

The Red Book is a privately published, electronic compendium of pharmaceutical and over-the-counter drug “AWPs” available online. (Reproduced Record (R.R.) at 792a); *Commonwealth v. TAP Pharm. Prods., Inc.*, 36 A.3d 1112, 1130 (Pa. Cmwlth. 2011) (*TAP*), *vacated on other grounds*, 94 A.3d 364 (Pa. 2014). It is updated regularly to reflect changes in prices. (R.R. at 818a.) At the time relevant to this matter, the publisher of the Red Book was IBM Health Watson, although the publisher can, and does, change. (*Id.* at 843a-44a); *see Indem. Ins. Co. of N. Am. v. Bureau of Workers’ Comp. Fee Rev. Hearing Off. (Insight Pharm.)*, 245 A.3d 1158, 1162 (Pa. Cmwlth. 2021) (*Indemnity Insurance*) (reflecting that the publisher of the Red Book then was Truven Health Analytics). In its statement of policy, IBM Health Watson indicates that the AWP it publishes “is, in most cases, the manufacturer’s suggested AWP and does not reflect the actual AWP charged by a wholesaler,” that the values used in the Red Book are reported to it by the manufacturer, and that IBM Health Watson does not independently analyze the data to ascertain the amounts paid by providers, such as pharmacies, to wholesalers. (R.R. at 843a.) Red Book values have been described as being similar to the manufacturer’s suggested retail price or “sticker price” of a car. (*Id.* at 836a.)

Petitioner argues the Bureau’s adoption and use of Red Book values in payment disputes is inconsistent with Section 306(f.1)(3)(vi)(A) of the Workers’ Compensation Act (Act),¹ which limits the reimbursement of pharmaceuticals to “one hundred ten per centum of the . . . [AWP] of the product.” 77 P.S. § 531(3)(vi)(A). Petitioner maintains Red Book values do not, and cannot, reflect the AWP, as defined by its plain meaning, because of how those values are derived, and, therefore, the Bureau exceeded its statutory authority by adopting the Red

¹ Act of June 2, 1915, P.L. 736, *as amended*, 77 P.S. § 531(3)(vi)(A).

Book. Petitioner further asserts that, if using the Red Book is not inconsistent with the Act, its ongoing adoption by the Bureau represents an improper delegation of legislative authority to a private entity under *Protz v. Workers' Compensation Appeal Board (Derry Area School District)*, 161 A.3d 827 (Pa. 2017). Respondent, in turn, maintains that AWP is a term of art used within the pharmaceutical industry and, as its expert witness credibly testified, the Red Book is an accepted source of AWP within that industry. It also argues there is no unlawful delegation to a private entity in violation of *Protz*, an argument that has previously been rejected by this Court. Upon review of the statutory language, case law, and record, we agree with Petitioner that the Red Book values do not reflect AWP as required by the Act. Accordingly, we reverse the Hearing Officer's Order, and remand the matter for further proceedings consistent with the following opinion.² Additionally, we direct the Bureau to promptly identify and publish in the *Pennsylvania Bulletin* a different nationally recognized schedule to be used to determine the AWP for purposes of resolving payment disputes for pharmaceuticals.

I. BACKGROUND

This Court has previously set forth the relevant factual and procedural background in a memorandum opinion, granting Petitioner's request for supersedeas from the Hearing Officer's Order, as follows:

Petitioner is the [workers' compensation (]WC[])] insurer for the employer of . . . [Claimant[]], who sustained a work injury in 2010 and is entitled to WC benefits under the . . . Act¹ (Hearing Officer Decision, Finding[s] of Fact (FOF) ¶¶ 3-4.) Respondent is an Arizona-

² Because we agree with Petitioner on this issue, we do not address Petitioner's constitutional arguments. See *Wertz v. Chapman Township*, 709 A.2d 428, 431 (Pa. Cmwlth. 1998) (stating "it is a cardinal principle of jurisprudence that where decision can be had on other than constitutional grounds, the court should decide the case on the nonconstitutional grounds").

based online pharmacy that provides Claimant with her prescription medication for her work injury. (*Id.* ¶ 4.) Beginning in 2019, Respondent submitted to Petitioner, and Petitioner paid to Respondent, bills for drugs dispensed to Claimant totaling approximately \$109,000, which were billed at a wholesale price proposed by Respondent. (Application [For Supersedeas] (Appl.), Attachment C.) In 2021, Petitioner determined that Respondent’s billed pricing was far above the actual . . . [AWP] of the drugs, as reported in the National Average Drug Acquisition Cost Index (NADAC). (Appl. ¶ 4.) Thus, for the bills Respondent submitted between April 15, 2021, and September 8, 2022, totaling about \$74,011.81, Petitioner adjusted its payments to be 110% of AWP as determined using NADAC, totaling \$1,511.93. (FOF ¶ 4; Appl. ¶ 4.) This left \$72,499.88 in disputed, unpaid bills, plus interest. (FOF ¶¶ 4, 7.)

Respondent filed applications for fee review. (*Id.* ¶ 5.) The Bureau’s Fee Review Section issued determinations applying a different cost index, known as “Red Book,” based upon the cost containment regulations promulgated under the Act. *See* 34 Pa. Code §§ 127.1-127.755; *see also* Section 306(f.1)(3)(vi)(A) of the Act, 77 P.S. § 531(3)(vi)(A) (limiting reimbursement for drugs and professional pharmaceutical services to “one hundred ten per centum of the . . . [AWP] of the product, calculated on a per unit basis, as of the date of dispensing”). The determinations ordered Petitioner to pay the disputed \$72,500. Petitioner filed 15 requests for fee review hearings ([1] for each separate bill), and Respondent filed 3 such requests, which were consolidated before the Hearing Officer for hearings over 6 days. (FOF ¶¶ 6-7.)

