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Jay D. Hartz
Director

MEMORANDUM

TO: Interim Joint Committee on Economic Development and Workforce Investment

FROM: Jay D. Hartz, LRC Director

SUBJECT: Administrative Regulations

DATE: July 3, 2019

At its June 11, 2019, meeting, the Administrative Regulation Review Subcommittee completed its review of the following administrative regulation: **803 KAR 025:270 & E.**

Pursuant to the provisions of KRS Chapter 13A, this regulation has been assigned to the Interim Joint Committee on Economic Development and Workforce Investment for review. Pursuant to KRS Chapter 13A, the committee has thirty (30) days from the date of this assignment to review this regulation.

The Subcommittee minutes will be delivered to your committee staff upon completion. The material considered by the Subcommittee in its review is attached to the appropriate administrative regulation.

Attachments

cc: Administrative Regulation Review Subcommittee
Carla Montgomery

LABOR CABINET

Department of Workers' Claims

(Amended After Comments)

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 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 that preauthorization is required for the prescribed drug.

(4) Except as provided in subsection (1) of this Section, **prescription** 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, 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.

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 — March 14, 2019

ROBERT L. SWISHER, Commissioner — Date

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Regulation #: 803 KAR 25:270
Contact person: B. Dale Hamblin, Jr.
Phone: (502) 782-4404
Email: dale.hamblin@ky.gov

(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 pro-

viders 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? Tiering is not applied; the regulation applies to all parties equally.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Regulation #: 803 KAR 25:270
Contact person: B. Dale Hamblin, Jr.
Phone: (502) 782-4404
Email: dale.hamblin@ky.gov

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.

STATEMENT OF CONSIDERATION
RELATING to 803 KAR 25:270

Labor Cabinet, Department of Workers' Claims
(Amended After Comments)

I.The public hearing on 803 KAR 25:270, scheduled for February 22, 2019, at 10:00 a.m., at the Department of Workers' Claims, 657 Chamberlin Avenue, Frankfort, Kentucky, was held by Commissioner Robert L. Swisher. Six (6) public comments were made at the hearing. Twenty-three (23) written comments were received during the public comment period.

II. The following persons were attendees or offered comment:

(a) Eric Lamb, Lamb & Lamb, PSC

(b) Adam Fowler, Senior Policy Analyst, Optum Workers' Comp and Auto No-Fault

(c) Ken Eichler, Vice President of Government Affairs, MCG Health and ODG

(d) Rosalie Faris, Occupational Managed Care Alliance

(e) Rosmond J. Dolen, Bingham Greenebaum Doll LLP, on behalf of Rx Development Associates, Inc.

(f) Lisa Anne Bickford, Director, Government Relations, Coventry

(g) Tim Wilson, Wilson & McQueen, PLLC, on behalf of the Kentucky Workers' Association

(h) Brian Allen, Vice President, Government Affairs, Mitchell International Pharmacy Solutions

(i) Julian Roberts, President, American Association of Payers Administrators and Networks (AAPAN)

(j) Danielle M. Jaffe, Esq., Injured Workers' Pharmacy (IWP)

(k) William R. Adams II, D.P.M., F.A.C.F.A.S., The Orthopaedic Institute of Western Kentucky

(l) Clint P. Hill, M.D., The Orthopaedic Institute of Western Kentucky

(m) K. Brandon Strenge, M.D., The Orthopaedic Institute of Western Kentucky

(n)Ryan Beck, M.D., The Orthopaedic Institute of Western Kentucky

(o)Shiraz Patel, M.D., The Orthopaedic Institute of Western Kentucky

(p)Spencer Romine, M.D., The Orthopaedic Institute of Western Kentucky

(q)Stephen Jackson, M.D., The Orthopaedic Institute of Western Kentucky

(r) Illegible, The Orthopaedic Institute of Western Kentucky

(s) Jennifer Bean, VP Government Affairs, Automated Healthcare Solutions

(t) Joseph A. Schwartz, III, Physicians Research Institute

(u)Sai Gutti, M.D., Pain Management Center

(v)Sujata Gutti, M.D.

(w) Sandy Shtab, AVP, Advocacy & Compliance, Healthesystems, LLC

(x)Kristie Griffin, myMatrixx, an Express Scripts Company. Workers' Compensation Regulatory Compliance

(y)David Price, Director of Government Affairs, Preferred Medical

(z)Dina Green, Claims Manager, Ladegast & Heffner Claims Service, Inc.

