LABOR CABINET

Department of Workers' Claims

(Amended After Comments)

803 KAR 25:092. Workers' compensation pharmacy fee schedule.

RELATES TO: KRS Chapter 342

STATUTORY AUTHORITY: KRS 342.020, 342.035, 342.260, 342.270, 342.735

NECESSITY, FUNCTION, AND CONFORMITY: KRS 342.035 requires the commissioner [Workers'-Compensation-Board] to periodically promulgate administrative regulations to adopt a schedule of fees for the purpose of ensuring that all fees, charges, and reimbursements under KRS 342.020 shall be fair, current, reasonable and limited to that paid for similar treatment of other patients in the same community. The increased security of payment afforded by the Workers' Compensation Act may be taken into consideration in determining what fees are reasonable. KRS 342.735 requires the commissioner [board] to establish administrative regulations to expedite the payment of medical expense benefits. The function of this administrative regulation is to regulate charges for pharmaceuticals provided pursuant to KRS 342.020, and to expedite the payment of this class of medical expense benefits.

Section 1. Definitions. (1) “Brand drug” means a drug product identified as a brand by Medi-span or any other drug product commercially available from only one source.

["Brand-name" has the meaning set forth in KRS 217.814(1).]
(2) “Compound” is defined in 803 KAR 25:270, Section 1(3).

(3) "Equivalent drug product" has the meaning set forth in KRS 217.814(5).

(4) “Generic drug” means a drug that is not a brand drug. "Generic name" has the meaning set forth in KRS 217.814(6)(2).

(5) "Hospital" has the meaning set forth in 803 KAR 25:091, Section 1(1).

(6) “Medical payment obligor” is defined in 803 KAR 25:260(10).

(7) “Medical provider” is defined in 803 KAR 25:260(11).

(5) “Practitioner” means any person licensed under the professional laws of Kentucky or any other state to prescribe and administer medicine and drugs.

(6) "Wholesale price" means the average wholesale price charged by wholesalers at a given time.

(8) “NDC number” means the unique 11-digit, 3-segment, number assigned to a drug product and maintained in the NDC Directory published by the U.S. Food and Drug Administration.

(9) “Pharmacist” is defined in 803 KAR 25:270(15).

(10) “Pharmacy benefit manager” means an entity licensed pursuant to KRS 304.9-053 that, on behalf of a medical payment obligor:

(a) Contracts directly or indirectly with pharmacies to provide prescription drugs to individuals;

(b) Administers a prescription drug benefit;

(c) Processes or pays pharmacy claims;

(d) Makes or assists in making prior authorization determinations on prescription drugs;

(e) Establishes a pharmacy network.
(11) “Prescription drug” is defined in 803 KAR 25:270 (18).

(12) “Repackage” means the act of taking a finished drug product from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the drug.

(13) “Usual and customary” means the charge a provider would apply to an otherwise uninsured patient.

Section 2. Payment for Pharmaceuticals. (1) Reimbursement shall be determined on the date of service. The maximum allowable reimbursement for prescription drugs shall be a dispensing fee of five dollars ($5.00) and the lesser of:

(a) The provider’s usual and customary charge for the drug;

(b) The amount the medical payment obligor has agreed to pay under its contract with a pharmacy benefit manager or other pharmacy service provider, in which case, upon request, the medical payment obligor shall certify or otherwise disclose the applicable reimbursement provision contained in the contract;

(b) [if it is a generic drug, eighty-five percent (85%) [sixty percent (60%)]] of the average wholesale price of the lowest priced equivalent drug product; or

(c) [if it is a brand [name] drug, ninety percent (90%) [eighty-five percent (85%)]] of average wholesale price.

(2) Average wholesale price shall be determined from the publication in effect on the date of service. The publication to be used is:

(a) Medi-Span, produced by Wolters-Kluwer;

(b) If the drug is not included in Medi-Span, then the Red Book, produced by Micromedex, shall be used.
(3) The usual and customary charge of the provider for the prescription drug must be included on each statement for services.

(4) A generic drug must be substituted for a brand [name] drug unless there is no equivalent drug product available or the prescribing medical provider indicates on the prescription that substitutions are prohibited [by including the words “Dispense as Written” or “No Substitution Allowed” along with a statement that the brand name drug is medically necessary].

(5) If a claimant chooses a brand [name] drug when a generic drug is available and allowed by the medical provider, the claimant shall pay the difference in price between the brand [name] and the generic drug as determined pursuant to subsection (1) of this section.

(6) A dispensing provider that is not a pharmacist shall be reimbursed the same as a pharmacist, but shall not receive a dispensing fee.

(7) Repackaged or Compounded Drugs
(a) Pharmaceutical bills submitted for repackaged or compounded drugs must include the NDC Number of the original manufacturer registered with the U.S. Food and Drug Administration.
(b) Reimbursement shall be determined using the original manufacturer’s NDC number for the product or ingredient, calculated on a per unit basis, as of the date of service. The maximum reimbursement limitations provided in subsection (1) of this section apply to each product or ingredient contained in the repackaged or compounded drug.
(c) An NDC number obtained for a repackaged or compounded drug shall not be considered the original manufacturer’s NDC Number.
(d) If the original manufacturer’s NDC Number is not provided on the bill, then the reimbursement shall be based on the average wholesale price of the lowest priced equivalent drug product, calculated on a per unit basis.
(e) A single compounding [dispensing] fee of $20 shall [may] be reimbursed for a
repackaged- or compounded drug [when applicable].

