803 KAR 25:270. Pharmaceutical formulary.

RELATES TO: KRS 342.0011(13), 342.020, 342.035.
STATUTORY AUTHORITY: 342.035, 342.260, 342.265, 342.270, 342.275.
CERTIFICATION STATEMENT:
NECESSITY, FUNCTION, AND CONFORMITY: KRS 342.260(1) requires the commissioner to promulgate administrative regulations necessary to carry on the work of the department and the work of administrative law judges so long as those administrative regulations are consistent with KRS Chapter 342 and KRS Chapter 13A. KRS 342.035 requires the commissioner to develop or adopt a pharmaceutical formulary and promulgate administrative regulations to implement the developed or adopted pharmaceutical formulary. This administrative regulation establishes the formulary and provides guidance to implement the adopted formulary.

Section 1. Definitions.

(1) "Carrier" or "Insurance Carrier" means any insurer authorized to insure the liability of employers arising under Chapter 342 of the Kentucky Revised Statutes, an employer authorized by the commissioner to pay directly the compensation provided in Chapter 342 of the Kentucky Revised Statutes as those liabilities are incurred, a self-insured group, and any person acting on behalf of or as an agent of the insurer, self-insured employer, or self-insured group.

(2) "Commissioner" means the commissioner charged in KRS 342.228 to administer the Department of Workers' Claims and whose duties are stated in KRS 342.230.

(3) "Compound" or "Compounding" means the process of combining, mixing, or altering ingredients to create a medication that is tailored to meet the needs of an individual patient.

(4) "Department" or "Department of Workers' Claims" means the governmental agency whose responsibilities are provided in KRS 342.228.

(5) "Dispense" means to deliver a drug to an ultimate user pursuant to the lawful order of a medical provider, including the packaging, labeling, or compounding necessary to prepare the drug for delivery.

(6) "Drug" means a substance recognized as a drug in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or any supplement to them, which is intended for use in the diagnosis, care, mitigation, treatment, or prevention of disease in man.

(7) "Employee" means those natural persons constituting an employee subject to the provisions of the Act as defined in KRS 342.640 and the employee's legal counsel.

(8) "Employer" means those persons constituting an employer as defined in KRS 342.630, the employer's insurance carrier, self-insured group or other payment obligor, third party administrator, other person acting on behalf of the employer in a workers' compensation matter, and the employer's legal counsel.

(9) "Formulary" or "Pharmaceutical Formulary" means the pharmaceutical formulary developed or adopted by the commissioner pursuant to KRS 342.035(8)(b).

(10) "Medical Provider" means a natural person who has prescriptive authority for drugs under the professional licensing laws of Kentucky, another state, or federal law, unless that person's license has been revoked, suspended, restricted, or probated.

(11) "N" or "N status" means the drug is a non-preferred drug.

(12) "Natural person" means a biological human being.

(13) "Non-prescription drug" or "over-the-counter-drug" means a drug that may be sold without a prescription.

(14) "Person" means an individual, corporation, government, governmental subdivision, agency, business, estate, trust, partnership, association, or any other legal entity.

(15) "Pharmacist" means a natural person lawfully licensed to engage in the practice of the profession of pharmacy.

(16) "Preauthorization" means the process whereby payment for a medical service or course of treatment is assured in advance by a carrier.

(17) "Prescription" or "prescribed" means a written, electronic, or oral order for a drug, signed, given, or authorized by a medical provider and intended for use in the diagnosis, care, mitigation, treatment, or prevention of disease in man.

(18) "Prescription Drug" means:

(a) A substance for which federal or state law requires a prescription before the substance may be legally dispensed to the public;

(b) A drug that under federal law is required, before being dispensed or delivered, to be labeled with the statement: "Caution: federal law prohibits dispensing without prescription"; "Rx only"; or another legend that complies with federal law; or

(c) A drug that is required by federal or state statute or regulation to be dispensed on prescription or that is restricted to use by a medical provider only.

(19) "Refill" means a prescription for the same drug, at the same dose or strength, in the same quantity and frequency, and with the same instructions as was initially prescribed.

(20) "Utilization Review" is defined by 803 KAR 25:190.

(21) "Y" or "Y status" means the drug is a preferred drug.

Section 2. Purpose and Adoption.

(1) The purpose of the formulary is to facilitate the safe and appropriate use of prescription drugs in the treatment of work-related injury and occupational disease.

(2) The commissioner adopts the current edition and any future published updates of the ODG formulary currently published by MCG Health. The commissioner shall review the formulary not less than annually and update or amend this administrative regulation, if necessary, to ensure that the formulary is consistent with the provisions of KRS 342.020 and 342.035.

(3) The formulary shall be made available by the department. Subsequent updates shall be effective on the first day of the month following the update.

(4) To the extent this administrative regulation or the formulary conflict with any state or federal statute or regulation limiting prescriptive authority, including KRS 218A.020(3), 218A.172, 314.011(8) and 201 KAR 9:260, the statute or administrative regulation limiting prescriptive authority shall apply.

Section 3. Application.

