Commonwealth of Kentucky
Workers' Compensation Board

OPINION ENTERED: April 15, 2022

CLAIM NO. 200064861

KIGA AS INSURER/PAYMENT OBLIGOR FOR
SAVE-A-LOT PETITIONER

VS. **APPEAL FROM HON. JOHN B. COLEMAN,
ADMINISTRATIVE LAW JUDGE**

EDNA CONLEY;
DR. SAI GUTTI/PAIN MANAGEMENT CENTER;
RX DEVELOPMENT; and
HON. JOHN B. COLEMAN,
ADMINISTRATIVE LAW JUDGE RESPONDENTS

AND

RX DEVELOPMENT and DR. SAI GUTTI PETITIONERS

VS.

EDNA CONLEY;
KIGA AS INSURER/PAYMENT OBLIGOR FOR
SAVE-A-LOT; and
HON. JOHN B. COLEMAN,
ADMINISTRATIVE LAW JUDGE RESPONDENTS

**OPINION
AFFIRMING**

* * * * * *

BEFORE: ALVEY, Chairman, STIVERS and MILLER, Members.

ALVEY, Chairman. The Kentucky Insurance Guarantee Association through Save-A-Lot ("KIGA") appeals from the Order issued on July 29, 2014, the Order issued on September 9, 2019, the Order on Petition for Reconsideration issued on October 7, 2019, the Opinion and Order (Medical Dispute) rendered December 22, 2020, and the Order on Petition for Reconsideration issued on January 21, 2021 by Hon. John B. Coleman, Administrative Law Judge ("ALJ"). The ALJ resolved a post-award medical dispute in favor of Edna Conley ("Conley"), and more particularly the cost of prescriptions from Dr. Sai Gutti/Pain Management Center and Rx Development. ("Dr. Gutti/Rx Development"). Dr. Gutti/Rx Development also appeal from the Opinion and Order (Medical Dispute) issued on December 22, 2020, and the Order on Petition for Reconsideration issued on January 21, 2021.

On appeal, KIGA argues Dr. Gutti/Rx Development refused to provide information regarding the actual acquisition costs for the prescriptions at issue. KIGA also argues Dr. T. Joseph Mattingly, II's opinions are unopposed. It argues the ALJ erred in applying the wholesale acquisition cost ("WAC")[1] x 1.2 + $5.00. It contends the NADAC value most accurately reflects the acquisition cost, and the reasonable fee should be based upon that index, plus a $5.00 dispensing fee. It also argues Dr. Gutti/Rx Development is not entitled to additional compensation because they failed to participate in the mandatory grievance procedure due to

[1] As noted by Dr. Mattingly, the WAC represents the manufacturer's "list price" for a drug to wholesalers or other direct purchasers without including any discounts or rebates.

KIGA's participation in a managed healthcare system. It additionally argues it is entitled to a reimbursement for overpayments to Dr. Gutti/Rx Development. In the alternative, KIGA argues that if it is not entitled to reimbursement, it is entitled to an offset/credit against any past due medical expenses for the "small minority" of prescriptions from the overpayments it made for other prescriptions.

On cross-appeal, Dr. Gutti/Rx Development argue they were not required to participate in KIGA's managed healthcare program. They also argue KIGA chose not to depose the spokesperson for Rx Development. They maintain the ALJ's decision is supported by substantial evidence, in particular the additional compensation owed. Therefore, the appeal should be dismissed. Dr. Gutti/Rx Development also argue KIGA is not entitled to any reimbursement, credit, or offset because it was billed at the average wholesale price ("AWP") of the medications in dispute. Dr. Gutti/Rx Development assert the ALJ erred in not utilizing the AWP set forth in the national publications to determine what payment was appropriate for the medications prescribed and dispensed. According to Dr. Gutti/Rx Development, the ALJ did not address the use of the AWP. For the foregoing reasons, we affirm.

Conley filed a Form 101 on September 9, 2002, alleging she sustained work-related low back and extremity injuries from lifting a box of cabbage at work on October 4, 2000. A Form 110-I Settlement Agreement was approved on February 21, 2003, by Hon. R. Scott Borders, Administrative Law Judge. The diagnoses in that agreement included LE radiculopathy, SI joint dysfunction; spinal stenosis; and disc herniation at L1, as well as L5-S1 and L5 radiculopathy. The claim was settled

for a lump sum payment of past due benefits, and weekly benefits payable at $104.00, for a total of $44,200.00, with medical benefits remaining open.