(1) An employee entitled to receive pharmaceuticals under KRS 342.020 may request and
require that a brand-name drug be used in treating the employee. Unless the prescribing practitioner
has indicated that an equivalent drug product should not be substituted, an employee who requests
a brand-name drug shall be responsible for payment of the difference between the equivalent drug
product wholesale price of the lowest-priced therapeutically equivalent drug the dispensing
pharmacist has in stock and the brand-name drug wholesale price at the time of dispensing.

(2) Any duly licensed pharmacist dispensing pharmaceuticals pursuant to KRS Chapter
342 shall be entitled to be reimbursed in the amount of the equivalent drug product wholesale price
of the lowest-priced therapeutically equivalent drug the dispensing pharmacist has in stock, at the
time of dispensing, plus a five (5) dollar dispensing fee plus any applicable federal or state tax or
assessment.

(3) If an employee's prescription is marked "Do Not Substitute," the employee
shall receive a brand-name drug.

[the dispensing pharmacist shall be entitled to reimbursement in an amount equal to the
brand-name drug wholesale price, at the time of dispensing, plus a five (5) dollar dispensing fee
plus any applicable federal or state tax or assessment.]

Section 3. Disputes; Applicability. (1) Any dispute arising under this administrative
regulation may [shall] be resolved pursuant to 803 KAR 25:012 or 803 KAR 25:110 (10).

(2) This administrative regulation shall apply to prescriptions dispensed to a workers'
compensation patient by a hospital pharmacy if the patient is not otherwise being treated or
obtaining medical care from the hospital.
(3) This administrative regulation shall not apply to prescriptions dispensed by a hospital pharmacy, of a hospital regulated pursuant to 803 KAR 25:091, to a workers' compensation patient receiving medical treatment or care from the hospital on an inpatient or outpatient basis.

(4) Any insurance carrier, self-insured employer, group self-insured employer, or pharmacy benefit manager may enter into an agreement with any pharmacy or other provider to provide reimbursement at a lower amount than that required in this administrative regulation.

Section 4. Balance Billing. No pharmacy filling a prescription covered under KRS 342.020 shall knowingly collect, attempt to collect, coerce, or attempt to coerce, directly or indirectly, the payment by a workers' compensation patient of any charge in excess of that permitted under this administrative regulation, except as provided in Section 2(2)(4) of this administrative regulation. This prohibition is applicable to prescriptions filled pursuant to KRS 342.020 and any prescription which is denied or disputed by the medical payment obligor may be billed directly to the party presenting the prescription for filling.
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
Department of Workers' Claims

March 15, 2021
Date
REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Administrative Regulation No.: 803 KAR 25:092

Contact person: B. Dale Hamblin, Jr, Assistant General Counsel

Telephone Number: (502) 782-4404

(1) Provide a brief summary of:

(a) What this administrative regulation does: The function of this administrative regulation is to regulate charges for pharmaceuticals provided pursuant to KRS 342.020, and to expedite the payment of this class of medical expense benefits.

(b) The necessity of this administrative regulation: Amendment to this administrative regulation is necessary to ensure reimbursement for pharmaceuticals is fair, current, reasonable and limited to that paid for similar treatment of other patients in the same community.

(c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 342.035 requires the commissioner to periodically promulgate administrative regulations to adopt a schedule of fees for the purpose of ensuring that all fees, charges, and reimbursements under KRS 342.020 shall be fair, current, reasonable and limited to that paid for similar treatment of other patients in the same community. The increased security of payment afforded by the Workers' Compensation Act may be taken into consideration in determining what fees are reasonable. KRS 342.735 requires the commissioner to establish administrative regulations to expedite the payment of medical expense benefits. This administrative regulation does so with respect to pharmaceuticals.
(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation establishes the reimbursement for pharmaceuticals.

(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: The amendment establishes the method by which reimbursement for pharmaceuticals is calculated.

(b) The necessity of the amendment to this administrative regulation: The current language created confusion; the amendment is to clarify the confusion.

(c) How the amendment conforms to the content of the authorizing statutes: The amendment updates language to comply with the current methodology for reporting required claims information.

(d) How the amendment will assist in the effective administration of the statutes: This administrative regulation provides guidance to those paying and receiving reimbursement for pharmaceuticals.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: Insurance companies writing workers' compensation policies in the Commonwealth, group of self-insurers, employers carrying their own risk, and those who dispense pharmaceuticals under the provisions of KRS Chapter 342.
(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: The entities will calculate reimbursement using the method in this administrative regulation.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There will be no additional cost to perform the calculation.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Reimbursement will be fair, current, reasonable and limited to that paid for similar treatment of other patients in the same community.