At the hearing, Petitioner bore the burden of proving, by a preponderance of the evidence, that it had properly reimbursed Respondent. *See* 34 Pa. Code § 127.259(f); *Liberty Mut. Ins. Co. v. Bureau of Workers’ Comp., Fee Rev. Hearing Off. (Kepko)*, 37 A.3d 1264, 1269 n.11 (Pa. Cmwlth. 2012). To do so, it sought to show that Red Book pricing is artificially inflated and does not represent actual AWP, which is what the Act requires be used to determine pricing. Petitioner presented the expert testimony of Fred Selck, Ph.D., a healthcare-market economic consultant. (Hearing Officer Decision, FOF ¶¶ 16-20 (summarizing Selck’s testimony); . . . R.R.[] at 35a-156a (notes of testimony).)³ Selck explained that a drug’s AWP is the average of the amounts that all purchasers pay to purchase that drug from a wholesaler. (R.R. at 99a [(emphasis omitted)].) Selck contrasted that meaning of AWP with Red Book, which is “just a

number that the . . . manufacturer provides,” and the manufacturer does not “do[] any kind of analysis to understand what providers are paying for their product” when determining the Red Book price. (*Id.* at 101a.) Red Book provides the list price that manufacturers use as a starting point in negotiations with wholesalers or insurers; it has “nothing to do” with the actual acquisition cost of the drug at wholesale. (*Id.*)

3. Respondent objected to Selck’s qualification as an expert. Selck admitted he had never worked as a pharmacist, was not familiar with the Act or the cost containment regulations, and has never testified as an expert in Pennsylvania about AWP. (R.R. at 87a-92a.) He also admitted he had never reviewed any of the Bureau’s annual statements specifying a benchmark for AWP, which are published annually in the Pennsylvania Bulletin pursuant to the cost containment regulations. (*Id.*); see 34 Pa. Code § 127.131(b). The Hearing Officer allowed Selck to testify as a healthcare economist and not as a legal expert. (R.R. at 96a.)

Selck explained that, unlike Red Book, NADAC AWP is determined through a monthly survey of pharmacies’ actual acquisition or “invoice” prices paid for a drug, and then by calculating an average of the responding pharmacies’ reported invoice prices. (*Id.* at 104a-06a.) In most cases the invoice price used in NADAC is paid to a wholesaler to acquire the drug, but in some cases the invoice price is paid directly to a manufacturer. (*Id.* at 108a.) Though manufacturers state a suggested retail price—which is approximated by Red Book—they routinely discount that price heavily in order to compete for sales to pharmacies. (*Id.* at 111a-12a.) NADAC reflects those discounted, actual wholesale prices. (*Id.* at 112a.) NADAC is used by several state Medicaid agencies, and increasingly by commercial insurers, to calculate reimbursement rates. (*Id.* at 108a-09a.) Generally, “everybody understands . . . within the generic [market] that the . . . Red Book AWP . . . nobody pays that price.” (*Id.* at 112a.) Respondent’s submitted prices reflected Red Book prices plus 10%, and “were far in excess of . . . [.] the actual acquisition cost[.]” reflected in NADAC. (*Id.* at 118a.)

On cross-examination, Selck acknowledged there are national cost indices other than NADAC, but reiterated that NADAC is by far the most reliable for determining actual [AWPs] paid. (*Id.* at 133a.) There are other cost indices that, like Red Book, measure list prices provided

by manufacturers rather than actual wholesale prices paid by pharmacies. (*Id.* at 135a-38a.) Selck also added that, when using NADAC price to calculate AWP for purposes of reimbursement, he added a 10% markup to allow a small profit margin to the pharmacy for making the transactions in question. (*Id.* at 142a.)

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In rebuttal, Respondent presented P.J. Ortmann, a consultant and licensed Pennsylvania pharmacist, as an expert on pharmaceutical pricing. (FOF ¶ 26; R.R. at 792a.) Ortmann agreed that NADAC reflects a drug's acquisition price, or "[t]he cost [at which] the pharmacy can buy [a] drug from a wholesaler." (*Id.* at 804a.) He explained, however, that pharmacies cannot profitably be compensated based on wholesale acquisition cost, even if the reimbursement includes a 10% markup, because the acquisition costs are extremely low. (*Id.* at 802a-03a.) For example, for a drug with a \$10 NADAC acquisition cost, reimbursement at 110% of the NADAC cost would leave the pharmacy with only \$1 to cover its overhead cost of filling the prescription. The average cost to fill a prescription is \$12.50, so the pharmacy would lose money on each transaction. (*Id.*) Thus, pharmacies are typically reimbursed based on the higher Red Book AWP in order to make it profitable to dispense drugs to recipients of WC benefits. (*Id.* at 806a-09a.) Red Book AWP often differs dramatically from NADAC acquisition prices, especially for generic drugs. (*Id.* at 808[a]-09a.) For example, the Red Book AWP for a bottle of generic Prozac is approximately \$2,000, but the NADAC acquisition price (which the pharmacy pays at wholesale) is \$9. (*Id.* at 809a.)

On cross-examination, Ortmann again distinguished between Red Book, which he stated provides an AWP, and NADAC, which measures average acquisition cost. (*Id.* at 815a.) He disagreed that NADAC could be described as reporting an [AWP]. (*Id.* at 815a, 822a.) He agreed that Red Book states a wholesale price suggested by manufacturers and "does not necessarily reflect the actual wholesale price charged by a wholesaler." (*Id.* at 817a.) Ortmann further agreed that pharmacies do not rely on Red Book prices when purchasing drugs at wholesale—Red [B]ook is used for reimbursement only. (*Id.* at 820a.) When asked about his earlier testimony about the disparity between a \$2,000 Red Book price and a \$9 wholesale acquisition price for a bottle of Prozac, Ortmann stated:

The reason that comes into play is the large [prescription benefit managers (]PBMs[)] offer the insurance company 85[%] discounts to make it look like they're getting a significant savings when, in fact, that's still much more than the drug actually costs.

