BEFORE ALLAN L. MCVEY, INSURANCE COMMISSIONER OF THE STATE OF WEST VIRGINIA

In the Matter of

WEST VIRGINIA PRIMARY CARE ASSOCIATION; WEST VIRGINIA HOSPITAL ASSOCIATION; CHARLESTON AREA MEDICAL CENTER/CAMC HEALTH SYSTEM; MOUNTAIN HEALTH NETWORK; WEST VIRGINIA UNIVERSITY HEALTH SYSTEM; FRUTH PHARMACY; MARSHALL HEALTH; and MARSHALL PHARMACY,

Admin. Proceeding No. 21-IC-02126

Complainants,

v.

EXPRESS SCRIPTS ADMINISTRATORS, LLC,

Respondent.

FINAL ORDER

The undersigned, Insurance Commissioner of the State of West Virginia, does hereby adopt and approve the Recommended Decision of the Hearing Examiner, appended hereto, as well as the findings of fact and conclusions of law therein contained. It is consequently ORDERED that Complainant West Virginia Primary Care Association, et al. proved that Express Scripts Administrators, LLC violated West Virginia Code § 33-51-9(d). Therefore, the consumer complaint of West Virginia Primary Care Association, et al. against Express Scripts Administrators, LLC., is hereby, granted.

The objections of any party aggrieved by this Order and to the Recommended Decision herein adopted is preserved.

ENTERED this 8th day of December, 2021.

Allan L McVey
Insurance Commissioner

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RECOMMENDED DECISION OF THE HEARING EXAMINER

On August 19, 2021, a hearing was held before Hearing Examiner Mark. W. Carbone, Esquire, at the Offices of the Insurance Commissioner. Peter Markham, Esq. and Jason Reddish, Esq. appeared on behalf of West Virginia Primary Care Association; West Virginia Hospital Association; Charleston Area Medical Center/CAMC Health Systems; Mountain Health Network; West Virginia University Health System; Fruth Pharmacy; Marshall Health; and Marshall Pharmacy (hereinafter "Complainants), and David Thomas, Esq. and Christopher Smith appeared on behalf of the Respondent, Express Scripts Administrators, LLC (hereinafter "Respondent"). The matter was deemed submitted for recommended decision.

Based upon a thorough review of the entire record in this case, the undersigned now

makes the following Findings of Fact and Conclusions of Law.

Statement of the Case

The Complainants filed this Complaint against the Respondent because of an alleged change to the Respondent's claims submission policies. The Complainants' allegations are that the Respondent's new policies require that pharmacies use a post claim adjudication modifier to identify retail and 340B submissions. The Complainants' allege that this change will cause them additional costs and time, thus, violating the West Virginia Pharmacy Audit Integrity Act (hereinafter "PAIA"),

Findings of Fact

1. According to the brief submitted by the Complainants, the Complainants represent the interests of health care providers and contract pharmacies that dispense discounted drugs to the patients of covered 340B entities.

2. Complainant West Virginia Primary Care Association is a non-profit organization that represents the interests of West Virginia federally-qualified health centers that receive funding under Section 330 of the federal Public Health Service Act, 42 U.S.C. § 254b, and entities designated by the federal government as federally-qualified health center "look-alikes", all of which are Covered Entities eligible to participate in the 340B Program.

3. Complainant West Virginia Hospital Association represents the interests of hospitals located in West Virginia, some of which participate in the 340B program.

4. Complainants Charleston Area Medical Center/CAMC Health System, Mountain Health Network and West Virginia University Health System, Inc., Fruth Pharmacy, Marshall Health and Marshall Pharmacy are 340B entities as defined under PAIA, W. Va. Code § 33-51-

3.

5. Express Scripts Administrators, LLC serves as pharmacy benefit manager (hereinafter "PBM") that manages prescription drug benefits on behalf of insurance and insurance like benefit programs. A PBM contracts with various pharmacies and reimburse the pharmacies for dispensing drugs to the PBM's insurance customers. The PBM will also determine drug formularies.

