

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 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; and
- (17) Self-care conditions appropriately treated with over-the-counter medications and products.

(44 Ky.R. 447; 961; 1215; 1813 eff. 12-13-2017; 47 Ky.R. 1422, 2404, 2577; eff. 6-16-2021.)