Q. And just to be clear for the record, PBM is [a] prescription benefit manager?

A. That is correct.

Q. Okay.

A. They're the companies that actually process the prescription claims, and they are the go-go [sic] between the insurance company, the pharmacy[,] and the patient.

Q. Do you have any documentation as to how much [Respondent] has paid for any of these medications in question, Doctor?

A. I have no idea.

(*Id.* at 830a-31a.) On redirect, Ortmann indicated that the phrase “average wholesale price” is a term of art in the pharmaceutical industry. (*Id.* at 836a.) In his view, AWP is not a mathematical average of actual prices paid, but rather a manufacturer’s suggested price that is used as a reference in benefit negotiations between pharmacies, PBMs, and third parties. (*Id.*)

In the January 11, 2023 Decision, the Hearing Officer affirmed the Bureau’s fee review determinations. He concluded that Selck’s credentials did not qualify him as an expert, and even if they did, he found Selck’s testimony “wholly unpersuasive, inapposite[, and] obfuscatious.” (FOF ¶¶ 17, 22.) The Hearing Officer found that, where the testimony of Ortmann and Selck conflicted, Ortmann’s testimony was more credible and accepted over Selck’s testimony. (*Id.* ¶ 25.) He concluded that Petitioner failed to meet its burden to show that its payment of 110% of NADAC price had properly reimbursed Respondent under the Act and the cost containment regulations. (*Id.* ¶ 28.) In so concluding, the Hearing Officer distinguished cases cited by Petitioner where courts have opined in other contexts that Red Book

pricing is inflated or fictitious. (Hearing Officer Decision at 15 (distinguishing . . . *TAP* . . . , 36 A.3d 1112 . . . (Commonwealth action against pharmaceutical manufacturers alleging the Red Book AWP were inflated and violated consumer protection laws) . . . ; *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20 (D. Mass. 2007) (*MDL 2007*) (class action against pharmaceutical manufacturers’ inflating prescription drug costs), *aff’d*, 582 F.3d 156 (1st Cir. 2009), *cert. dismissed sub nom. AstraZeneca Pharms. LP v. Blue Cross Blue Shield of Mass.*[], 561 U.S. 1056 (2010).) He also disagreed that a recent decision of this Court allowed an insurer “to ignore [the] Red Book” or required or supported the use of NADAC, and, in fact, rejected an argument similar to Petitioner’s here. (*Id.* (discussing *Indem. Ins.* . . . , 245 A.3d [at] 1168 . . .).)

Federated Ins. Co. v. Summit Pharm. (Bureau of Workers’ Comp. Fee Rev. Hearing Off.) (Pa. Cmwlth., No. 115 C.D. 2023, filed June 13, 2023) (single-judge op.) (Cohn-Jubelirer, P.J.), slip op. at 2-7 (emphasis omitted) (some alterations added). Accordingly, the Hearing Officer directed Petitioner to reimburse Respondent the amounts set forth in the fee review determinations using the Red Book values. Petitioner now asks this Court to review that Order.³

II. DISCUSSION

A. Parties’ Arguments

Petitioner argues the Bureau’s continued adoption of the Red Book to provide default values in payment disputes, and the Hearing Officer’s application of those values here, are inconsistent with Section 306(f.1)(3)(vi)(A)’s language, which utilizes the AWP of a drug to determine the maximum reimbursement amount. According to Petitioner, while the Act provides that reimbursement is to be made at 110% of the AWP, it does not define AWP, which, in Petitioner’s view, should be

³ “This Court’s review of the Hearing Office’s adjudication considers whether necessary findings of fact are supported by substantial evidence, whether constitutional rights were violated, and whether the Hearing Office erred as a matter of law.” *Indem. Ins.*, 245 A.3d at 1163 n.5.

defined by the plain and common usage of “average” and “wholesale price,” not as a term of art. Petitioner maintains AWP means “actual” AWP, or an average of the AWP’s pharmacies throughout the country pay for the prescription drugs, they then resell to their customers, a definition Petitioner contends is supported by our decision in *Indemnity Insurance*. Petitioner argues the Red Book, adopted as the default AWP by the Bureau, cannot be used to calculate AWP because it is not an average of actual acquisition costs, or the prices paid by any pharmacies to manufacturers/wholesalers. Instead, Petitioner asserts, this Court in *Indemnity Insurance* and *TAP*, and federal district courts in *MDL 2007*, recognized that the Red Book is an entirely fictitious and inflated index made up of a manufacturer’s “suggested” AWP that far exceeds, as both Ortmann and Selck testified, the amounts actually paid by any pharmacy. Petitioner notes that Medicare, along with other state legislatures, no longer use the Red Book for this reason. In contrast to the fictitious numbers used in the Red Book, Petitioner argues, the NADAC reflects the AWP paid by pharmacies and satisfies the factors identified in *Indemnity Insurance* as being the qualities of an AWP, facts that were unrebutted by Respondent’s evidence. And, Petitioner contends, the use of the NADAC would significantly decrease costs, which furthers the purpose of the cost containment amendments that added the limiting language to Section 306(f.1)(3)(vi)(A). Finally, Petitioner argues the issue is not whether pharmacies can make a profit, on which the Hearing Officer appeared to focus, but whether the Bureau is complying with the Act’s language, and it is not.

