.

ANDY BESHEAR, Governor
CHRISTOPHER HARLOW, Executive Director

BOARDS AND COMMISSIONS

Board of Pharmacy

(Emergency Amendment)

201 KAR 2:380E. 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 or pharmacists 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(s) authorized to initiate the dispensing of noncontrolled medications, over-the-counter medications, or other professional services. A pharmacist not party to the executed protocol has no authority to utilize the protocol for medication dispensing or other professional service provision;

(2) The protocol directs the care, based on current clinical guidelines, for acute self-limiting conditions and other minor ailments, preventative health services, and disease state monitoring and management as deemed appropriate by the board;

(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 or pharmacists documents the dispensing event in the pharmacy management system, including:

(a) Documentation as required by 201 KAR 2:171 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 3(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 the pharmacist(s) authorized to initiate dispensing of medications or other professional services under the protocol.

CHRISTOPHER HARLOW, Pharm.D., Executive Director

APPROVED BY AGENCY: August 8, 2022
FILED WITH LRC: August 8, 2022 at 2:30 p.m.
PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall be held on September 27, 2022 at 9:00 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 September 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.