Conley filed a Motion to Reopen on February 1, 2007, alleging her condition had worsened. A Form 110-I settling the claim was approved on August 4, 2008, by Hon. Howard E. Frasier, Jr., Administrative Law Judge. The terms of the agreement included commuting the remaining periodic payments to lump sum, with waivers of the right to reopen for a worsening of condition, neurosurgeon referral, past/present/future injections, and vocational rehabilitation benefits, for a lump sum of $17,000.00.

KIGA filed a Motion to Reopen the claim on February 13, 2014,[2] challenging the prescription drug charges submitted by Dr. Gutti/Rx Development. KIGA filed a Motion for Interlocutory Relief asking to be relieved from payment of invoices from Dr. Gutti/Rx Development during the pendency of the claim. That motion was overruled by Hon. John B. Coleman, Administrative Law Judge, by Order dated July 29, 2014. KIGA then filed a Motion to Bifurcate the claim requesting the ALJ to determine the properly payable amount for the prescription invoices at issue.

Rosalie Faris ("Nurse Faris"), a Registered Nurse, and Vice President of Managed Care for Occupational Managed Care Alliance ("OMCA"), testified by deposition on July 30, 2015, at KIGA's request. Nurse Faris testified OMCA oversees utilization reviews, bill reviews, telephonic case management, network

[2] We note that although this dispute was filed in February 2014, the ALJ did not render his decision until December 2020 due to various delays caused by discovery issues and motions for extension of time.

development, and networking. OMCA is an approved managed care provider, and KIGA is its client. OMCA's managed care plan has a pharmacy network approved by the Kentucky Department of Workers' Claims, managed by M. Joseph. She testified most pharmacies in Kentucky are listed in the OMCA network. She stated M. Joseph is a facilitator, not a Pharmacy Benefit Manager ("PBM"). PBMs negotiate with drug manufacturers to obtain medications at specific prices. She stated Rx Development, like M. Joseph, is considered an intermediary. Neither is considered a PBM. The medications go from the intermediary to the dispensing pharmacy. A manufacturer sets a price, which is the AWP, and the final price is established by the end dispenser.

Nurse Faris testified Medi-Span and Red Book are publications that take information from multiple sources to establish an average price, but this is not truly representative of the AWP. Those publications/services do not take rebates into consideration. Price is established based upon contracts between manufacturers and PBMs. Price varies from day-to-day. She testified M. Joseph's pricing is usually below Medi-Span's AWP. She noted the Pharmacy Fee Schedule allows for a dispensing pharmacy to receive a $5.00 dispensing fee. The fee schedule is based upon an AWP plus the dispensing fee. She noted Medi-Span and Red Book may not be truly representative of the average price for individual medications. OMCA recommends reimbursement based upon M. Joseph pricing, which she testified is below the AWP and is up to thirty percent below Medi-Span/Red Book averages.

KIGA filed Dr. Mattingly's report dated October 8, 2019. Dr. Mattingly is an Associate Professor at the University of Maryland Department of

Pharmacy Practice and Science. Dr. Mattingly reviewed this claim at KIGA's request and provided his thoughts regarding pharmaceutical pricing. Dr. Mattingly discussed his estimation of the acquisition cost for prescriptions filled by Rx Development. He also provided his thoughts regarding acquisition costs based upon multiple indexes. Dr. Mattingly also provided a chart with applicable definitions for the pharmaceutical supply chain, which is attached as an addendum to this Opinion.

Dr. Mattingly noted AWP is not federally defined, but there are several commercial publications, including Medi-Span and the Red Book, as well as the suggested wholesale price ("SWP") from the manufacturer. He noted, "If the manufacturer does not supply the SWP, then the compendia estimates the AWP by simply multiplying the WAC by 1.2 (essentially a standard markup)."

Dr. Gutti testified by deposition on December 17, 2015. He is an anesthesiologist and an interventional pain specialist. Dr. Gutti hired Rx Development to manage his in-office dispensary. Rx Development receives 40% of the gross revenue for the services it provides. Dr. Gutti provides office space. Rx Development provides shipping, labeling, and oversees the dispensing. It also bills and collects for the prescriptions. He testified the medications are received in pre-packaged, sealed containers. He also testified only non-controlled substances are dispensed through his office and Rx Development. If controlled substances are prescribed, they must be filled at a pharmacy. Rx Development trained some of Dr. Gutti's staff to assist with dispensing. Dr. Gutti testified he writes prescriptions for medications, which he provides to patients. The patient may then provide the

prescription to Rx Development for filling. Dr. Gutti testified patients are not required to use the dispensing service.