III. The following persons from the administrative body were present at the hearing or responded to comments:

(1)Robert L. Swisher, Commissioner, Department of Workers' Claims

(2)B. Dale Hamblin, Jr., Assistant General Counsel, Workers' Claims Legal Division

IV Summary of Comments and Responses

(1)SUBJECT MATTER: Notice of Denial to Employee.

(a)Comment: Tim Wilson - The comment lists multiple provisions within KRS Chapter 342 and accompanying regulations that require direct notice to the employee. The comment requests that a provision be added to the administrative regulation to require written notice to an employee of the denial of a drug and an explanation of that denial.

(b)Response: Notice of a denial and an explanation of that denial is already required by 803 KAR 25:190 Section 7. 803 KAR 25:270, Section 4(2) provides that 803 KAR 25:190, Section 7, applies except as modified in 803 KAR 25:270, which means 803 KAR 25:190, Section 7, applies to all prescriptions for which preauthorization is required. The notice requirements of 803 KAR 25:190 are not modified or abrogated by 803 KAR 25:270.

(2)SUBJECT MATTER: Various

(a) Comment: Eric Lamb - The comment is in favor of the pharmaceutical formulary being available on the Department's website, of the provision allowing latitude in the drugs prescribed, and the provision allowing the filing of a medical fee dispute upon denial of a prescribed drug. The comments stated (1) there may be confusion regarding whether a "medical provider" is intended to be only one person or whether it could refer to any number of medical service providers; (2) there should be a mechanism to receive an extension of time to provide sound medical reasoning under the utilization review provisions; (3) there should be a specific provision stating that an employee and the employee's attorney must be notified upon denial of a prescription; (4) approval of a drug should not have a res judicata effect so that an employee is precluded from being prescribed a different drug in the future when the old drug is no longer effective or is less effective than the new drug; (5) insurance carriers should provide an explanation of benefits each time a drug is approved or denied; (6) there should be a stated time limit within which a carrier must either approve or deny a drug and the failure to do so should constitute denial of that drug and require the carrier to issue a denial letter to the employee; (7) there should be a provision that provides, prior to the rendering of an award or approval of an agreement, an opportunity for interlocutory relief without an in-person hearing before an administrative law judge; (8) there should be a provision that provides, in a medical fee dispute filed as a result of a utilization review denial, an administrative law judge the ability to issue an interlocutory order to continue a drug or allow a prescription for a drug until the medical fee dispute is resolved; and (9) the same preauthorization procedure should apply to all drugs, regardless of the assigned status under the pharmaceutical formulary.

(b) Response: 803 KAR 25:270 Section 4 (2) specifies where the medical provider has provided sound medical reasoning, the employer shall not deny a prescribed drug based solely on the status of the drug in the pharmaceutical formulary. The Department's experience demonstrates that it is wholly appropriate to require the prescribing provider to offer sound medical reasoning for prescribing an "N" status drug. The absence of that information may well constitute an admission by the prescriber that there is no sound medical reasoning for the prescription. Allowing a non-prescribing doctor to offer support for the "N" status drug is problematic because the non-prescribing doctor does not share the "risk" associated with an inappropriate prescription. However, the prescribing doctor or claimant may offer additional support from other doctors as part of or in addition to the provided sound medical reasoning. This provision does not create a burden on the prescribing doctor that does not already exist as the prescribing doctor would be expected to support the use of any out-of-the-ordinary drug.

It is unclear what the commenter meant by "time prescribed by UR." Utilization Review is addressed in 803 KAR 25:190 and is applicable to all treatment, not just prescriptions. Also, 803 KAR 25:270 Section 4 (5) provides where the requesting medical provider or designee fails to participate in the peer-to-peer conference, which the requesting provider would have scheduled, it "may" result in denial; the language does not include the mandatory "shall." The issue presented by the commenter was discussed at length by the Department and the mandatory language was removed in anticipation that various life events may prevent participation. The administrative regulation does not preclude further efforts to reschedule a peer-to-peer conference.

Section 3 (3) of the administrative regulation provides that within two (2) business days of the presentation of a prescription for a drug with an "N" status without articulated sound medical reasoning, the carrier shall notify the medical provider that preauthorization is required for the drug. 803 KAR 25:190 Section 5 (2) requires that the initial UR decision be communicated

to the provider and employee within two days of initiation of UR process or if additional information is required, within two days of receipt of that information. 803 KAR 25:190 Section 7(1) requires a written notice of UR denial be issued which is required to contain a statement of the medical reasons for the denial. It is the Department's position that there are sufficient "notice" processes already in place.