Respondent argues the General Assembly used “average wholesale price” in Section 306(f.1)(3)(vi)(A), 77 P.S. § 531(3)(vi)(A), not “actual wholesale price” or “actual average wholesale price,” and the Court may not substitute language that it

might prefer for that used by the General Assembly. *Keystone Rx LLC v. Bureau of Workers' Comp. Fee Rev. Hearing Off. (Compservs. Inc./Amerihealth Case Servs.)*, 265 A.3d 322, 330-31 (Pa. 2021). Respondent asserts the General Assembly's use of AWP in Section 306(f.1)(3)(vi)(A), as interpreted in the Bureau's regulations to include the Red Book's values, is consistent with how the phrase is used in the pharmaceutical industry, as well as within other Pennsylvania statutes and regulations. (Respondent's Brief at 31-33 n.9, 40-41 (citing various statutory and regulatory provisions that use "average wholesale price" or similar language).) Because the Bureau's regulation is consistent with the Act's plain language, Respondent argues the Court should not substitute its judgment for that of the Bureau, which the Bureau has exercised since it first promulgated regulations on this topic in November 1995. According to Respondent, numerous stakeholders were involved in that process, and the Bureau's adoption of the Red Book occurred at that time. Respondent observes that the regulation identifying the Red Book is repromulgated annually in a process subject to review and objection by stakeholders, but none have ever been made by Petitioner.

Respondent contends Petitioner's other arguments are likewise without merit, pointing in particular to the fact that the Hearing Officer credited Ortmann's testimony and rejected Selck's testimony. Respondent maintains the credited testimony supports the continued use of the Red Book, rather than the NADAC plus 110%, as suggested by Selck, because the latter standard has never been adopted and does not account for the fact that Medicare (and every state that bases reimbursement on the NADAC) allows for the charge of "dispensing fees" to cover pharmacy costs. Respondent argues *Indemnity Insurance* did not authorize the abandonment of the Red Book in all instances; it held that alternative evidence as to a more accurate

AWP could be introduced but did not require that the alternative evidence be credited. Respondent further argues *TAP* should not be relied upon to determine what AWP means under the Act because *TAP* was not a WC case, did not examine the Act's language, and was decided before the Supreme Court's admonition in *Keystone Rx LLC* that this Court should not rewrite the Act where it believes the Act should have been drafted differently.

B. The Statutory and Regulatory Language

The parties have placed the meaning of “AWP” in Section 306(f.1)(3)(vi)(A), and the regulations promulgated to implement that provision, before the Court. Section 306(f.1)(3)(vi)(A) relates, in part, to “medical services and supplies,” and provides, in relevant part: “The reimbursement for drugs and professional pharmaceutical services shall be limited to one hundred ten per centum of the . . . []AWP[] of the product, calculated on a per unit basis, as of the date of dispensing.” 77 P.S. § 531(3)(vi)(A). This subsection was added to the Act, via amendment, by Section 8 of the Act of July 2, 1993, P.L. 190, No. 44 (Act 44), which also renumbered the section as Section 306(f.1) of the Act. It was subsequently amended to its current language by Section 1 of the Act of October 27, 2014, P.L. 2894, No. 184 (Act 184).⁴ Neither Act 44, Act 184, nor the Act more broadly, define “AWP.” 77 P.S. § 531(3)(vi)(A).

The Bureau promulgated cost containment regulations pursuant to, *inter alia*, Act 44, and those regulations provide:

**§ 127.131. Payments for prescription drugs and pharmaceuticals--
generally.**

⁴ Relevantly, Act 184 added “calculated on a per unit basis, as of the date of dispensing” after “average wholesale price (AWP) of the product.” 77 P.S. § 531(3)(vi)(A).

(a) Payments for prescription drugs and professional pharmaceutical services shall be limited to 110% of the . . . [AWP] of the product.

(b) Pharmacists and insurers may reach agreements on which Nationally recognized schedule shall be used to define the AWP of prescription drugs. The Bureau in resolving payment disputes, may use any of the Nationally recognized schedules to determine the AWP of prescription drugs. The Bureau will provide information by an annual notice in the *Pennsylvania Bulletin* as to which of the Nationally recognized schedules it is using to determine the AWP of prescription drugs.

(c) Pharmacists may not bill, or otherwise hold the employe liable, for the difference between the actual charge for the prescription drugs and pharmaceutical services and 110% of the AWP of the product.

34 Pa. Code § 127.131. As described in subsection (b), the Bureau publishes annual notices in the *Pennsylvania Bulletin* designating the Red Book as the schedule to use in determining the AWP of prescription drugs. *See, e.g.*, 52 Pa.B. 7792 (Dec. 17, 2022); 46 Pa.B. 3389 (June 25, 2016); 40 Pa.B. 5025 (Aug. 28, 2010). The version of such notice in effect at the time the parties filed the fee review applications here provided that “[u]nder 34 Pa. Code § 127.131(b) (relating to payments for prescription drugs and pharmaceuticals--generally), the . . . Bureau . . . [] gives notice that it utilizes the *IBM Micromedex Red Book* to determine the average wholesale price of prescription drugs.” 51 Pa.B. 7804 (Dec. 11, 2021).