KIGA also filed a printout of the bills received from Dr. Gutti/Rx Development. That printout notes the amount billed and the amount paid. KIGA paid Dr. Gutti/Rx Development the same amount it pays to M. Joseph.

Dr. Gutti/Rx Development filed the deposition of Dwight T. Lovan, Commissioner of the Kentucky Department of Workers' Claims ("Commissioner Lovan"), taken in another claim also involving KIGA and Dr. Gutti/Rx Development on June 13, 2015. Commissioner Lovan testified a medical provider is required to disclose an investment relationship to the injured worker, the Commissioner, and the employer/obligor within thirty days from the date of the referral. He was unaware of Dr. Gutti ever providing such notification.

On December 22, 2020, the ALJ entered an Opinion and Order (Medical Dispute). He noted the issues pending before him for decision included whether the billings from the medical provider exceed the pharmacy fee schedule, and the entitlement to payment or reimbursement. The ALJ outlined the evidence, and noted AWP is sometimes determined by multiplying the WAC by 1.2. The ALJ cited to the holding in Steel Creations ex. Rel. KESA v. Injured Workers Pharmacy, 532 S.W.3d 145 (Ky. 2017). The ALJ also noted KIGA did not present any evidence setting forth the amounts it believed appropriate under the fee schedule despite being directed to do so on multiple occasions. KIGA argued it was only responsible for payment based upon M. Joseph pricing; however, the ALJ determined this is

inconsistent with the holding in Steel Creations ex. Rel. KESA v. Injured Workers Pharmacy, supra.

Based upon his review of the evidence and his understanding of the application of the applicable statute and regulations, the ALJ determined the WAC multiplied by 1.2, plus the applicable dispensary charge of $5.00 per prescription filled is the appropriate reimbursement rate. The ALJ determined KIGA is responsible for payment to Dr. Gutti/Rx Development in the amount of $839.73, in addition to the amount it had previously paid based upon his application of the formula and the dispensing fee. The ALJ also determined KRS 342.020(4) does not preclude Newsome's continuing treatment with Dr. Gutti/Rx Development despite the approval of a managed care plan. Specifically, 803 KAR 25:110, in effect at both the date the medical dispute was filed and on the date the ALJ rendered his decision, provides: "For those injuries or diseases for which continuing treatment was initiated prior to the date the managed care plan for the employer was approved, the employee may continue with its current treating physician."

Both KIGA and Dr. Gutti/Rx Development filed Petitions for Reconsideration. Other than correcting a notation regarding the amount KIGA requested to recoup, the ALJ denied the Petitions for Reconsideration in an Order entered January 21, 2021.

We note 803 KAR 25:092 Section 2 was amended effective August 31, 2021, as follows:

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

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

(b) If the drug is not included in Medi-Span, then the Red Book, produced by Micromedex, shall be used.

However, the previous version of the regulation that was in effect on the date the medical dispute was filed and on the date the ALJ rendered his decision, did not provide specific guidance regarding which index, or resource, would be utilized. Section 2 of the previous version in effect on the date both the medical dispute was filed, and on the date the ALJ rendered his decision, states as follows:

> (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 request a brand name drug shall be responsible for payment of the difference between the equivalent drug product wholesale price of the lowest priced therapeutically 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 the dispensing, plus a five (5) dollar dispensing fee plus any applicable federal or state tax or assessment.

Section 1(6) of that same version of the regulation defines "Wholesale price" as "the average wholesale price charged by wholesalers at a given time".