(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: There should be no additional cost.

(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 was amended after receiving comments; as a result, a compounding fee of $20 was established. This fee is paid by a medical payment obligor to the compounding pharmacist.

(9) TIERING: Is tiering applied? (Explain why or why not) Tiering is not applied; the administrative regulation applies to all parties equally.
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, 342.270, 342.735.

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. Without knowing the compensation to which employees of those agencies may be entitled under KRS Chapter 342, it is impossible to estimate the effect on expenditures; however, any change from current expenditures should be minimal.

(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? None

(d) How much will it cost to administer this program for subsequent years? 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: There should be no increase or decrease in the cost to administer this amendment.
I. The public hearing on 803 KAR 25:092, scheduled for January 21, 2021, at 10:00 a.m., to be held by videoconference by the Department of Workers’ Claims, Mayo-Underwood Building, 3rd Floor, 500 Mero Street, Frankfort, Kentucky, was held by Commissioner Robert L. Swisher. Four (4) public comments were made at the hearing. Eighteen (18) written comments were received during the public comment period.

II. The following persons were noted as attendees or offered comment:

(a) Anne-Tyler Morgan, McBrayer, Rx Development

(b) Bill Londrigan, president, Kentucky State AFL – CIO

(c) Julian Roberts, Pres., American Association of payers administrators and networks (AA PAN)

(d) John B. Simkins, RPh.

(e) Marshall W. Davis, Davis Drugs

(f) Sam Willett RPh.
(g) Joel Thornbury, RPh., Ben Mudd, PharmD/RPh., Kentucky Pharmacists Association

(h) Brian Allen, Vice President Government Affairs, Mitchell

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

(j) Mary Colvin, Vice President Claims, Kentucky Employers Mutual Insurance

(k) Katie Lee, Director of Account Management, M. Joseph Medical, LLC

(l) Ralph Bouvette, RPh., PhD, JD, Executive Vice President, American Pharmacy Services Corporation

(m) Greg M Gilbert, Chief Government Relations Office, Concentra

(n) Jayne Kresac, Esq., VP of Legal, Government Affairs, and Communications, Injured Workers Pharmacy

(o) Adam Fowler, Manager, Public Policy & Regulatory Affairs, Optum Workers' Comp and Auto No-Fault

(p) Sandy Shtab, AVP, Advocacy & Compliance, Healthe Systems

(q) Christopher P Evensen, Pres., Kentucky Workers Association

(r) Lee Ann C. Stember, President & CEO, National Council for Prescription Drug Programs (NCPDP)

(s) Dr. Ron Poole, Pharmacist
(t) David Figg, Pharmacist

(u) Shannon Stiglitz, Vice President of Government Affairs, Kentucky Retail Federation

(v) Richard Slone, Pharmacist

(w) Rosemary C. Smith, RPh., Secretary/Treasurer, Kentucky Independent Pharmacist Alliance

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

(3) Scott Wilhoit, Special Assistant to the Commissioner, Department of Workers’ Claims

(4) Robert Walker, Deputy Commissioner, Department of Workers’ Claims

(5) John Gaelian, General Counsel, Workers’ Claims Legal Division

IV Summary of Comments and Responses

(1) SUBJECT MATTER: Reimbursement Rates.

(a) Comment: Jayne Kresac - The comment stated that the ODG formulary, implemented in 2019, had not had a chance to fully demonstrate the cost savings available in the short period of time in which it had been in effect. Therefore, the comment urged the department
to allow time in which the ODG formulary could demonstrate cost savings before making additional reimbursement cuts. The comment reiterated the proposed fee schedule cuts were too deep and would negatively impact injured workers access to quality prescription care.

The following made a similar comment:

1. Anne-Tyler Morgan, McBrayer, Rx Development

(b) Response: The Department amended the proposed administrative regulation to reduce any impact from the reimbursement rates. Reimbursement for a brand drug has been amended to ninety percent (90%) of average wholesale price and reimbursement for a generic drug has been amended to eighty-five percent (85%) of average wholesale price.

(2) SUBJECT MATTER: Payment for Pharmaceuticals – Brand name required by physician.

(a) Mary Colvin, Vice President Claims, Kentucky Employers Mutual - The comment stated that Section 2 (4) and a Section 2 (8) were in conflict and recommended removing section 2 (8). The comment further noted that a prescriber does not have to provide the rationale for brand drug when a generic drug is also available, which may cause the request to be placed into utilization review, potentially causing a delay.

The following made a similar comment:

1. Joel Thornbury, RPh., Ben Mudd, PharmD/RPh., Kentucky Pharmacists Association
2. Brian Allen, Vice President Government Affairs, Mitchell

3. Adam Fowler, Manager, Public Policy & Regulatory Affairs, Optum Workers’ Comp and Auto No-Fault

4. Dr. Ron Poole, Pharmacist

5. Shannon Stiglitz, Vice President of Government Affairs, Kentucky Retail Federation

6. Richard Slone, Pharmacist

(b) Response: The Department has amended the proposed administrative regulation; Section 2 (8) has been deleted and Section 2 (4) amended so that it reads “or the prescribing medical provider indicates on the prescription that substitutions are prohibited.”