The comment is unclear but appears to state that a prescribing provider should not be precluded from changing a drug if it is no longer effective even though the current drug was approved for payment. A prescribing provider always has the option to change prescriptions if the current drug not is no longer working or is less effective than another drug. The new drug may or may not require preauthorization. There is nothing in the regulation that gives a UR decision "res judicata effect."

It is beyond the scope of this administrative regulation to require Explanation of Benefit forms. It would appear that sort of requirement would be better addressed through 803 KAR 25:190, which speaks to utilization review. The administrative regulation does include an obligation to provide written notice of denial with the medical reason stated therein.

It is beyond the scope of this administrative regulation to speak to a time limit for accepting or denying a claim. Also, as stated above, there is a two (2) day requirement to inform the claimant once utilization review has been initiated. 803 KAR 25:240 Section 5 provides a carrier shall, as soon as practicable, advise an injured employee of its acceptance or denial of the claim. There may be significant issues of compensability to be investigated and determined before a claim can be accepted or denied; as such, it would be imprudent to assign an arbitrary period by which an employer must do so.

It is beyond the scope of this administrative regulation to speak to interlocutory relief. The parties to an interlocutory relief proceeding can always waive a hearing. An administrative law judge may also schedule a hearing under 803 KAR 25:010 Section 12. If interlocutory relief is requested after an application has been filed, the hearing may be held telephonically, by video, or other electronic means. Under the current statutes and regulations, hearings are not routinely held when there has been a request for interlocutory relief.

Subsequent to an award or approved agreement, a carrier may not unilaterally cease payment for a drug the claimant has been taking until the issue has been presented to and decided by an administrative law judge. However, if the claimant is seeking prospective approval for a new drug, the same does not hold true. An administrative law judge will not pre-emptively award a medication which has been challenged as not reasonable or necessary.

(3) SUBJECT MATTER: Drugs dispensed by anyone other than a pharmacist require preauthorization.

(a) Comment: Rosmond Dolen - 803 KAR 25:270 §3(4) provides that drugs dispensed by anyone other than a pharmacist require preauthorization. The comment alleges this provision exceeds the scope of the Labor Cabinet's statutory authority, violates Section 2 of the Kentucky Constitution, was in contravention of a Kentucky Supreme Court decision wherein pharmacies constitute medical providers, and will lead to protracted litigation.

(b)Response: The administrative regulation does not prevent a doctor from prescribing any drug the doctor believes is appropriate or from dispensing that drug. The administrative regulation does require preauthorization for any drug dispensed by anyone other than a pharmacist. KRS 342.020(9) provides when a provider of medical services makes a referral for a medical service or treatment in which the provider has a financial interest, the provider must disclose that interest to the injured employee, the commissioner, and the employer's payment obligor. This provision acts as a safeguard to prevent a provider from taking advantage of her role as both the one ordering the service or treatment and the one financially benefitting from providing that service or treatment. 803 KAR 25:270, section 3 (4), is intended to provide a similar safeguard where a provider is both the one prescribing the drug and the one financially benefitting from dispensing the drug. A pharmacist cannot prescribe drugs and therefore cannot control which drug is prescribed, thereby lessening the opportunity for unchecked financial gain.

Further, studies indicate that employees who receive drugs through physician dispensing have longer periods of temporary total disability before reaching maximum medical improvement than those whose drugs are dispensed by a pharmacist. Studies further indicate medical costs are greater when an employee's drugs are dispensed by a treating physician than when medications are dispensed by a pharmacist.

Additionally, there are a large number of pharmacies throughout Kentucky, as well as many mail-order services that will provide medications directly to an injured employee's home. Thus, there should be little if any inconvenience to the injured employee caused by the requirement to obtain preauthorization if dispensed by someone other than a pharmacist. Likewise, should the physician choose to dispense the drug, there should be minimal delay because a drug assigned a "Y" status in the formulary for the work injury, if appropriate for the work injury, may be readily approved. In most cases, an email or phone call is all that will be required. Conversely, a drug assigned "N" status in the formulary for the work injury requires preauthorization regardless of who dispenses the drug.

Section 3(4) of the regulation does not exceed the statutory authority of the Labor Cabinet. House Bill 2 of the 2018 Session of the General Assembly amended KRS 342.035 8 (b) to require the commissioner of the Department of Workers' Claims to develop or adopt a pharmaceutical formulary and "promulgate administrative regulations to implement the developed or adopted pharmaceutical formulary on or before December 31, 2018." As stated in Section 2 (1) of the regulation, 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. Section 3(4) is in complete compliance with the legislative/statutory mandate in that it relates to the implementation of the formulary by prescribing the conditions under which it is to be applied and function. For the reasons set forth in the preceding paragraphs, requiring preauthorization for the dispensing of medications facilitates the goal of assuring the appropriate use of prescription drugs in the treatment of work-related injury and occupational disease.