C. Analysis

The arguments currently presented to the Court raise an issue of statutory construction regarding the meaning of AWP, which forms the basis of the reimbursement scheme of Section 306(f.1)(3)(vi)(A) and the cost containment regulations. Our statutory interpretation is guided by the Statutory Construction Act of 1972 (SCA). 1 Pa.C.S. §§ 1501-1991. Under Section 1921(a) of the SCA, “[t]he

object of all interpretation and construction of statutes is to ascertain and effectuate the intention of the General Assembly.” 1 Pa.C.S. § 1921(a). “The clearest indication of legislative intent is generally the plain language of a statute.” *Walker v. Eleby*, 842 A.2d 389, 400 (Pa. 2004). “When the words of a statute are clear and free from all ambiguity, the letter of it is not to be disregarded under the pretext of pursuing its spirit.” 1 Pa.C.S. § 1921(b). The Court employs statutory construction only if “the words of the statute are not explicit[.]” 1 Pa.C.S. § 1921(c). In doing so, the general rule is that “[w]ords and phrases shall be construed . . . according to their common and approved usage.” Section 1903(a) of the SCA, 1 Pa.C.S. § 1903(a); *Walker*, 842 A.2d at 400. However, “technical words and phrases and such others as have acquired a peculiar and appropriate meaning or are defined in this part, shall be construed according to such peculiar and appropriate meaning or definition.” Section 1903(a) of the SCA, 1 Pa.C.S. § 1903(a). “[T]he proper interpretation of a statute[] [] is a question of law.” *Walker*, 842 A.2d at 392.

We begin by observing that we are **not** starting our review of Section 306(f.1)(3)(iv)(A) on a blank slate. An en banc panel of this Court in *Indemnity Insurance* has already construed the AWP by using its plain meaning, not as a term of art.

In *Indemnity Insurance*, the insurer determined that a WC pharmacy’s use of Red Book values on its invoices was excessive and paid a reduced amount, and the pharmacy challenged that reduced payment by filing a fee review application. At the hearing, the insurer offered an affidavit identifying the difference in the retail price, (i.e., the price charged by the pharmacy), and the wholesale price of one of the five ingredients in the compound cream in question, reflecting that the retail price appeared less than the wholesale price, as well as an excerpt from the Red Book

editor's policy stating the book did not contain "the *actual* AWP charged by a wholesaler." *Indem. Ins.*, 245 A.3d at 1161-62 (emphasis in original). Arguing that a pharmacy obviously would not sell drugs at a price lower than the AWP, the insurer maintained that the lower retail price demonstrated that the Red Book AWP did not represent **actual** AWP, but an inflated, fictitious AWP. *See id.* at 1164-65 (summarizing insurer's argument before hearing officer). The hearing officer did not credit the insurer's evidence on the retail price and held that the insurer had not met its burden of showing it properly reimbursed the pharmacy and, therefore, had to reimburse at the Red Book rate. *Id.* at 1162.

Before this Court, the insurer asserted, as Petitioner does here, that the Act requires use of actual AWP for reimbursement, and the Red Book demonstrably does not represent AWP, but fictitious prices. *Id.* at 1163. The insurer also argued that the regulations' use of the Red Book's fictitious pricing, rather than actual AWP, was not consistent with the Act's language. Last, the insurer asserted, based on *Protz*, that there was a violation of the nondelegation doctrine because the General Assembly delegated its legislative authority to a private entity, the Red Book's editor. The Court addressed these arguments in turn.

On the first issue, the Court observed that the hearing officer had rejected the insurer's evidence of retail prices as not credible and that the Court could not consider the extra-record factual allegations contained in its appellate brief. *Id.* at 1164-65. Based on the credibility determination and noting that proper appellate review is confined to the record made before the government unit, the Court rejected the insurer's unsupported assertions that Red Book AWP is "fictitious" based on the contrary retail prices. *Id.* at 1165. With the insurer's evidence rejected as not credible, the Court held the insurer failed to meet its burden of proving that it

properly reimbursed the pharmacy. *Id.*

The Court then considered whether the regulations' use of Red Book violated the Act's requirement that reimbursement be based on AWP, summarizing the history of Section 306(f.1)(3)(vi)(A), as follows:

The General Assembly did not define the term “[AWP].”

In . . . *TAP* . . . , this Court explained as follows:

Since the late 1960s, almost every branded prescription drug sold in the United States has an [AWP], which is published in commercial compendia like Red Book, First DataBank, and Medispan. During the period covered by this lawsuit, AWP is provided in a current, digital format for each available branded pharmaceutical, in each dosage and packaging size. The digital format and the constantly updated value are essential for use in computer-dominated reimbursement systems, such as those used by [the Department of Human Services and Department of Aging]. . . .

[36 A.3d] at 1130. While critical of the AWP-based system for drug reimbursement, **this Court explained that the AWP provided an efficient estimate of acquisition costs for pharmaceuticals.** Further, this Court observed:

The reference to published prices was not intended to modify the accuracy of the average price phrase; rather, the reference to published prices was intended to establish a widely[]available third-party source of average prices. Establishing such a source relieves the [Department of Human Services and Department of Aging] of legal mandates to ascertain, by alternative methods, estimated acquisition costs. . . . In short, the reference to published prices does not change the plain meaning of the cost to be ascertained.

Id. at 1161 (citing *Commonwealth v. TAP Pharm[.] Prod[s.], Inc.* (Pa. Cmwlth., No. 212 M.D. 2004, filed Oct[.] 14, 2010) (single-judge op.) (Simpson, J.), slip op. at 8) (citation omitted). **In short, the AWP**

provides an objective estimate of acquisition costs for pharmaceuticals available through national pricing schedules.

In 2014, after the extensive *TAP* litigation, the General Assembly amended Section 306(f.1)(3)(vi) of the Act. . . . **The amendment did not define the term “average wholesale price.” It did, however, add [the] phrase [“calculated on a per unit basis, as of the date of dispensing” to the end of] Section 306(f.1)(3)(vi)(A)**

Indem. Ins., 245 A.3d at 1166-67 (some alterations and emphasis added). Thus, in *Indemnity Insurance*, we held that AWP was intended to be an objective estimate of the costs of acquiring drugs derived on a national basis.