As an initial matter, we note KIGA does not challenge the work-relatedness, nor the reasonableness and necessity of the medications prescribed and dispensed by Dr. Gutti/Rx Development. We also note KIGA, as the moving party,

bore the burden of establishing the correct payment amount for the medications dispensed by Dr. Gutti/Rx Development. The ALJ provided multiple extensions of time and opportunities to KIGA to fulfill this requirement, but it failed to do so. Since KIGA was unsuccessful in its burden, the question is whether a different conclusion is compelled. Wolf Creek Collieries v. Crum, 673 S.W.2d 735 (Ky. App. 1984). Compelling evidence is defined as evidence that is so overwhelming no reasonable person could reach the same conclusion as the ALJ. REO Mechanical v. Barnes, 691 S.W.2d 224 (Ky. App. 1985). In other words, an unsuccessful party on appeal must prove that the ALJ's findings are unreasonable and, thus, clearly erroneous, considering the evidence in the record. Special Fund v. Francis, 708 S.W.2d 641 (Ky. 1986).

As fact-finder, the ALJ has the sole authority to determine the quality, character, and substance of the evidence. Square D Company v. Tipton, 862 S.W.2d 308 (Ky. 1993). Similarly, the ALJ has the sole authority to judge the weight to be accorded the evidence and the inferences to be drawn therefrom. Miller v. East Kentucky Beverage/Pepsico, Inc., 951 S.W.2d 329 (Ky. 1997); Luttrell v. Cardinal Aluminum Co., 909 S.W.2d 334 (Ky. App. 1995). The fact-finder may reject any testimony and believe or disbelieve various parts of the evidence, regardless of whether it comes from the same witness or the same adversary parties' total proof. Magic Coal Co. v. Fox, 19 S.W.3d 88 (Ky. 2000); Whittaker v. Rowland, 998 S.W.2d 479 (Ky. 1999); Halls Hardwood Floor Co. v. Stapleton, 16 S.W.3d 327 (Ky. App. 2000).

The determination of the AWP, and the amount reimbursable to a provider pursuant to the Pharmacy Fee Schedule as it existed on the date of the medical dispute, and as of the date of the ALJ's decision is confusing. Multiple publications/price listings could have been relied upon in establishing the correct payment amount. As Nurse Faris testified, the actual cost can vary from day-to-day. The ALJ determined KIGA was given multiple opportunities but failed to submit evidence establishing the AWP. The ALJ correctly determined the terms of KIGA's contract with M. Joseph could not be imputed to Dr. Gutti/Rx Development. He likewise determined Dr. Gutti/Rx Development were not required to provide information regarding the actual pharmaceutical costs until KIGA fulfilled its obligation of establishing the AWP. We find the ALJ did not err in reaching this determination.

We also determine the ALJ did not err in utilizing the WAC multiplied by 1.2, plus the $5.00 dispensing fee in determining the amount KIGA owes to Dr. Gutti/Rx Development is $839.73, in addition to the amount it previously paid. This is consistent with one of the methods described by Dr. Mattingly. Because the ALJ determined KIGA owes an amount to Dr. Gutti/Rx Development, in addition to the amount previously paid, any issue pertaining to reimbursement or credit is moot.

We emphasize it is well-settled that the ALJ has complete authority to control the taking of evidence before him. The ALJ possesses wide latitude to control the introduction of evidence and absent due process considerations, it is rare that the exercise of this discretion constitutes error. Searcy v. Three Point Coal

Company, 134 S.W.3d 351 (Ky. App. 1939); *See also* Cornett v. Corbin Materials, Inc., 807 S.W.2d 56 (Ky. 1991); Kentucky National Park Commission, ex rel. Com. v. Russell, 301 Ky. 187, 191 S.W.2d 214 (Ky. 1945).

The ALJ acted within the scope of his authority, and his decision is neither arbitrary nor capricious in requiring KIGA to first establish the AWP. Dr. Gutti/Rx Development were not obligated to provide cost information prior to KIGA satisfying its burden. The ALJ afforded KIGA ample opportunity to establish its threshold obligation. However, rather than doing so, it merely argued it should be required to pay Dr. Gutti/Rx Development no more than it would pay M. Joseph. We agree with the ALJ, the terms of the contract with M. Joseph have no bearing on the outcome of this dispute. We find the ALJ appropriately analyzed the claim and properly determined the amount owed to Dr. Gutti/Rx Development based upon the statutory and regulatory requirements existing on the date the medical dispute was filed, and the date of the ALJ's decision.

Likewise, we determine the ALJ did not err in his determination regarding the amount Dr. Gutti/Rx Development claim they are owed. The ALJ performed his analysis based upon the evidence of record, and he utilized a formula both Nurse Faris and Dr. Mattingly discussed. The ALJ explained the basis of his methodology, and the factors he considered in reaching his determination. Again, we find his determinations are consistent with the administrative regulations existing on the date the dispute was filed, and the date the ALJ reached his determination.