In addition, KRS 342.260 authorizes the commissioner to promulgate administrative regulations "for carrying out the provisions of this chapter." The commissioner deems Section 3(4) of this regulation to be consistent with carrying out the requirement of KRS 342.020 regarding provision of appropriate medical treatment for injured employees.

Section 3(4) does not violate §2 of the Kentucky Constitution. That Section provides that "(A)bsolute and arbitrary power over the lives, liberty and property of freemen exists nowhere in

a republic, not even in the largest majority." Section 3(4) is not an arbitrary exercise of power and is wholly consistent with the legislative mandate of House Bill 2. As set forth above, physicians who both prescribe and dispense medication are in a very different posture than pharmacists who can only dispense. The physician controls which drugs are prescribed, in addition to the formulation, strength, and dosage of the medication as well as whether the medication is a generic or brand name. A pharmacist has no control over which drugs are prescribed. Adding the additional 'check' of requiring preauthorization for one both prescribing and having a financial interest in dispensing the medication prescribed is both reasonable and appropriate.

Section 3(4) does not contravene the holding in the case of *Steel Creations By and Through KESA, The Kentucky Workers' Compensation Fund v. Injured Workers Pharmacy*, 532 S.W.3d 145 (Ky. 2017), in which the Kentucky Supreme Court held a pharmacy is considered a "medical provider" in the context of a workers' right to choose his/her medical provider under the Workers' Compensation Act. Nothing in the regulation precludes an injured worker from choosing to have his or her medications dispensed by a non-pharmacist and the regulation does not prohibit non-pharmacy dispensing.

The following persons made a similar comment:

(1) William R. Adams II, D.P.M., F.A.C.F.A.S., The Orthopaedic Institute of Western Kentucky

(2) Clint P. Hill, M.D., The Orthopaedic Institute of Western Kentucky

(3) K. Brandon Strenge, M.D., The Orthopaedic Institute of Western Kentucky

(4) Ryan Beck, M.D., The Orthopaedic Institute of Western Kentucky

(5) Shiraz Patel, M.D., The Orthopaedic Institute of Western Kentucky

(6) Spencer Romine, M.D., The Orthopaedic Institute of Western Kentucky

(7) Stephen Jackson, M.D., The Orthopaedic Institute of Western Kentucky

(8) Illegible, The Orthopaedic Institute of Western Kentucky

(9) Jennifer Bean, VP Government Affairs, Automated Healthcare Solutions

(10) Joseph A. Schwartz, III, Physicians Research Institute

(11) Sai Gutti, M.D., Pain Management Center

(12) Sujata Gutti, M.D.

(4) SUBJECT MATTER: Clarification of 803 KAR 25:270, Section 3(3), which requires the insurance carrier to notify the medical provider that preauthorization is required for a drug assigned an "N" status within two (2) business days of presentation of the prescription.

(a) Comment: Brian Allen – The comment requests the language be modified so that the two day period begins upon notification to the insurance carrier that the prescription was presented. Additionally, does this requirement extend to a pharmacy benefit manager performing services for the insurance carrier?

(b)Response: Ultimately, the employer is responsible for payment; the insurance carrier is the employer's payment obligor. By extension, anyone acting on behalf of the insurance carrier could be responsible to meet the requirement; however, that is an issue to be decided between the insurance carrier and those acting on its behalf. The Department does not find the requirement to be overly burdensome in light of the two (2) day time limitation in the utilization review regulation, 803 KAR 25:190.

The following persons made a similar comment:

(1)Lisa Anne Bickford

(2)Julian Roberts

(5)SUBJECT MATTER: Work relatedness and limitation following first fill.

(a) Comment: Lisa Anne Bickford – The comment requested clarification that all medications may be validated for injury relatedness. The comment further requested clarification as to whether there were fill limitations after the initial seven (7) day period following the date of injury.

(b) Response: 803 KAR 25:270, Section 3(2) specifically states the prescription should be filled "if prescribed for and appropriate for the work injury or occupational disease." Thus, all drugs may be challenged for a lack of relatedness to a work injury, although the review may only be required retrospectively in certain situations. Further, the pharmaceutical formulary is expected to work in concert with the treatment guidelines adopted by the commissioner.