The insurer asserted that the best proxy for actual AWP, which it argued was not reported by the Red Book or any other readily available source, was average retail price. The Court rejected this position, holding that “[t]he legislature could have amended Section 306(f.1)(3)(vi)(A) to define ‘average wholesale price’ to mean ‘average retail price,’ as suggested by [the i]nsurer. It did not do so.” *Id.* at 1167. The Court concluded that the plain meaning of the phrase “average wholesale price” does not contemplate use of an “average **retail** price,” which is what the insurer in *Indemnity Insurance* sought to prove and use before the Bureau. *Id.* at 1168 (emphasis added).

In response to Judge Ceisler’s concurring and dissenting opinion that agreed with the insurer’s “persuasive statutory construction argument that the AWP” denotes the “**actual** average wholesale price, **not** a fictitious AWP,”⁵ the majority

⁵ Judge Ceisler, joined by Judge McCullough, filed a concurring and dissenting opinion. The minority opinion agreed with the majority regarding the procedural and factual posture: the insurer had failed to meet its burden before the Bureau because it presented evidence of only retail price—it did not attempt to prove actual AWP. The minority dissented, however, from the Court’s construction of the phrase “average wholesale price.” Citing *TAP* and *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 460 F. Supp. 2d 277, 287 (D. Mass. 2006) (*MDL 2006*), the minority would have held the phrase to be construed according to its plain meaning, not (Footnote continued on next page...)

agreed “that [its] task is to construe ‘AWP’ according to its plain meaning.” *Id.* at 1167 (emphasis added). Relevant to our current inquiry, the majority went on, explaining:

[t]he majority opinion does just that. First, the legislature dictated the use of the industry AWP, not the AWP charged by a single manufacturer. The AWP is a number derived by averaging the wholesale prices of all manufacturers or wholesalers. The *TAP* litigation developed the “fictitious” moniker for “AWP.” Other than conveying a derogatory connotation, this adjective has little meaning. A number calculated from data collected from the market[]place is neither “fictitious” nor “actual.” The number is either accurate or inaccurate, but it has no “actual” existence.

Id.

Thus, pursuant to *Indemnity Insurance*, the “plain meaning” of AWP is a price that is an industry average not one that is “charged by a single manufacturer,” and “is a number derived by averaging the wholesale prices of all manufacturers or wholesalers.” *Id.* Because “in its plain meaning, Section 306(f.1)(3)(vi) requires the use of ‘average wholesale price’ and not ‘average retail price,’” the insurer’s attempt to rely on the latter, through “a conclusory affidavit laden with simple math errors,” did “violence to the words used by the legislature.” *Id.* at 1167-68. However, this did not mean that an insurer could not “produce[] evidence to support a calculation of an AWP **more accurate** than the one authorized by the regulation and listed by the Bureau in the *Pennsylvania Bulletin*,” such as “proposing a Nationally recognized schedule other than the one listed by the Bureau in the

as a term of art, and the plain meaning was not a “fictitious” AWP but the “actual” AWP that was tied to prices actually paid by providers. *Indem. Ins.*, 245 A.3d at 1171-72 (Ceisler, J., concurring and dissenting) (emphasis in original). The minority opinion emphasized that the obvious purpose of the Act’s cost containment provisions was to prevent inflated drug prices and reasoned that AWP must be read to require “the **actual** average wholesale price” of a drug, “**not** a fictitious AWP” such as Red Book’s. *Id.* at 1172-74 (emphasis in original).

Pennsylvania Bulletin when litigating a repricing dispute . . .”; it was just that the insurer in *Indemnity Insurance* had not done so. *Id.* at 1168 (emphasis added).⁶

“Under *stare decisis*, we are bound to follow the decisions of our Court unless overruled by the Supreme Court or where other compelling reasons can be demonstrated.” *Crocker v. Workers’ Comp. Appeal Bd. (Georgia Pac. LLC)*, 225 A.3d 1201, 1210 (Pa. Cmwlth. 2020) (citation omitted). Although Respondent cites Ortmann’s testimony to argue AWP has a technical meaning within the pharmaceutical industry, the meaning of the statutory language is a question of law, not fact. *Walker*, 824 A.2d at 392. And, while Respondent asserts arguments supporting a contrary interpretation, we are not persuaded it has demonstrated compelling reasons, *Crocker*, 225 A.3d at 1210, or “a special justification, over and above the belief that the precedent was wrongly decided,” to reverse this Court’s prior interpretation of AWP by its plain meaning, *Commonwealth v. Alexander*, 243 A.3d 177, 196-97 (Pa. 2020) (quoting *Allen v. Cooper*, 140 S. Ct. 994 (2020)). Accordingly, we are bound by our interpretations in *Indemnity Insurance* and apply them here.

The parties frame the question as whether the Red Book values are “fictitious” or “actual” AWPs, but the question is really whether the Red Book values are “accurate” or “inaccurate” AWPs. *Indem. Ins.*, 245 A.3d at 1167-68. The Bureau’s regulations adopt the Red Book as an AWP to be used in payment disputes. However, an insurer may introduce evidence challenging the “accuracy” of the Red

⁶ The *Indemnity Insurance* Court also rejected the insurer’s nondelegation claim based on *Protz*. The Court observed that the regulation does not require the use of any particular nationally recognized schedule of prices or preclude an employer from offering a different schedule to establish an AWP for the pharmaceuticals at issue. *Indem. Ins.*, 245 A.3d at 1169. Instead, the insurer “made no attempt to establish the so-called ‘actual’ AWP” in its effort to reprice the invoice. *Id.* Accordingly, the Court found that the insurer had no basis for its constitutional claim.

Book pricing for a particular drug's AWP. *Id.* Or, as here, an insurer can challenge the use of the Red Book at all on the basis that its values can never reflect an accurate AWP as used in Section 306(f.1)(3)(vi)(A), as that phrase has been interpreted by this Court. In *Indemnity Insurance*, we set forth standards that provided meaning to AWP: it is a price that is an industry average, not one that is “charged by a single manufacturer,” and “is a number derived by averaging the wholesale prices of all manufacturers or wholesalers.” 245 A.3d at 1167.