6. Under the PAIA, "340B entity" means an entity participating in the federal 340B drug discount program, as described in 42 U.S.C. § 256b, including its pharmacy or pharmacies, or any pharmacy or pharmacies, contracted with the participating entity to dispense drugs purchased through such program

7. PAIA defines a covered entity as a contract holder or policy holder providing pharmacy benefits to a covered individual under a health insurance policy pursuant to a contract administered by a pharmacy benefits manager.

8. When an individual submits a prescription to be filled, he usually will present an insurance card containing various information about the individual.

9. The information from the insurance card is then transferred to a third party called a "switch." The third party will charge the pharmacy $.20 to $.40 for each claim submitted. The third party will then determine whether the individual's insurance policy will cover the drug.

10. Typically, a pharmacy will have specific software that converts information on the insurance card into the NCPDP[1] D.0 format to be sent to the switch for adjudication.[2]

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[1] National Council for Prescription Drug Program

[2] Adjudication is the process that is used to evaluate the claim and to determine whether the claim will be paid or not.

11. To use drugs purchased through the 340B program, the pharmacy must know for certain that the individual is eligible. An individual is eligible if the individual has an established relationship with covered entity, that the individual has received health care from a professional who is either employed or has a contractual relationship with a covered entity or if the individual receives health care for services for which the Covered entity received grant funding.

12. Third Party Administrators (hereinafter "TPA") obtain information from both the covered entity and the pharmacy to determine whether the prescription qualifies as a 340B prescription. Once that is determined, the TPA informs both the covered entity and the pharmacy that a 340B drug may be issued.[3]

13. Whether a prescription qualifies as a 340B drug is usually not available at the time the drug is dispensed. Many covered entities identify 340B prescriptions after the drug has been dispensed and then replenish their stock with 340B drugs. Under the prior submission policy, theis information was not provided to the PBM.

14. If it is later determined that the drug dispensed was not a proper 340B transaction, the pharmacy can reverse and resubmit the claim. When the claim is resubmitted, there are additional switch and PBM costs. In addition to these additional costs, there is also time and labor associated with a resubmission.

15. On February 24, 2021, Respondent issued a bulletin via e-mail from ProviderOutreach@esrxcommunications.com to pharmacies in the State of West Virginia, including Covered Entities and Contract Pharmacies, describing a new submission policy that would take effect March 1, 2021.

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[3] This Third Party Administrator is a different entity that a switch company.

16. The Bulletin stated that, effective March 1, 2021, Respondent would require a "new identification method for submitting and identifying 340B eligible claims." Pharmacies that determine "post-adjudication that a previously submitted claim is 340B eligible" would be required "to submit an N1 transaction with the proper Submission Clarification Code (Field 420-DK) of 20, and Software Vendor/Certificate ID (Field 110-AK) of 340B." The new submission policy would require pharmacies to resubmit every 340B claim.

17. The Bulletin referred recipients to Section 2.5 of the Express Scripts Network Provider Manual, which states that "[u]nless otherwise required by law, Network Providers that bill claims using pharmaceutical stock purchased under Section 340B must identify the claims using NCPDP[4] values as applicable." Manual Section 2.5 also states that "[e]ffective March 1, 2021," Network Providers that identify a drug claim as a "340B claim" must submit an "N1" transaction to Respondent within 10 business days of identification.

18. The "Submission Clarification Code" and "Software Vendor/Certificate ID" in the Bulletin and Manual Section refer to data fields in the NCPDP current format for submitting pharmacy claims to payers and PBMs[5], including Respondent, for adjudication (*i.e.*, validation of eligibility) and payment. The "N1 transaction" refers to an NCPDP format for submitting information relating to a previously submitted pharmacy reimbursement claim.

19. The Complainants filed the instant complaint ("Complaint") on March 4, 2021, with the West Virginia Offices of the Insurance Commissioner. The Complaint alleged that the claims submission policies that require pharmacies to identify 340B drugs post adjudication violate PAIA, W. Va. Code § 33-51-1, *et seq.* *See* Compl. at 1.

