LABOR CABINET

Department of Workers' Claims

(New Administrative Regulation)

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.

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 or 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 42 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/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, or governmental subdivision or 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 or 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, and in the same quantity and frequency, and with the same instructions as was initially prescribed.

(20) "Utilization Review" means utilization review as defined in 803 KAR 25:190 §1 (6).

(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 regulation, if necessary, to ensure that the formulary is consistent with the provisions of KRS 342.020 and KRS 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 regulation or the formulary conflict with any state or federal statute or regulation limiting prescriptive authority, including KRS 218A.172, KRS 218A.020(3), KRS 314.011(8) and 201 KAR 9:260, the statute or 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 that preauthorization is required for the prescribed drug.

(4) Except as provided in subsection (1) of this Section, drugs dispensed for outpatient use by any person other than a pharmacist require preauthorization.

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

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

(7) 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.

(8) 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 §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.

This is to certify that the commissioner has reviewed and recommended this administrative regulation prior to its adoption, as required by KRS 342.260 and 342.035.

Robert L. Swisher

Robert L. Swisher, Commissioner
Department of Workers' Claims

12/27/18

Date

PUBLIC HEARING AND PUBLIC COMMENT PERIOD

A public hearing on this administrative regulation shall be held on February 22, 2019, at 10:00 a.m. (EDT) at the offices of the Department of Workers' Claims, Prevention Park, 657 Chamberlin Avenue, Frankfort, Kentucky 40601. Individuals interested in being heard at this hearing shall notify this agency in writing of their intent to attend no later than five (5) workdays prior to the hearing. If no notification of intent to attend the hearing is received by that date, the hearing may be cancelled. 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, 2019. 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:

B. Dale Hamblin, Jr., Assistant General Counsel
Workers' Claims Legal Division
Prevention Park
657 Chamberlin Avenue
Frankfort, Kentucky 40601
Telephone Number: (502) 782-4404
Fax Number: (502) 564-0681
dale.hamblin@ky.gov

REGULATORY IMPACT ANALYSIS

AND TIERING STATEMENT

Administrative Regulation No.: 803 KAR 25:270

Contact person: B. Dale Hamblin, Jr.
dale.hamblin@ky.gov

Phone number: (502) 782-4404

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation adopts a pharmaceutical formulary for medications prescribed for the cure of and relief of a work injury or occupational disease and provides guidance for its implementation and use.

(b) The necessity of this administrative regulation: KRS 342.035(8) requires the commissioner to promulgate an administrative regulation to implement the pharmaceutical formulary.

(c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 342.035 requires the commissioner to adopt a pharmaceutical formulary for medications prescribed for the cure of and relief of a work injury or occupational disease and to promulgate an administrative regulation to implement that formulary.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: KRS 342.020 provides an employer is responsible to pay for the cure and relief from the effects of an injury or occupational disease as may reasonably be required at the time of injury and thereafter during disability or as may be required for the cure and treatment of an occupational disease. KRS 342.035 requires the commissioner to adopt a pharmaceutical formulary for medications prescribed for the cure of and relief of a work injury or occupational disease. This administrative regulation provides guidance to the employee and employer with respect to that pharmaceutical formulary.

(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: N/A

(b) The necessity of the amendment to this administrative regulation: N/A

(c) How the amendment conforms to the content of the authorizing statutes: N/A

(d) How the amendment will assist in the effective administration of the statutes: N/A

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: All injured employees, physicians and medical providers providing services to injured workers pursuant to KRS Chapter 342, insurance carriers, self-insurance groups, self-insured employers, insured employers, and third party administrators.

(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: Physicians and medical providers are required to use the pharmaceutical formulary adopted by the commissioner. Employers and their payment obligors will apply the pharmaceutical formulary when paying for treatment as required by KRS 342.020.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): The cost of completing the medical report cannot exceed $100. The cost to the payment obligors cannot be ascertained until treatment is sought and provided to the injured employee.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Injured employees are less likely to receive inappropriate prescription drugs and more likely to receive the appropriate prescription drugs in a more timely fashion. Employers may experience a long-term reduction in medical benefit costs.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: None

(b) On a continuing basis: The cost associated with this administrative regulation is the cost of maintaining the pharmaceutical formulary on the Cabinet's website.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The Department of Workers' Claims normal budget is the source of funding.

(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 is needed to implement this administrative regulation.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This administrative regulation does not establish or increase any fees.

(9) TIERING: Is tiering applied? (Explain why or why not) Tiering is not applied; the regulation applies to all parties equally.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Administrative Regulation No.: 803 KAR 25:270

Contact Person: B. Dale Hamblin, Jr.
dale.hamblin@ky.gov

Phone number: (502) 782-4404

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 Department of Workers' Claims and all agencies or departments of government with employees.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 342.020, 342.035, 342.260, 342.265, 342.275.

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. There should be no direct effect on expenditures.

(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? No revenue will be generated.

(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? No revenue will be generated.

(c) How much will it cost to administer this program for the first year? The cost of maintaining the pharmaceutical formulary on the Cabinet's website is nominal.

(d) How much will it cost to administer this program for subsequent years? Other than the cost to maintain the pharmaceutical formulary on the Cabinet's website, it does not appear there will be additional costs.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation: It is possible the application of the pharmaceutical formulary will cause drug costs to stabilize or reduce, providing a reduction of costs to the workers' compensation system as a whole.