(3) SUBJECT MATTER: Reimbursement for Pharmaceuticals – reimbursement rates for brand and generic drugs.

(a) Adam Fowler - The comment stated that language proposed in section 2 (1) would seem to be limited to just prescription drugs and may not apply to over-the-counter drugs. The comment further urged the language in section 2 (1) be amended to ensure the five dollar dispensing fee is not carved out from the established “lesser of” reimbursement calculation. The comment alleged the construction would seem to always require a five dollar dispensing fee be paid regardless of any agreements to the contrary reached between the medical payment obligor, the PBM, or the pharmacy. The comment also alleged the five dollar dispensing fee, in addition to the agreed to contract amount, would likely add unnecessary cost to employers and insurers beyond
what had already been agreed. The comment recommended substitute language to rectify this situation.

The following made a similar comment:

1. Joel Thornbury, RPh., Ben Mudd, PharmD/RPh., Kentucky Pharmacists Association

2. David Price, Director of Government Affairs, Preferred Medical

3. Mary Colvin, Vice President Claims, Kentucky Employers Mutual

(b) Response: The Department amended the proposed administrative regulation; Section 2(1)(b) has been deleted. The issue to which it spoke is still addressed in Section 3(4). The conflict between third party contracts and the language regarding the five dollar ($5.00) dispensing fee has been resolved.

(4) SUBJECT MATTER: Reimbursement for Pharmaceuticals — reimbursement rates for brand and generic drugs.

(a) Adam Fowler - The comment stated the proposed rates represented significant cuts to reimbursement rates for both brand and generic drugs. The rates, if adopted, would give Kentucky one of the lowest workers compensation pharmacy fee schedules in the country. The comment alleged this would have a negative effect on the Kentucky workers compensation system, including additional costs to providers and lack of access to pharmacy care for injured workers. The comment further noted the Department had recently adopted and implemented a pharmaceutical formulary and a treatment guideline, both of which are now in effect. The addition
of reduced reimbursement rates in the proposed regulation, in combination with the other two recently added administrative regulations, would make it more difficult to collect data necessary to ascertain the impact of these significant policy reforms with respect to pharmacy cost, utilization, and access.

The following made a similar comment:


2. John B. Simkins, RPh.

3. Marshall W. Davis, Davis Drugs

4. Joel Thornbury, RPh., Ben Mudd, PharmD/RPh., Kentucky Pharmacists Association

5. Katie Lee, Director of Account Management, M. Joseph Medical, LLC

6. Ralph Bouvette, RPh., PhD, JD, Executive Vice President, American Pharmacy Services Corporation

7. Jayne Kresac, Esq., VP of Legal, Government Affairs, and Communications, Injured Workers Pharmacy

8. Christopher P Evensen, Pres., Kentucky Workers Association

9. David Figg, Pharmacist
10. Dr. Ron Poole, Pharmacist.

11. Shannon Stiglitz, Vice President of Government Affairs, Kentucky Retail Federation

12. Richard Slone, Pharmacist

13. Rosemary C. Smith, RPh., Secretary/Treasurer, Kentucky Independent Pharmacist Alliance

(b) Response: The Department amended the proposed administrative regulation to reduce any impact from the reimbursement rates. Reimbursement for a brand drug has been amended to ninety percent (90%) of average wholesale price and reimbursement for a generic drug has been amended to eighty-five percent (85%) of average wholesale price.

(5) SUBJECT MATTER: Reimbursement for Pharmaceuticals — reimbursement rates for brand and generic drugs.

(a) Jayne Kresac - The comment stated support for the use of a single source as the pricing methodology for average wholesale prices but urged the adoption of a higher reimbursement rate; specifically, average wholesale price minus 10% plus a dispensing fee of $5.00 for brand drugs and average wholesale price minus 5% plus a dispensing fee of $5.00 for generic drugs.

The following made a similar comment:

1. Brian Allen, Vice President Government Affairs, Mitchell
2. Ralph Bouverette, RPh., PhD, JD, Executive Vice President, American Pharmacy Services Corporation

(b) Response: The Department amended the proposed administrative regulation to reduce any impact from the reimbursement rates. Reimbursement for a brand drug has been amended to ninety percent (90%) of average wholesale price and reimbursement for a generic drug has been amended to eighty-five percent (85%) of average wholesale price. The Department retained the five dollar ($5.00) dispensing fee but removed a provision that appeared to create a conflict between the stated dispensing fee and a contractually agreed upon dispensing fee.

(6) SUBJECT MATTER: Adoption of a mandatory billing form.

(a) Lee Ann C. Stember - The comment recommended the Department adopt the National Council for Prescription Drug Program’s (NCPDP) pharmacy billing standards. The comment noted administrative regulation 803 KAR 25:096 does not adopt a specific form but only references a small number of minimum data requirements for pharmaceutical bills. The comment alleged this permitted an assortment of nonstandard, proprietary forms and invoices be used with wide variation in the information included or excluded. The comment further stated the ILIAC had incorporated the NCPDP forms as part of their latest model rules for use in workers’ compensation pharmacy billing transactions across the country in order to advance adoption of standards, remove administrative burdens, costs, and confusion often seen with the use of an assortment of proprietary forms and invoices. The comment provided language to adopt the form.