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[4] National Council for Prescription Drug Programs
[5] Pharmacy Benefit Manager

20. The Respondent's Bulletin and Manual Section provisions solely applies to Covered Entities that own pharmacies and Contract Pharmacies when those entities dispense drugs purchased under the 340B program, and do not apply to any other pharmacies.

21. The Respondent's Bulletin and Manual Section provisions relating to 340B drug claim identification solely apply to drugs purchased under the 340B Program.

22. Complainants have proffered that a Covered Entity or Contract Pharmacy must make a factual determination using external information to determine whether drugs purchased by a Covered Entity can be used to fill a pharmacy claim, including:

a. whether the individual to whom the drugs will be dispensed is a "patient" of the Covered Entity under federal guidance from the Health Resources and Services Administration ("Patient Guidance");

b. whether the prescriber has a requisite relationship with the Covered Entity under the Patient Guidance;

c. whether the Covered Entity service resulting in the prescription is consistent with the scope of the Covered Entity's grant (for grantee Covered Entities) under the Patient Guidance;

d. whether the Covered Entity maintains complete records of the care leading to the prescription;

e. and other factual considerations that are not known to the dispensing pharmacy at the time a drug is actually dispensed to the patient and billed for reimbursement.

23. Complainants have proffered that compliance with the Bulletin and Manual Section requires a Covered Entity or Contract Pharmacy to perform work outside of the normal

activities of dispensing a drug to a pharmacy customer and make an adjustment to the way in which a claim is typically billed, either at the time the drug is dispensed or through a special retrospective transaction submitted manually after the original dispense and adjudication. [6]

24. Specifically, the Complainants claim Express Scripts, a PBM, as of March 1, 2021, requires that pharmacies use a post claim adjudication modifier to distinguish retail and 340B submissions. The Complainants allege this procedure violates W. Va. Code § 33-51-9(d), by characterizing this new policy as a forbidden under the Act.

25. On or about June 11, 2021, the Insurance Commissioner of the State of West Virginia (hereinafter "Commissioner"), acting through Supervising Attorney Jeffrey C. Black, notified Complainants and Respondent that Hearing Examiner Mark Carbone would hold a hearing on July 13, 2021, regarding the allegations raised in the Complaint. The hearing will determine whether the Respondent is in violation of W.Va. Code § 33-51-9(d) or the W.Va. Code of State Rules § 114-99-5.7.[7] The hearing was rescheduled for August 19, 2021, following a continuance requested by Respondent and granted by the Hearing Examiner.

26. On July 27, 2021, while this action was pending, the Office of the Insurance Commissioner approved a proposed legislative rule which explicitly redefines the term "other adjustments" for the purposes of § 33-51-9(d). *See* W. Va. Code St. R. § 114-99-5.7 (2021 Amendments). Once this is approved by the Commissioner, the proposed rule is then forwarded

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[6] The Complainants point out that the Respondent's new policies require this information to be submitted within ten days of the filling of the prescription, however, there are occasions when the patient does not even pick up the drugs until later than ten days.

[7] The two requirements are identical in relevant part as of September 2021, all references to § 33-51-9(d) of the West Virginia Code should be interpreted to be references to § 114-99-5.7 of the West Virginia Code of State Rules, and vice versa.

to the Legislative Rule Making Review Committee (hereinafter "LRMRC'). If approved by the LRMRC, the proposed rule is then sent to the Legislature for final approval.

27. During a pre-hearing conference on August 6, 2021, the Hearing Examiner ordered pre-hearing briefing on the legal and factual issues raised in the Complaint, Respondent's Response, and Complainants reply to that Response. The Hearing Examiner determined that the hearing on August 19, 2021, would focus on the legal issues, and that fact witnesses would be called later if deemed necessary.

28. Prior to the August 19, 2021, hearing, the parties held a prehearing conference at which time both parties suggested that the issue presented by the Complaint could be decided as a matter of law, without the need for testimony from any witnesses or other evidence. The undersigned agreed to this procedure but asked that the parties include in their briefs any proffer of facts that might bear on the issues to clarify whether any factual testimony might be required.

29. Complainants submitted their brief in support of their claims on August 11, 2021, to which Express Scripts filed its response brief on August 17, 2021.