As a final note, we find Dr. Gutti/Rx Development's assertion KIGA chose not to take the deposition of an Rx Development is contrary to the evidence in

the record and is disingenuous. The deposition of such representative was scheduled, and the record reflects neither Rx Development's counsel nor its representative appeared despite proper notice having been provided. We also note counsel for KIGA and the court reporter were present. However, we believe such testimony would not have had any bearing on whether KIGA satisfied its threshold requirement as found by the ALJ.

We find the ALJ acted within the scope of his authority. The ALJ was free to reach his determination based upon the evidence provided, and we perceive no error. Therefore, we affirm on all issues.

KIGA requested oral arguments be held. As stated in the Board's April 7, 2022 Order, oral arguments are unnecessary in arriving at a decision, and therefore the request is **DENIED**.

Accordingly, the Order issued July 29, 2014, the Order issued September 9, 2019, the Order issued October 7, 2019, the December 22, 2020 Opinion and Order, and the January 21, 2021 Order on Petition for Reconsideration rendered by Hon. John B. Coleman, Administrative Law Judge, are hereby **AFFIRMED**.

ALL CONCUR.

/s/ *Michael W. Alvey*
MICHAEL W. ALVEY, CHAIRMAN
WORKERS' COMPENSATION BOARD

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A. Description of Pharmaceutical Supply Chain

Unlike consumer goods that flow directly from a supplier to a consumer, the distribution of pharmaceuticals includes a complex supply chain that is influenced heavily by market and government forces. To complicate matters, experts frequently use different acronyms or specific terms that can add to the confusion for the lay public. For this report, please refer to the definitions in Table 1 as a reference for these commonly used drug pricing and pharmaceutical supply chain terms.

Table 1: Definitions of commonly used terms in the pharmaceutical supply chain.

Term	Definition
Average Manufacturer Prices (AMP)	The price a manufacturer charges wholesalers or pharmacies that purchase directly from the manufacturer after discounts (Defined by federal law)
Average Sales Price (ASP)	A calculation of the weighted average of manufacturer's sales prices for drugs from all purchasers (Defined by federal law)
Average Wholesale Price (AWP)	An estimate of the price retail pharmacies pay when purchasing from a wholesale distributor.
Federal Upper Limit (FUL)	A price ceiling set by the Centers for Medicare and Medicaid Services (CMS) to control prices for certain medications paid to pharmacies.
Maximum Allowable Cost (MAC)	A price ceiling, similar to FUL, established at the state level
National Average Drug Acquisition Cost (NADAC)	A drug cost calculation developed through a national sample of drug acquisition costs estimated by CMS using actual pharmacy invoices representing what the pharmacies paid to the wholesaler from the previous 30 days. NADAC represents a weighted average of the NDCs used for each drug group.[1]
Manufacturer Net Price (MNP)	In 2017, a few drug manufacturers began publishing "price transparency" reports estimating the net revenues for drug sales to delineate the size of rebates and discounts (proprietary to PBMs) given back to insurers. This price is not publicly known, but may be estimated from publicly available sources.[2]
National Drug Code (NDC)	An 11-digit code used by Medicaid to identify a drug based on its manufacturer, strength, and package size.
Pharmacy Benefits Manager (PBM)	A company that operates between pharmaceutical manufacturers, pharmacies, patients, and payers to design the terms of drug coverage in a plan's drug benefit, improve prescribing, and secure rebates and discounts from manufacturers.[3]
Wholesale Acquisition Cost (WAC)	Represents the manufacturer's "list price" for a drug to wholesalers or other direct purchasers that does not include discounts our rebates. (Defined by federal law)
Veterans Affairs Federal Supply Schedule (VAFSS)	Section 8126(b) of title 38, United States Code describes the brand-name drug discount program outlined in the Federal Supply Schedule. The VAFSS reports the acquisition costs for the "Big Four" federal purchasers of pharmaceuticals.[2]
Wholesale Distributor	A company that buys medications in bulk from the manufacturer and transports them to clinics, pharmacies, and hospitals.
Manufacturer	A company that develops and produces pharmaceuticals, typically divided into "Brand" and "Generic" drug manufacturers based on the business model of the company.