The following made a similar comment:
1. Adam Fowler, Manager, Public Policy & Regulatory Affairs, Optum Workers' Comp and Auto No-Fault

(b) Response: The Department made no amendment as a result of this comment. Mandating the use of a specific form appears to be an unnecessary burden on pharmacists at this time.

(7) SUBJECT MATTER: Lower reimbursement rates creates additional burdens and hurdles for injured employees.

(a) David Price - The comment stated the proposed reimbursement rates for brand and generic drugs was less than that paid outside of workers compensation. The comment cautioned that lower rates may preclude pharmacies from providing medications in workers' compensation matters, reduce pharmacy participation, making it more difficult for injured workers to receive medications, and may require injured employees to pay out-of-pocket and then seek reimbursement for those out-of-pocket expenses.

The following made a similar comment:

1. Anne-Tyler Morgan, McBrayer, Rx Development

2. Bill Londrigan, President, Kentucky State AFL-CIO

(b) Response: The Department amended the proposed administrative regulation to reduce any impact from the reimbursement rates. Reimbursement for a brand drug has been amended to ninety percent (90%) of average wholesale price and reimbursement for a generic drug has been amended to eighty-five percent (85%) of average wholesale price. The Department
retained the five dollar ($5.00) dispensing fee but removed a provision that appeared to create a conflict between the stated dispensing fee and a contractually agreed upon dispensing fee.

(8) SUBJECT MATTER: Reimbursement for Pharmaceuticals — Pharmacy Benefit Managers.

(a) Joel Thornbury and Ben Mudd - The comment stated “[s]pread pricing occurs when health plans contract with pharmacy benefit managers (PBMs) to manage their prescription drug benefits, and PBMs keep a portion of the amount paid to them by the health plans for prescription drugs instead of passing the full payment on to pharmacies.” The comment urged that spread pricing be eliminated from the workers compensation system.

The following made a similar comment:

1. Anne-Tyler Morgan, McBrayer, Rx Development

2. Sam Willett, RPh.

3. Ralph Bouvette, RPh., PhD, JD, Executive Vice President, American Pharmacy Services Corporation

4. Dr. Ron Poole, Pharmacist

5. Marshall W. Davis, Davis Drugs

6. Shannon Stiglitz, Vice President of Government Affairs, Kentucky Retail Federation

7. Richard Slone, Pharmacist
8. Rosemary C. Smith, RPh., Secretary/Treasurer, Kentucky Independent Pharmacist Alliance

(b) Response: The comment requests a response that is beyond the scope of this administrative regulation; the Department is only authorized to establish fees, charges, and reimbursements that are fair, current and reasonable. Pursuant to Section 3 (4) of this administrative regulation, parties may voluntarily enter into agreements providing reimbursement at a lower rate than would otherwise be required by the administrative regulation. As such, no amendment was made in response to this comment.

(9) SUBJECT MATTER: Reimbursement for Pharmaceuticals – Pharmacy Benefit Managers.

(a) Joel Thornbury and Ben Mudd - The comment stated pharmacy benefit managers use effective rate contracts to “clawback” reimbursements paid at the time the claim was adjudicated. The comment urged that effective rate contracts be eliminated from the workers compensation system.

The following made a similar comment:

1. Dr. Ron Poole, Pharmacist

2. Shannon Stiglitz, Vice President of Government Affairs, Kentucky Retail Federation

3. Richard Slone, Pharmacist
4. Rosemary C. Smith, RPh., Secretary/Treasurer, Kentucky Independent Pharmacist Alliance

(b) Response: The comment requests a response that is beyond the scope of this administrative regulation; the Department is only authorized to establish fees, charges, and reimbursements that are fair, current and reasonable. Pursuant to Section 3 (4) of this administrative regulation, parties may voluntarily enter into agreements providing reimbursement at a lower rate than would otherwise be required by the administrative regulation. As such, no amendment was made in response to this comment.

(10) SUBJECT MATTER: Reimbursement for Pharmaceuticals – Appeals Process.

(a) Dr. Ron Poole - The comment urged the creation of an appeals process for under-reimbursed pharmacies.

The following made a similar comment:

1. Ralph Bouvette, RPh., PhD, JD, Executive Vice President, American Pharmacy Services Corporation

2. Shannon Stiglitz, Vice President of Government Affairs, Kentucky Retail Federation

3. Richard Slone, Pharmacist

(b) Response: The Department understands this comment to request a response that is beyond the scope of this administrative regulation; the Department is only authorized to establish
fees, charges, and reimbursements that are fair, current and reasonable in this administrative regulation. The Department understands this comment to refer to reimbursements made under a private contract, not the reimbursement established by this administrative regulation. Otherwise, 803 KAR 25:012 establishes a process by which a medical dispute, including a dispute regarding payment or non-payment of a medical expense or service, may be resolved. As such, no amendment was made in response to this comment.