30. The matter having been fully briefed, both parties appeared for and presented arguments at an August 19, 2021, hearing before the undersigned Hearing Examiner.

31. At the end of the hearing, it was determined that each party would submit a proposed Order and Proposed Findings of Fact and Conclusions of Law. The parties were scheduled to submit their proposals by September 3, 2021. Each Party complied and submitted their proposed Order and proposed Findings of Fact and Conclusions of Law by September 3, 2021.

ISSUE

Whether the Respondent violated W.Va. Code § 33-51-9(d) when it required the Complainant to use a post claim adjudication modifier to identify 340B drug submissions.

Burden of Proof

The Complainants have the burden of proof to prove, by a preponderance of the evidence, that the Respondent violated the insurance laws of the State of West Virginia.

Jurisdiction

The West Virginia Offices of the Insurance Commissioner has jurisdiction over this Complaint under W.Va. Code § 33-2-3.

Analysis

Simply stated, the Complainant alleges that the new submission procedure required by the Respondent violates the PAIA. The procedural change by the Respondent requires the Complainants to insert a new modifier on post adjudication submissions. The purpose of this modifier is to clarify that the filled prescription is either retail or a 340B type of prescription. The Complainant states that this requirement is over burdensome and costly, thus violating W.Va. Code § 33-51-9(d), which states as follows:

> PHARMACY AUDIT INTEGRITY ACT.
>
> *§33-51-9. Regulation of pharmacy benefit managers.*
>
> d) A pharmacy benefit manager, or any other third party, that reimburses a 340B entity for drugs that are subject to an agreement under 42 U.S.C. § 256b shall not reimburse the 340B entity for pharmacy-dispensed drugs at a rate lower than that paid for the same drug to pharmacies similar in prescription volume that are not 340B entities, and shall not assess any fee, charge-back, or other adjustment upon the 340B entity on the basis that the 340B entity participates in the program set forth in 42 U.S.C. §256b.
>
> (Hereinafter, "PAIA" or "Act")

Through oral arguments and the submitted briefs, neither party is asserting that the new requirement by the Respondent is either a fee or a chargeback as forbidden in the Code. The issue is whether the new requirement is an "other adjustment", as listed in the statute.

The Complainants allege that the change by the Respondent will force the Complainants to incur additional expenses. According to the Complainants, the additional expenses will occur by forcing the Complainants to go back and review every transaction within ten days of the filling of the prescription to determine whether it was a 340B transaction. Once it identifies that a transaction was a 340B transaction, the Complainants will then have to resubmit the claim and identify it as such.

The first cost identified by the Complainants was the transaction fees they would incur from both the switch companies and the PBM.[8] There was testimony that a switch fee can cost between $.20 to $.40 per submission. In addition to the charges from the switch companies and the PBM, there are time and labor costs for each of the Complainants. While it is difficult to quantify the labor and time costs, however, the Complainants proffered that the amount may be a significant amount of money for the Complainants.

Both the Complainant and the Respondent rely on arguments concerning which standard should be used to arrive at the correct interpretation of the Act. However, the Parties do agree that the starting point in any analysis is to first look at the plain meaning of the statute.

The Complainant first cites Devane v. Kennedy, 519 SE2d 622 (W.Va. 1999) to indicate that the analysis must begin with a plain reading of the Act. In Devane the West Virginia

[8] There was no evidence as to what charge that the PBM would charge for processing a new submission.

Supreme Court states that "[w]here the language of a statutory provision is plain, its terms shall be applied as written and not construed." Devane at 632.

The Complainants argue that there are key words in the statute which must be reviewed to ascertain the plain meaning of the statute. The Complainants believe that that the key words in the statute are "assess" and "other adjustment". As to the issue of the meaning of assess, the Complainants argue that the term means the "imposition of something such as a tax or fine..." The Complainants go on to argue that the imposition of the new claim requirement is simply the Respondent assessing a fee on the Complainants.