After the initial seven (7) day period following the date of injury, limitations may or may not be provided depending upon the status of the drug within the formulary.

(6)SUBJECT MATTER: 803 KAR 25:270, Section 3(4)

(a) Comment: Adam Fowler – The comment supports the administrative regulation as written but requests inclusion of the word "prescription" in 803 KAR 25:25:270, Section 3 (4), in order to clarify and prevent confusion.

(b)Response: The Department agrees that inclusion of the word "prescription" in 803 KAR 25:25:270, Section 3 (4), would clarify that provision and prevent confusion.

(7)SUBJECT MATTER: Drugs dispensed by anyone other than a pharmacist require preauthorization.

(a)Comment: David Price – The comment supports the regulation as written with specific emphasis supporting the requirement for preauthorization for all drugs not dispensed by a pharmacist and requesting the development of template notification letters.

(b)Response: The Department agrees with the need for preauthorization for all drugs not dispensed by a pharmacist. The Department has developed notification templates but does not believe they are appropriate for inclusion in this administration regulation.

The following persons made similar comments in support of the preauthorization for all drugs not dispensed by a pharmacist:

(1)Brian Allan

(2)Julian Roberts

(3)Lisa Anne Bickford

(8)SUBJECT MATTER: Administrative regulation as drafted

(a)Comment: Ken Eichler – Comment in favor of the administrative regulation as filed. The comment stated the administrative regulation will provide improved outcomes for injured workers while expediting the delivery of healthcare and medications because consideration was given to the roles and responsibilities of all participants involved in prescribing, processing, and delivering of medications.

(b)Response: The Department agrees.

The following persons made similar comments in support of the administrative regulation as drafted:

(1) Rosalie Faris

(2) Adam Fowler

(3) Lisa Anne Bickford

(9) SUBJECT MATTER: Drug inclusion

(a) Comment: Danielle M. Jaffe – The comment states the pharmaceutical formulary fails to include all drugs and there is no requirement that a payment obligor respond to a request for preauthorization in a timely matter.

(b) Response: The ODG pharmaceutical formulary specifically includes hundreds of medications most commonly prescribed in the treatment of work injuries. For example, the twenty-five (25) drugs most commonly prescribed in workers' compensation claims in Kentucky, as determined by the National Council on Compensation Insurance, are included in the formulary and more are being added on a continual basis. Additionally, 803 KAR 25:190 requires a response to a request for preauthorization be provided within two (2) business days thereby minimizing any administrative burden or delay.

(10) SUBJECT MATTER: Drugs dispensed by anyone other than a pharmacist require preauthorization.

(a)Comment: Dina Green – The comment provided examples from the commenter's experience. In the commenter' experience, only 14 claimants have received medication via a physician dispensing program, with most being from the same physician. Secondly, ninety-nine (99) percent of the time, the claimant had to travel to a pharmacy to obtain the prescribed medication because it was not available through the physician dispensing system. Additionally, some of the medications marketed through physician dispensing systems are not FDA pharmaceuticals, do not have an assigned NDC number, and are the subject of exorbitant billing.

(b)Response: The comments supports the Department's reasoning to retain the provision that a drug dispensed by anyone other than a pharmacist requires preauthorization.

Summary of Statement of Consideration and
Action Taken by Promulgating Administrative Body

The public hearing on this administrative regulation was held as scheduled. In addition, written comments were received. The Department of Workers' Claims responded to the comments and amends the administrative regulation as follows:

Page 5
Section 3(4)
Line 12

After "Except as provided in subsection (1) of this Section,", insert "**prescription**".

Agency Amendment
6/5/2019
Labor Cabinet
Department of Workers' Claims
(Amended After Comments)

803 KAR 25:270. Pharmaceutical Formulary.

Page 5
Section 3(3)
Line 10

After "medical provider", insert "and injured employee".

Page 5
Section 3(4)
Lines 12 and 13

After "(4)", delete the following:

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

Renumber subsequent subsections accordingly.

LABOR CABINET
Department of Workers' Claims
(As Amended at ARRS, June 11, 2019)

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 ***and[~~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 ***342[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" or "Compounding"*** ***[~~"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" ***is defined by 803 KAR 25:190[~~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 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)[~~218A.172, 218A.020(3), 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)***[Except as provided in subsection (1) of this Section, prescription 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.

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

(6)[(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.

(7)[(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 ap-

proval 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.

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, Commissioner

APPROVED BY AGENCY: March 14, 2019

FILED WITH LRC: March 14, 2019 at 4 p.m.

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