(11) SUBJECT MATTER: Reimbursement for Pharmaceuticals — Average Wholesale Price.

(a) Adam Fowler - The comment supported the adoption of Medi-Span as the primary average wholesale price source, with the Redbook as a backup source. The comment stated this adoption would sufficiently remove the existing state of ambiguity in the regulatory language concerning the definition of wholesale price.

The following made a similar comment:


2. Brian Allen, Vice President Government Affairs, Mitchell

3. David Price, Director of Government Affairs, Preferred Medical

(b) Response: No amendment was made as a result of this comment.
(12) SUBJECT MATTER: Reimbursement for Pharmaceuticals — Repackaged and compound drugs.

(a) Sandy Shtab - The comment supported the addition of repackaged and compound language to the pharmacy fee schedule regulation. The comment urged the Schedule of Fees for Physicians be updated concerning pharmaceuticals at its next scheduled update in order to be consistent with the proposed administrative regulation. The comment specifically supported the amendments that tied the reimbursement of repackaged and compounded drugs to the underlying NDC number of the original manufacturer. The current Schedule of Fees for Physicians states that if the original manufacturer’s NDC number is not included on the bill, the payer may return the bill to the physician as incomplete; in the proposed regulation, if the original manufacturer’s NDC number is not on the bill, the reimbursement is to be based on the average wholesale price of the lowest-priced equivalent drug product, calculated on a per unit basis. The comment urged the latter language be adopted in the Schedule of Fees for Physicians when it is updated because it eliminates administrative costs associated with returning and resubmitting bills, both for the payer and the provider.

The following made a similar comment:

1. Adam Fowler, Manager, Public Policy & Regulatory Affairs, Optum Workers’ Comp and Auto No-Fault

2. David Price, Director of Government Affairs, Preferred Medical

(b) Response: No amendment was made to the proposed administrative regulation in response to this comment. This comment appears to speak to an administrative regulation other
than 803 KAR 25:092. The Department notes, however, the instructions for the Schedule of Fees for Physicians provides that in the event of a conflict between the Schedule of Fees for Physicians and the Pharmacy Fee Schedule, the Pharmacy Fee Schedule governs.

(13) SUBJECT MATTER: Reimbursement for Pharmaceuticals — Reimbursement rates for brand and generic drugs.

(a) David Figg - The comment stated that setting the reimbursement rate too low would jeopardize the quality of care for injured workers.

The following made a similar comment:

1. Anne—Tyler Morgan, McBrayer

2. Christopher P Evensen, Pres., Kentucky Workers Association

3. Rosemary C. Smith, RPh., Secretary/Treasurer, Kentucky Independent Pharmacist Alliance

(b) Response: The Department amended the proposed administrative regulation to reduce any impact from the reimbursement rates. Reimbursement for a brand drug has been amended to ninety percent (90%) of average wholesale price and reimbursement for a generic drug has been amended to eighty-five percent (85%) of average wholesale price. The Department retained the five dollar ($5.00) dispensing fee but removed a provision that appeared to create a conflict between the stated dispensing fee and a contractually agreed upon dispensing fee.
(14) SUBJECT MATTER: Reimbursement for Pharmaceuticals – Repackaged and compound drugs.

(a) Joel Thornbury and Ben Mudd - The comment stated an NDC number is a unique 11 digit number, not a 10 digit number.

The following made a similar comment:

1. Dr. Ron Poole, Pharmacist
2. Shannon Stiglitz, Vice President of Government Affairs, Kentucky Retail Federation
3. Richard Slone, Pharmacist

(b) Response: The definition of “NDC number” was amended in response to this comment.

(15) SUBJECT MATTER: Reimbursement for Pharmaceuticals.

(a) Joel Thornbury and Ben Mudd - The comment stated a concern that the proposed fee schedule did not adequately account for the full cost of prescription drugs, guarantee the pharmacist would be reimbursed for ingredient costs, or guaranteed an amount no less than the actual acquisition cost.

The following made a similar comment:

1. Ralph Bouvette, RPh., PhD, JD, Executive Vice President, American Pharmacy Services Corporation
2. Dr. Ron Poole, Pharmacist

3. Shannon Stiglitz, Vice President of Government Affairs, Kentucky Retail Federation

4. Richard Slone, Pharmacist

(b) Response: The Department has amended the reimbursement rates in response to comments; however, to the extent this comment is meant to address reimbursement under the terms of a contract between private parties, modifying the terms of a private contract is beyond the scope of this administrative regulation. No amendments were made in response to this comment.

16) SUBJECT MATTER: The definitions of “brand name” and generic name.”

(a) Brian Allen - The comment stated the definitions of “brand-name” and “generic name” did not clearly reflect the common application of the terms in the pharmaceutical marketplace. As such, the comment suggested new definitions for both terms. The comment urged a revision to the proposed language in the administrative regulation to ensure an “outlier” did not control reimbursement of generic drugs.

(b) Response: The Department amended “brand name” to “brand drug” and “generic name” to “generic drug” and amended the definitions for both.