Also, the Complainants argue that the imposition of the new claim requirement will automatically cause the Complainants to incur additional submission costs with the switch companies and the PBM. In addition, they argue that there are also labor and time costs associated with each resubmission.

The Complainants' argument is that the word "assess" is applicable to not only the words "fee" and "charge-back" but also to the words "other adjustment". If one interprets that the word "assess" is related to the words "other adjustment", then the Complainants believe that the Respondent's change is simply another assessment against the Complainants. By changing the reporting requirements, the Complainants' assert that the effect is that the Respondent is assessing additional costs, as well as, the time and labor costs associated with the change. Therefore, under the Complainants' argument, the word "assess" is applicable to "other adjustment", the new submission is just another cost assessed by the Respondent and is forbidden under the Act.

The Respondent takes the opposite view, and contends that the plain meaning of the statute does not indicate that "other adjustment" are to be assessed but the term should be applied to the word "reimburse" to determine whether other adjustments are fees or charge-backs. In other words, something that reduces reimbursements.

The Respondent's argument concerning the plain meaning of the statute requires that you review the statute in context. The Respondent cites W.Va. Human Rights Commission v. Garretson, 196 W.Va.118, 468 S.E. 2d 733 (1996) in support of their position. Garretson states that "A statute is interpreted on the plain meaning of its provision in the statutory context, informed when necessary, by the policy that the statute was designed to serve." The Respondent goes on to argue that the policy that the statute was designed to serve is reimbursements. Therefore, the terms "other adjustment", "fees" and "charge-back" are only applicable to reimbursements, and since the costs that the Complainant's contend that they are incurring with the new reporting requirements are not related to reimbursements, the Respondent argues that interpretation by the Complainants cannot be correct.

The undersigned agrees that the first step in any statutory analysis is a plain reading of the Act to determine the plain meaning. However, neither party is correct in their interpretation of a plain reading of the Act.

The first part of the Act indicates that a PBM cannot reimburse a 340B entity at a rate lower than the rate paid to non-covered entities. Following that statement concerning drug reimbursement rates is the word "and". By using this word, the legislature, in addition to requiring the PBM to not reimburse the 340B entity at a rate lower than other entities, intends to forbid the PBM from assessing the covered entities any fees, charge-back or other

adjustments. The key words to this interpretation of the Act are the words that follow "and shall not access any fee, charge-back or other adjustment". The words "upon the 340B entity or the basis that the 340B entity participates in the program set forth in 42 U.SC. 256b" can only mean that a PBM cannot cause the entity to incur "fee, charge-back or other adjustment' due solely to the fact that the entity is a 340B entity.

Contrary to the position of the Respondent, the plain meaning of the Act is to deal with discrimination by PBMs against covered entities and does not solely address reimbursements. If the context of the statute was simply reimbursements, there would be no need to have the second admonition about fee, charge-back or other adjustment. By including the second potential violation in the Act, the legislature was indicating there is also a violation if there is discrimination by PBMs against covered entities. The Act does not limit these discriminatory actions solely to reimbursements.

The plain meaning of the Act indicates that the first violation in the statute would be to reimburse a 340B entity at a lower rate than the reimbursement rate paid to a non 340B entity. The second violation contained in the statute is to assess the 340B entity any fee, charge-back or other adjustment because the entity participates in the program found in 42 U.S.C. §256b.

Both violations deal with discriminatory action against 340B entities by a PBM. With this understanding of the statute the term "other adjustment" would encompass anything that results in discrimination against a covered entity when compared to an entity that does not participate in the 340B program.

The new submission requirement by the Respondent is only applicable to covered entities that dispense 340B drugs and not to non-covered entities. In other words, under the new procedures, the Complainants, would be required to perform an action that other pharmacies and entities would not. To process the new submission requirements, according to the Complainants, the Complainants would incur additional expenses that non-covered entities would not be forced to incur.

By forcing the covered entities to incur additional expenses, the Respondent is discriminating against the covered entities, which is obviously against the protections contained within the Act. Therefore, the language of the Act is not ambiguous and based on the plain reading of the statute, the Respondent's new requirements violate W.Va. Code § 33-51-9(d) due to its discriminatory nature.