Respondent argues Petitioner's challenges to the Red Book must fail because, as in *Indemnity Insurance*, the testimony of Petitioner's witness, Selck, was not credited by the Hearing Officer. Petitioner acknowledges that this credibility determination cannot be revisited, but argues it is not relying on **its** witness's testimony, but on that provided by **Ortmann**, Respondent's expert. This Court acknowledges that the Hearing Officer, to whom it defers on credibility matters, credited Ortmann's testimony over Selck's testimony. However, the Hearing Officer only did so to the extent that the two experts gave **conflicting** testimony. (*See* FOF ¶ 25.)

A review of that testimony reveals that the witnesses' disagreements were more terminological than factual. Both witnesses agreed that NADAC pricing is based on the aggregated and averaged prices pharmacies actually pay for a drug at wholesale nationally, while Red Book pricing is chosen unilaterally by a drug's manufacturer, is not a mathematical average, and is not based on prices in any actual wholesale transactions. (R.R. at 104a-06a, 108a, 110a-12a, 135a-39a, 804a, 815a, 817a-22a, 824a.) They also agreed that NADAC and Red Book prices differ considerably, sometimes by orders of magnitude, particularly for generic drugs. (*Id.* at 118a, 808a-09a.) For example, Ortmann testified that while the wholesale

acquisition price for a bottle of Prozac was \$9, the Red Book price for reimbursement was \$2,000. (*Id.* at 808a-09a, 830a-31a.) Ortmann admitted that Red Book’s AWP is **not a mathematical average**, but rather **a manufacturer’s suggested price** that is used **as a reference in benefit negotiations** between pharmacies, PBMs, and third parties. (*Id.* at 836a.)

Ortmann’s testimony is confirmed by the policy statement of “IBM Watson Health,” the publisher of the Red Book in 2020, which was admitted as Exhibit J-1. That policy statement provides:

[t]he . . . [AWP] as published . . . is, in most cases, **the manufacturer’s suggested AWP and does not reflect the actual AWP charged by a wholesaler**. . . . IBM Watson Health bases the AWP data it publishes on the following:

- **AWP is reported by the manufacturer**[, defined as manufacturers, distributors, repackagers, and private labelers,] or
- **AWP is calculated based on a markup specified by the manufacturer**. This markup is typically based on the Wholesale Acquisition Cost (WAC) or Direct Price (DIRP), **as provided by the manufacturer**, but may be based on other **pricing data provided by the manufacturer**, or
- **Suggested Wholesale Price (SWP) [a]s reported by the manufacturer**[.]

....

Please note that IBM Watson Health **does not perform any independent analysis to determine or calculate the actual AWP paid by providers**[, defined as retailers, hospitals, physicians, and others buying from the wholesaler or directly from the manufacturer for distribution to a patient,] **to wholesalers**.

(*Id.* at 843a (emphasis added).)

Returning to the standards set forth in *Indemnity Insurance*, an “accurate”

AWP under Section 306(f.1)(3)(vi)(A) is a price “use[d by] the industry” not one that is “charged by a single manufacturer,” and “is a number derived by averaging the wholesale prices of all manufacturers or wholesalers.” *Indem. Ins.*, 245 A.3d at 1167. The above cited evidence, found credible by the Hearing Officer, does not in any way reflect that the “AWP” contained in the Red Book meets the standards set forth in *Indemnity Insurance* for an “accurate” AWP. Thus, the Red Book values cannot be an “accurate” AWP.

Further, in rejecting Petitioner’s argument that the Red Book should not be used, the Hearing Officer faulted Petitioner for not presenting “evidence of what the Red Book manufacturers[’] prices are reported to Red Book for the drugs herein involved,” “evidence as to what the wholesalers’ prices are for the involved drugs as reported (or not reported) to Red Book,” or “evidence as to any alleged average acquisition costs reported to Red Book” (Hearing Officer’s Decision at 16.) While the first of this list was at least possible for Petitioner to have provided, if it had chosen to challenge the accuracy of the Red Book AWP for each of the disputed drugs, the latter items—the wholesalers’ price and the average acquisition cost—are not data that is reported to or analyzed by Red Book per its policy statement. That statement reflects that it receives pricing data **from the manufacturer**, that data is **unrelated to what is actually charged by wholesalers to providers**, and that IBM Watson Health **performs no independent analysis to determine what is actually paid by providers to wholesalers**, i.e., acquisition costs. Ironically, these last two data points are more akin to what this Court identified in *Indemnity Insurance* as being needed to establish an accurate AWP, and neither are reported to Red Book. *See Indem. Ins.*, 245 A.3d at 1166 (“In short, the AWP provides an objective estimate of acquisition costs for pharmaceuticals available through national pricing

schedules.”).

For these reasons, we agree with Petitioner that the Bureau’s regulatory adoption and use of the Red Book’s values as the “AWP” to resolve payment disputes for pharmaceuticals are inconsistent with the phrase “AWP” as used in Section 306(f.1)(3)(vi)(A), as interpreted by this Court. “An administrative agency’s regulations cannot conflict with the statutory intention.” *Stanish v. Workers’ Comp. Appeal Bd. (James J. Anderson Constr. Co.)*, 11 A.3d 569, 575 (Pa. Cmwlth. 2010). If an agency’s regulations “are contrary to the legislative intent of [the] statutory provisions to which they relate,” they are invalid. *Id.* Accordingly, the regulations identifying the Red Book values as the AWP to be used to resolve payment disputes over pharmaceuticals are invalid, and the Hearing Officer erred in relying thereon to calculate the amount Petitioner must reimburse Respondent for the disputed drugs.