17) SUBJECT MATTER: The definition of “usual and customary.”

(a) Mary Colvin - The comment stated there was no definition of “usual and customary” as a pricing reference and suggested a definition.
(b) Response: The Department added a definition of “usual and customary.”

(18) SUBJECT MATTER: The definition of “pharmacist.”

(a) Sandy Shtab - The comment noted the term “pharmacist” was defined in 803 KAR 25:270 (15) rather than an 803 KAR 25:260 (15).

(b) Response: The administrative regulation was amended in response to this comment.

(19) SUBJECT MATTER: Reimbursement for Pharmaceuticals – Non-pharmacist dispensing fee.

(a) Greg M. Gilbert - The comment argued that dispensing physicians have the same overhead costs as a pharmacy and, as a consequence, urged the proposed administrative regulation be revised to allow dispensing physicians a dispensing fee during the first 30 days from the initial treatment.

(b) Response: No amendment was made in response to this comment.

(20) SUBJECT MATTER: Reimbursement for Pharmaceuticals – Compounding fee.

(a) Joel Thornbury and Ben Mudd - The comment stated a pharmacist should be reimbursed for the expertise and time it takes to compound a prescription.

The following made a similar comment:

1. Dr. Ron Poole, Pharmacist
2. Shannon Stiglitz, Vice President of Government Affairs, Kentucky Retail Federation

3. Richard Slone, Pharmacist

(b) Response: The department amended the proposed administrative regulation to add a compounding fee.

(21) SUBJECT MATTER: Stakeholder meetings.

(a) Bill Londrigan - The comment stated the Kentucky State AFL-CIO was not invited to participate in any stakeholder meetings regarding the proposed amendments to the fee schedule. The comment requested the proposed fee schedule be withdrawn until stakeholder meetings were held to discuss amendments. The comment further requested, if stakeholder meetings were held, information regarding when meetings were held, who participated, and, if there were no stakeholder meetings where the fee schedule and methodology for calculating the fee schedule arose, and what other states utilized the proposed regulation.

(b) Response: Two sessions of stakeholders meetings were held July 31, 2018. In attendance from the Department were Commissioner Robert L. Swisher, Deputy Commissioner Robert Milligan, Mike Nemes, Deputy Secretary of the Labor Cabinet, Laura Horton, Pam Knight, Douglas Gott, Dale Hamblin and Tina Gillis. Others in attendance were Joe Ardery, attorney, Danielle Jaffee, Injured Workers Pharmacy, Sandy Shtab, HealtheSystems, Lisa Anne Bickford, Coventry, Mike Bartlett, M. Joseph Medical, Rosalie Faris, OMCA, Amy Wrightsel, Preferred Medical, Dina Green, Ladegast & Hefner, Morgan Kirkland, KEMI, and Craig Towner, Preferred Medical. While no state has the exact statutory and regulatory language as Kentucky, the various
amendments were developed as a result of observing the methodology used in multiple states and stakeholder comments. No specific amendments were made to the administrative regulation as a result of this comment.

(22) SUBJECT MATTER: Disputes — Ability to enter into agreements to provide lower reimbursement.

(a) Joel Thornbury and Ben Mudd - The comment questioned whether the deletion of the phrase “with any pharmacy” in Section 3 (4) meant the administrative regulation would allow non-pharmacies to enter into contracts to provide pharmacy care.

b) Response: The issue of who may provide pharmacy care is not regulated by the Department of Workers’ Claims; however, in response to this and other comments, the Department has amended Section 3 (4) to include the phrase “with any pharmacy or other provider.”

(23) SUBJECT MATTER: General support.

(a) Brian Allen - The comment stated general support for the amendments to the administrative regulation.

(b) Response: While the Department has made amendments in response to the comments received in an effort to improve this administrative regulation, no specific amendments were made in response to this comment.

(24) SUBJECT MATTER: Disputes.
(a) Mary Colvin - The comment stated that Section 3 did not address managed care plans in disputes over the fee schedule. The comment recommended adding language referencing 803 KR 25:110 section 10.

(b) Response: Section 3(1) was revised to include 803 KR 25:110 (10).

(25) SUBJECT MATTER: Reimbursement for Pharmaceuticals.

(a) Dr. Ron Poole – The comment stated the administrative regulation should prohibit pharmacy benefit managers from mandating injured workers use pharmacies in which the pharmacy benefit manager has an interest and should require transparent/pass-through reimbursement.

The following made a similar comment:

1. Shannon Stiglitz, Vice President of Government Affairs, Kentucky Retail Federation

2. Richard Slone, Pharmacist

(b) Response: In the absence of an employer providing medical treatment through an approved managed care plan, an injured employee may choose his or her own medical provider without direction by the employer. Otherwise, the comment addresses matters beyond the scope of this administrative regulation. No amendments were made in response to this comment.

(26) SUBJECT MATTER: Reimbursement for Pharmaceuticals.
(a) Adam Fowler - The comment stated that pharmacy benefit managers assisted in controlling costs within the workers compensation system and work on behalf of insurers and employers to manage networks of pharmacies and reimburse agreements with those pharmacies and requested clarity.