Assuming arguendo, that the plain reading of the statute, as described above, is incorrect, the Respondent argues that one must then look at the canons of statutory construction. The Respondent states that the principle of *ejusdem generis* is applicable to the instant action. In support of this argument, the Respondent cites Parkins v. Londeree, 146 W. Va. 1051, 124 S.E.2d 471 (1962). Parkins states "where general words follow the enumeration of particular classes of person or things, the general words will be construed as applicable only to persons or things of the same general nature or class as those enumerated."

This argument implies that the words "other adjustment" is referring to "fees" and "charge-back," therefore, is limited to items like those words. In Parkins, the Court defined the term "other employees" as being interpreted by the words that immediately preceded it, "all officers, policemen" id at 1061. Therefore, the term "other employees" was limited to

only include officers and policemen. Under this argument, the term "other adjustment" can only refer to fees and charge-backs.

The Complainants also refer to the rule of *ejusdem generis* in its argument. Unlike the Respondent, the Complainants state that this rule is not applicable to the instant matter. The Complainants argue that for this rule to apply, the words "other adjustment" must be a subset of the general terms, "fee" and "charge-back". It goes on to state that the general term must be interpreted narrowly such that it only includes things of the same class as the general term. Vector Co. v. Bd. of Zon. App. (City of Martinsburg), 184 S.E.2d 302, 303-304 (W.Va. 1971).

The Complainants assert that since the terms "fee" or "charge-back" are not a form of "other adjustment" then the Legislature intended that the term "other adjustment" to mean something different than "fee" or "charge-back". This analysis, according to the Complainants, allows the Act, under the term "other adjustment', to capture all forms of cost, harm, or burden that a PBM may impose on the 340B entity, thus prohibited by the PAIA.

Another argument, made by the Respondents, is that the rule of *noscitur a sociis* [9] supports its argument that the meaning of "other adjustment" "may be ascertained by reference to the meaning of other words or phrases with which it is associated" Wolfe v. Forbes, 159 W.Va.34, 44, 217 S.E.3d 899, 905 (1975).

Based on this rule of construction, the Respondents argue that all three terms in the Act, "fees", "charge back" and "other adjustment" refer only to the term reimbursement. The

[9] The meaning of the term *noscitur a sociis* is literally "it is known from its associates."

Respondent then asserts that any other interpretation of "other adjustment" would refer to non-reimbursement rate topics.

The reliance on either the rule of construction *ejusdem generis* or *noscitur a sociis*, by the Respondent, assumes that the purpose of the Act is limited to reimbursements. As discussed above, a plain reading of the Act is that it deals with discrimination against 340B entities, whether it be concerning reimbursements, fees, charge-backs or other adjustment. Therefore, neither argument concerning rules associated with statutory construction are applicable. These rules are only used when a statute is ambiguous, and, as stated above, the plain reading of the Act indicates that it is not ambiguous.

In support its interpretation of the meaning of the Act, the Complainants also invoke the canon *in pari materia*. *Pari materia* requires one to look at the surrounding material to determine the correct interpretation of an ambiguous provision. In Longwell v. Bd. Of Educ. of County of Marshall, 583 S.E.2d 109, 114 (W.Va. 2003) the West Virginia Supreme Court of Appeals held the following:

> "A Statute should be so read and applied as to make it accord with the spirit, purposes, and objects of the general system of law of which it is intended to form a part, it being presumed that the legislators who drafted and passed it were familiar with all existing law applicable to the subject matter, whether constitutional, statutory, or common, and intended the statute to harmonize completely with the same and aid in the effectuation of the general purpose and design thereof, if its terms are consistent therewith."

The Complainants assert, based on the legislative history of the Act, that it is the Legislature's intent to regulate the behavior of PBMs. To that end, Complainants argue that if the intent of the Legislature is to regulate the behavior of the PBMs it is only natural that

the Commissioner's proposed legislative rule is in line with that intent and should be given great weight.

