

BOARDS AND COMMISSIONS

Board of Pharmacy

(Amended at ARRS Committee)

201 KAR 2:380. Board authorized protocols.

RELATES TO: KRS 315.010(25), 315.121(1)(a), 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. Definitions.

- (1) "Fully executed" means a protocol has been signed and dated by the prescriber and the pharmacist or pharmacists who are the party or parties to the protocol agreement as required by Section 3 of this administrative regulation.
- (2) "Prescriber" means any Kentucky licensed physician or advanced practice registered nurse practitioner.
- (3) "Protocol" means a written agreement between a pharmacist or pharmacists and a prescriber that outlines the plan to initiate the dispensing of noncontrolled medications, over-the-counter medications, or other professional services within the prescriber's statutory scope of practice.
- (4) "Protocol registry" means the records maintained by the board of any fully executed protocol that is being utilized to initiate the dispensing of noncontrolled medications, over-the-counter medications, or other professional services.

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

- (1) The protocol:
 - (a) Meets the minimum requirements in Section 3 of this administrative regulation;
 - (b) Directs the care, based on current clinical guidelines, for conditions listed in Section 5 of this administrative regulation;
 - (c) States the permit number of the Kentucky permitted pharmacy where the protocol will be utilized;
 - (d) Has been reviewed and authorized by the board prior to its execution; and
 - (e) Has been fully executed and submitted to the board for inclusion in the protocol registry, which shall be made available to the prescriber's licensing board upon request.
- (2) 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;
- (3) 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;

(4) Any pharmacist not party to the fully executed protocol shall not utilize the protocol;

(5) A pharmacist utilizing the protocol shall be employed by or contracted with the permit holder;

(6) A fully executed protocol shall not be used to initiate the dispensing of medications or to provide other professional services until it has been submitted to the board for inclusion in the protocol registry; and

(7) The pharmacist-in-charge shall be responsible for:

(a) Submitting the fully executed protocol to the board for inclusion into the registry; and

(b) Submitting a written notification to the board to remove a protocol from the registry no later than thirty (30) days after discontinuing a protocol.

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 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. A failure to be educated and trained before utilizing the prescriber-approved protocol may result in disciplinary action pursuant to KRS 315.121(1)(a).

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 or mucocutaneous fungal infection;

(5) Alcohol use disorder utilizing naltrexone-based therapy pursuant to recommendations from the American Psychiatric Association;

(6) Allergic rhinitis;

(7) Anaphylaxis;

- (8) Colorectal cancer prevention and screening;
- (9) HCV infection screening;
- (10) HIV infection prophylaxis, pre-exposure and post-exposure pursuant to recommendations by the CDC;
- (11) HIV infection screening pursuant to recommendations by the CDC;
- (12) Nutritional supplementation with vitamins and minerals;
- (13) Opioid use disorder pursuant to recommendations by the American Society of Addiction Medicine;
- (14) Tobacco use disorder;
- (15) Traveler's health pursuant to recommendations by the CDC;
- (16) Tuberculosis prevention and control through skin testing, and referral as necessary, pursuant to recommendations by the CDC;
- (17) Self-care conditions appropriately treated with over-the-counter medications and products; and
- (18) Covid-19 infection pursuant to recommendations by the CDC.

Section 6. Protocol Review Committee.

- (1) The board shall form a committee comprised of four (4) pharmacists and one (1) physician. This committee shall meet no less than quarterly to:
 - (a) Evaluate new protocols proposed for board approval to ensure compliance with Section 2(1)(b) and Section 3 of this administrative regulation; and
 - (b) Review previously authorized protocols no later than three (3) years from the authorization date to ensure alignment with current practice guidelines.
- (2) The protocol review committee may consult with an expert with relevant practice experience.
- (3) The pharmacists shall be appointed by the Board of Pharmacy and the physician by the Kentucky Board of Medical Licensure.
- (4) Terms for the pharmacist and physician members on the committee shall be for a term of four (4) years.
- (5) The chair of the committee shall be a pharmacist member.

(44 Ky.R. 447; 961; 1215; 1813 eff. 12-13-2017; 47 Ky.R. 1422, 2404, 2577; eff. 6-16-2021; 49 Ky.R. 625, 1451, 1755, 2078; eff. 6-21-2023.)

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