(b) Response: No amendment was made in response to this comment.

(27) SUBJECT MATTER: Reimbursement for Pharmaceuticals – reimbursement for the difference between the cost of a brand drug and a generic drug when brand drug is requested.

(a) Adam Fowler - The comment supported the Department’s proposed removal of the language “in stock” in relation to reimbursement for generic medications under Section 2. In support, the comment noted that determining what specific drugs a dispensing pharmacist had in stock at a given time was not practical.

(b) Response: No amendment was made in response to this comment.

(28) SUBJECT MATTER: Use of only the terms “medical provider” and “pharmacist.”

(a) Adam Fowler - The comment urged the limitation of only two provider types, a “medical provider” and a “pharmacist.” The comment proposed language that would limit discussion of providers to just these two categories.

(b) Response: The Department believes the current language is in line with the language used in other related administrative regulations. As such, no amendment was made in response to this comment.
(29) SUBJECT MATTER: Payment for pharmaceuticals – use of pharmacy benefit managers.

(a) Ralph Bouvette - The comment encourage the use of: (1) a third-party administrator rather than a pharmacy benefit manager; (2) if a pharmacy benefit manager must be used, a single pharmacy benefit managers should be chosen; (3) there should be prohibitions placed on spread pricing and the steering of patients to pharmacies in which a pharmacy benefit manager has an interest; (4) the administrative regulation should require disclosure of all direct or indirect fees, effective rates, and any other price reduction or cost concessions associated with the dispensing and reimbursement of a prescription; (5) an appeal process should be provided to challenge underwater claims; and (6) the administrative regulation should require the third party administrator/pharmacy benefit administrator or pharmacy benefit manager to act as a fiduciary of the workers compensation program.

The following made a similar comment:

1. Dr. Ron Poole, Pharmacist.

2. Joel Thornbury, RPh., Ben Mudd, PharmD/RPh., Kentucky Pharmacists Association.

3. Shannon Stiglitz, Vice President of Government Affairs, Kentucky Retail Federation

4. Richard Slone, Pharmacist
5. Rosemary C. Smith, RPh., Secretary/Treasurer, Kentucky Independent Pharmacist Alliance

(b) Response: The comment addresses matters beyond the scope of this administrative regulation. No amendments were made in response to this comment.
STATEMENT 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 1
Section 1. Definitions.
Line 18
After “(1)” insert ““Brand drug” means a drug product identified as a brand by Medispan or any other drug product commercially available from only one source.” and delete ““Brand name” has the meaning set forth in KRS 217.814(1).”.

Page 2
Section 1. Definitions.
Line 3
After “(4) [3]” insert ““Generic drug” means a drug that is not a brand drug.” And delete “[“Generic name” has the meaning set forth in KRS 217.814(6)][(2)].”.

Page 2
Section 1. Definitions.
Line 11
After “. . . means the unique” insert “11” and delete “10”.

Page 3
Section 1. Definitions.
Line 4
Before “Section 2. Payment for Pharmaceuticals.” insert “(13) “Usual and customary” means the charge a provider would apply to an otherwise uninsured patient.”.
Section 2. Payment for Pharmaceuticals.

Delete "[(b) The amount the medical payment obligor has agreed to pay under its contract with a pharmacy benefit manager or other pharmacy service provider, in which case, upon request, the medical payment obligor shall certify or otherwise disclose the applicable reimbursement provision contained in the contract; ]".

Line 12

Before "(c)" insert "(b)" and delete "(c)".

After "If it is a generic drug," insert "eighty-five percent (85%)" and delete "sixty percent (60%)".

Line 14

Before "(d)" insert "(c)" and delete "(d)".

After "If it is a brand" delete "name".

After "drug," insert "ninety percent (90%)" and delete "eighty-five percent (85%)".

Line 22

After "substituted for a brand" delete "name".

Line 23

After "prescribing medical provider indicates" insert "on the prescription".
Section 2. Payment for Pharmaceuticals.

Line 1

After "prohibited" delete "by including the words "Dispense as Written" or "No Substitution Allowed" along with a statement that the brand name drug is medically necessary".

Line 3

After "chooses a brand" delete "name".

Line 4

After "between the brand" delete "name".

Line 20

After "A single" insert "compounding" and delete "dispensing".

After "fee" insert "of twenty dollars ($20.00) shall" and delete "may".

After "be reimbursed for a" delete "repackaged or".

After "compounded drug" delete "when applicable".

Line 10

Delete "(8) (3) If an employee's prescription is marked "Do Not Substitute," the employee shall receive a brand name drug.".
Section 3. Disputes; Applicability.

Line 16
After “regulation” insert “may” and delete “shall”.
After “803 KAR 25:012” insert “or 803 KAR 25:110 (10)”.

Page 6
Section 3. Disputes; Applicability.

Line 1
After “self-insured employer” insert “,” and delete “or”.
After “group self-insured employer” insert “, or pharmacy benefit manager”

Page 6
Section 3. Disputes; Applicability.

Line 2
After “enter into an agreement” insert “with any pharmacy or other provider”.