The final arguments made by the parties is whether the proposed legislative rule submitted to the LRMRC by the Commissioner is binding upon this decision. The Complainants argue that the recommendation of the proposed rule by the Commissioner which define the words "other adjustment" is simply a clarification of the definition of "other adjustment" in the current Act. This clarification would include the Respondent's new procedures, thus they would be in violation of W.Va. Code § 33-51-9(d). Simply stated, the Complainants' argument is that under the proposed legislative rule the intent of the Commissioner is clear.

The Respondent argues that the proposed legislative rule is simply that, a proposal. The Respondent asserts, that as a proposal, the rule has no effect on the interpretation of the current Act and current legislative rules.

The Respondent's position is that to use a proposed legislative rule to interpret the Act, is not allowed since the legislative rule that has not yet been approved by the Legislature. While the Respondent concedes that the proposed legislative rule may reflect the Commissioner's view on what should be prohibited by the Act, but that cannot be applied now until the Legislature approves the proposed rule.

The Respondent asserts that if the undersigned's decision is based on the proposed legislative rule or endorses that rule, prior to approval by the Legislature, that would undermine the legislative process and be a violation of the separation of powers.

In support of its position, the Respondent cites State ex rel. Mountaineer Park, Inc. v. Polan, 190 W.Va. 276, 280, 438 S.E.2d 308, 312, (1993), which states "an administrative agency can only

exercise such powers as those granted by the legislature and if such agency exceeds its statutory authority, is (???) action may be nullified..." The Respondent also cites the Administrative Procedures Act, W.Va, Code §29A-3-9, which in relevant parts states as follows:

"Such final agency approval of the rule under this section is deemed to be approval for submission to the Legislature only and does not give any force and effect to the proposed rule. The rule shall have full force and effect only when authority for promulgation of the rule is granted by an act of the Legislature and the rule is promulgated pursuant to the provisions of section thirteen of this article."

Based on this provision of the Administrative Procedures Act, any interpretation of the Act that uses the Commissioner's proposed rule violates the Constitution of West Virginia Article 5 Section 1. This article deals with the separation of powers and states as follows:

> Division of Powers 1. The Legislative, Executive and Judicial Departments shall be separate and distinct, so that neither shall exercise the powers properly belonging to either of the others; nor shall any person exercise the powers of more than one of them at the same time, except that justices of the peace shall be eligible to the Legislature.

In other words, if the undersigned bases his decision on a proposed legislative rule, he would encroach on those powers that are specifically reserved to the Legislature and violate the West Virginia Constitution.

Finally, the Respondent states that if an interpretation of the statute, which is penal in nature, is based on arguments outside the text of the Act, the action would be a violation of the void-for-vagueness doctrine. The Respondent cites Papachristou v. City of Jacksonville, 405 U.S.156, 162 (1972) for the proposition that the law must give notice that a particular conduct is not allowed for the law to be valid.

The Complainants look at the proposed legislative rule differently from the Respondent, they state that the proposed legislative rule is simply the Agency's interpretation of the rule

as it currently stands. In addition, the Complainants urge that when interpreting a statute, "the construction of such statute by the person charged with the duty of executing the same is accorded great weight." Pa. & W. Va. Supply Corp. v. Rose, 368 S.E.2d 101, 106 (W.Va. 1988). By stating this, the Complainants are saying that the Commissioner's opinion of the meaning of the Act should be given great weight, since he is charged with executing the Act. Therefore, the opinion expressed by the Commissioner in the comments to the proposed legislative rule, should be controlling as to the meaning of the words "other adjustment". If the argument of the Complainants is accurate, then the words "other adjustment would not be directly referring to "fees" or "charge-back."

The undersigned agrees with the Respondent that this opinion cannot be based on the proposed legislative rule. While it may be true that the proposed legislative rule may reflect the opinion of the Commissioner, it is still a proposed rule which has not be approved by the Legislature. I agree with the contention that putting this rule into effect prior to approval by the Legislature, would be a breach of the separation of powers and forbidden by the West Virginia Constitution. Therefore, this decision is not based on the proposed legislative rule in any shape or manner.