We must now turn to the remedy in this matter, as we hold that the Red Book’s values cannot be used as AWP as a matter of law because they are inconsistent with the Act pursuant to our interpretation in *Indemnity Insurance*. Petitioner asserts this Court should simply reverse the Hearing Officer’s Order and direct the use of the NADAC plus 110% as the appropriate AWP to resolve payment disputes. However, as Respondent points out, the Hearing Officer did not credit Selck’s testimony regarding using the NADAC as a replacement index AWP for payment disputes. The Hearing Officer, in rejecting Petitioner’s reliance on *Indemnity Insurance*, explained that *Indemnity Insurance* did not hold that an insurer “[wa]s ‘free’ to ignore [the] Red Book . . . and select some other modality which this adjudicator [wa]s somehow **obligated to accept.**” (Hearing Officer Decision at 15 (emphasis added).) During the hearing, the Hearing Officer indicated, in response to

Petitioner's citation to *Indemnity Insurance*, that "reasonable minds may differ as to what *Indemnity Insurance* . . . means." (R.R. at 827a.)

We believe this opinion clarifies the meaning of *Indemnity Insurance*. And, although we agree with the Hearing Officer that he is not "obligated to accept," (Hearing Officer Decision at 15), an alternative modality or index offered by an insurer, any modality or index used as the AWP to resolve a payment dispute over pharmaceuticals must be "accurate" pursuant to the standards set forth in *Indemnity Insurance*. As discussed, the Red Book does not meet those standards. Thus, we are left with a record that includes the Red Book, which cannot be used due to its legal inconsistency with the Act, and an alternative index, the NADAC, which cannot be used due to the Hearing Officer's credibility determination. Accordingly, while we reverse the Hearing Officer's Order, a remand is required for further proceedings to determine the appropriate reimbursement due to Respondent.

However, per Section 127.131(b) of the regulations, the Bureau has the obligation to identify a "Nationally recognized schedule" that it will "us[e] to determine the AWP of prescription drugs" to resolve payment disputes and give notice of that schedule in the *Pennsylvania Bulletin* annually. 34 Pa. Code § 127.131(b). That is the AWP to be used to resolve that dispute **unless** an insurer submits an alternative AWP that is credited as being more "accurate" than the one identified by the Bureau. *Indemnity Insurance*, 245 A.3d at 1167-68. Having invalidated the Red Book, we direct the Bureau to promptly identify and publish in the *Pennsylvania Bulletin* a "Nationally recognized schedule," 34 Pa. Code § 127.131(b), that provides an AWP for pharmaceuticals that comports with Section 306(f.1)(3)(vi)(A) of the Act, as interpreted by *Indemnity Insurance* and this opinion, to be used to resolve payment disputes. The Hearing Officer shall stay the remand

evidentiary hearing until the Bureau publishes a new schedule, after which the hearing will be held to allow the parties to introduce, if necessary, evidence regarding alternative indices or schedules they believe provide a more “accurate” AWP under the *Indemnity Insurance* standard. In evaluating that evidence, the Hearing Officer must consider which of the indices or schedules offered present the more “accurate” AWP under *Indemnity Insurance* and resolve the payment dispute using that AWP plus 110% as directed by Section 306(f.1)(3)(vi)(A).

III. CONCLUSION

Because we conclude that the Red Book values adopted and used by the Bureau as the AWP to resolve payment disputes for pharmaceutical drugs is inconsistent with the statutory language of Section 306(f.1)(3)(vi)(A) and is, therefore, invalid, *Stanish*, 11 A.3d at 575, we reverse the Order directing Petitioner to reimburse Respondent 110% of the Red Book values for the disputed drugs in this matter. We remand for further proceedings before the Hearing Officer. However, the Hearing Officer shall stay those proceedings pending the Bureau’s identification of a “Nationally recognized schedule” of AWP to be used in payment disputes and publication of that schedule in the *Pennsylvania Bulletin* as required by Section 127.131(b) of the regulations, 34 Pa. Code § 127.131(b). The Bureau is directed to perform these actions promptly. Upon the Bureau’s completion of this obligation, the Hearing Officer shall hold an evidentiary hearing and render a new decision in accordance with the foregoing opinion.

RENÉE COHN JUBELIRER, President Judge

IN THE COMMONWEALTH COURT OF PENNSYLVANIA

Federated Insurance Company,	:	
Petitioner	:	
	:	
v.	:	No. 115 C.D. 2023
	:	
Summit Pharmacy (Bureau of	:	
Workers' Compensation Fee	:	
Review Hearing Office),	:	
Respondent	:	

ORDER

NOW, January 2, 2024, the Order of the Bureau of Workers' Compensation (Bureau) Fee Review Hearing Office, entered in the above-captioned matter, is **REVERSED**, and this matter is **REMANDED** for further proceedings and a new determination in accordance with the foregoing opinion. Additionally, the Bureau is **DIRECTED** to promptly identify and publish in the *Pennsylvania Bulletin* a "Nationally recognized schedule[] to determine the [average wholesale price] of prescription drugs" to be used to resolve payment disputes, 34 Pa. Code § 127.131(b), that comports with Section 306(f.1)(3)(vi)(A) of the Workers' Compensation Act, Act of June 2, 1915, P.L. 736, *as amended*, 77 P.S. § 531(3)(vi)(A), as interpreted by *Indemnity Insurance Company of North America v. Bureau of Workers' Compensation Fee Review Hearing Office (Insight Pharmacy)*, 245 A.3d 1158, 1167 (Pa. Cmwlth. 2021), and the foregoing opinion. The Hearing Officer shall stay the remand proceedings pending the Bureau's publication of a new schedule, after which the remand proceedings shall be held.

Jurisdiction relinquished.

RENÉE COHN JUBELIRER, President Judge