(1) An employer or its payment obligor is liable for payment of up to a seven (7)-day supply of a "Y" drug dispensed to or prescribed for an injured employee within seven (7) days of a work-related injury in treatment of that work-related injury even if the employer ultimately denies liability for the claim. Payment by the employer or its payment obligor pursuant to this subsection does not waive the employer's right to contest its liability for the claim or benefits to be provided.

(2) Unless the employer, in good faith, denies the claim as not compensable, drugs assigned "Y" status in the formulary on the date the prescription is issued shall be filled without the need for preauthorization and without delay if prescribed for and appropriate for the work injury or occupational disease. Utilization review shall not be required for a "Y" drug but may be conducted retrospectively to determine medical reasonableness and necessity. A denial of a "Y" drug based on retrospective utilization review shall apply only to refill prescriptions of that drug after the date of the utilization review.

(3) Unless the employer, in good faith, denies the claim as not compensable, drugs assigned "N" status in the formulary on the date the prescription is issued shall require preauthorization. A prescription for a drug with an "N" status issued without articulated sound medical reasoning does not constitute a request for preauthorization nor a request

for payment. Within two (2) business days of presentation of a prescription for a drug with an "N" status without articulated sound medical reasoning, the insurance carrier shall notify the medical provider and injured employee that preauthorization is required for the prescribed drug.

(4) Any prescription drug not listed in the formulary shall require preauthorization. Any non-prescription drug shall not require preauthorization.

(5) Compound medications require preauthorization even if all of the components of the compound are listed as "Y" drugs in the formulary.

(6) Medical providers are required to prescribe in accordance with the formulary unless the medical provider can sufficiently articulate sound medical reasoning for deviating from the formulary, which may include:

(a) Documentation that reasonable alternatives allowable in the formulary have been adequately trialed and failed;

(b) The clinical rationale that justifies the proposed treatment plan, including criteria that will constitute a clinically meaningful benefit; or

(c) Any other circumstances that reasonably preclude the approved formulary options.

(7) Before an employer denies authorization for a drug that requires preauthorization, the employer must consider any sound medical reasoning furnished by the medical provider for prescribing that drug.

Section 4. Preauthorization.

(1) Requests for preauthorization shall be subject to utilization review unless the employer waives utilization review.

(2) Except as modified in this section, 803 KAR 25:190 Sections 5, 7, and 8 apply to all prescriptions for which preauthorization is required under this administrative regulation. If the medical provider has provided sound medical reasoning for the prescription, the employer shall not deny a prescribed drug based solely on the status of the drug in the formulary.

(3) If as a result of utilization review the carrier denies a request for preauthorization, the medical provider may request reconsideration of the denial to include a peer-to-peer conference with a utilization review physician. The request for a peer-to-peer conference shall be made by electronic communication and shall provide:

(a) A telephone number for the reviewing physician to call;

(b) A date for the conference not less than two (2) business days after the date of the request; and

(c) A one (1) - hour period during which the requesting medical provider (or its designee) will be available to participate in the conference between the hours of 8:00 a.m. and 6:00 p.m. (Eastern Time), Monday through Friday.

(4) The peer-to-peer conference must be conducted by a physician of the same specialty as the medical provider requesting reconsideration.

(5) Failure of the reviewing physician to participate in the peer-to-peer conference during the date and time specified shall result in the approval of the request for preauthorization and approval of the requested prescription. Failure of the requesting medical provider or its designee to participate in the peer-to-peer conference during the time he or she specified availability may result in denial of the request for reconsideration.

(6) Pursuant to 803 KAR 25:190 Section 8(1)(c), a written reconsideration decision shall be rendered within ten (10) days of date of the peer-to-peer conference. The written decision shall be entitled "FINAL UTILIZATION REVIEW DECISION".

(7) If a Final Utilization Review Decision is rendered denying authorization for a prescribed drug before an award has been entered by or agreement approved by an administrative law judge, the requesting medical provider or the injured employee may file a medical dispute pursuant to 803 KAR 25:012. If a Final Utilization Review

Decision is rendered denying authorization for a prescribed drug after an award has been entered by or agreement approved by an administrative law judge, the employer shall file a medical dispute pursuant to 803 KAR 25:012.

(8) Pursuant to KRS 342.285(1), a decision of an administrative law judge on a medical dispute is subject to review by the workers' compensation board under the procedures set out in 803 KAR 25:010, Section 22.

Section 5. Effective Dates.

(1) For claims with a date of injury or last exposure on or after January 1, 2019, the formulary applies to all drugs that are prescribed or dispensed on or after July 1, 2019, for outpatient use.

(2) For claims with a date of injury or last exposure prior to January 1, 2019, the formulary applies as follows:

(a) For a prescription that is not a refill prescription, the formulary applies to all drugs prescribed or dispensed on or after July 1, 2019, for outpatient use;

(b) For a refill prescription of a drug initially prescribed prior to July 1, 2019, the formulary applies to all drugs prescribed or dispensed on or after January 1, 2020, for outpatient use.

(45 Ky.R. 2534, 2928; 46 Ky.R. 33; eff. 7-11-2019; Crt to Am 3-5-2026.)