The basis of this decision is on a plain reading of the Act. The purpose of the Act is to keep PBMs from discriminating against 340B entities, simply because they are 340B entities. To that end, the Act forbids paying reimbursements to a 340B entity at a lower rate than to non-participating entities. In addition, the Act forbids a PBM from charging fees or charge backs to 340B entities. Contrary to the argument of the Respondent, these words do not only apply to reimbursements but to any fee or charge-back forced upon a 340B entity.

With that being said, the key issue is whether the change in the submission policy by the Respondent falls under the category of "other adjustment". The Respondent did not challenge the Complainants' assertion that the change in its submission policy would cost the Complainants time and money. While no testimony was taken to quantify the additional costs, it is immaterial. The only important fact is that the change does cost the Complainant.

The Legislature, by using the words "other adjustment" they were using a phrase design to regulate any costs to covered entities that would be discriminatory. It is obvious that those entities not participating in the 340B program will not have to submit any identifier for 340B transactions. Therefore, the 340B entities will be forced to incur expenses that other not-participating entities will not have to pay. Therefore, the fact that 340B entities must pay costs that other entities don't have to pay, is discriminatory on its face and a violation of W.Va. Code § 33-51-9(d).

Finally, the Respondent states that if an interpretation of the statute, which is penal in nature, is based on arguments outside the text of the Act, the action would be a violation of the void-for-vagueness doctrine. The Respondent cites Papachristou v. City of Jacksonville, 405 U.S.156, 162 (1972) for the proposition that the law must give notice that a particular conduct is not allowed for the law to be valid.

It is unknown, at this point, whether the Commissioner will impose any monetary penalty on past violations of this Act. It was represented to me, that the Respondent has not been requiring the Complainants to follow the new submission procedures. Assuming that is true, there would be no need to assess and monetary penalty since there has been no violation. However, whether to impose any penalty for past actions will be deferred to the

Commissioner to determine what, if anything, to do if there has been a past violation by the Respondent.

Conclusions of Law

The following are made as conclusions of law:

1. The Complainants have the burden to prove, by a preponderance of the evidence, that the Respondent's change in its submission policies violated the insurance laws of West Virginia.

2. The West Virginia Offices of the Insurance Commissioner has jurisdiction over this Complaint under W.Va. Code § 33-2-3.

3. The first step in analyzing the meaning of a statute is to look at the language of the statute.

4. If "the language of a statutory provision is plain, its terms shall be applied as written and not construed." Devane v. Kennedy 519 S.E.2d 622 (W.Va. 1999)

5. A plain reading of W.Va.Code § 33-51-9(d) indicates that the meaning of the Act is to regulate PBMs in such a way that the PBM does not discriminate against 340B entities when compared to non 340B entities.

6. The rules of statutory construction of *ejusdem generis, noscitura sociis* and *pari materia* are not applicable to the interpretation of W.Va. Code § 33-51-9(d) since the plain reading of the Act indicates the meaning of the Act.

7. W.Va. § 33-51-9(d) forbids the Respondent from discriminating against 340B

entities when it comes to reimbursements, fees, charge-backs, or other adjustments.

8. The term "other adjustment" refers to any requirement by the PBM that causes the covered entities to incur additional costs that non-covered entities do not incur.

9. The new policy of the Respondent concerning submissions will force the Complainants to incur costs from the switch companies, PBMs, as well as, labor and time costs.

10. A proposed legislative rule does not have the force of law until the rule is approved by the LRMRC and approved by the Legislature.

11. This decision is based solely on the plain meaning of the Act and is not based on the proposed legislative rule submitted to the LRMRC by the Commissioner.

12. There was no evidence presented to show prior violations by the Respondent, however, the Commissioner can determine if there are past violations, and if so, what penalty if any, will be assessed.

Recommended Decision

It is recommended that the Complainants proved, by a preponderance of the evidence, that the Respondent's new submission policy is discriminatory and violates W.Va. Code § 33-51-9(d) since the costs associated with this change will be assessed on 340B entities and not upon other similar entities.

Respectfully recommended,

Mark W. Carbone

MARK W. CARBONE
HEARING EXAMINER

Date: Nov 17, 2021