STATE OF WEST VIRGINIA
Offices *of the* Insurance Commissioner

James A. Dodrill
Insurance Commissioner

December 5, 2019

The Honorable Mac Warner
West Virginia Secretary of State
Building 1, Suite 157-K
1900 Kanawha Blvd., East
Charleston, WV 25305

Re: Comments Received Concerning 114 CSR 99

Dear Secretary Warner,

During the public comment period for the above-referenced Legislative Rule relating to pharmacy auditing entities and pharmacy benefit managers, the Offices of the Insurance Commissioner ("OIC") of the Department of Revenue received comments from fifteen persons or entities, including independent and chain pharmacies, pharmacy associations, a pharmacy benefit managers association, a pharmacy benefit management company, a hospital association, a hospital network, a community health center association, and a health insurer association. Of the fifteen comments received, twelve were supportive of the rule. These twelve comments came from local hospitals, primary care provider groups, independent and chain pharmacy associations, and pharmacists. Two comments from organizations representing pharmacy benefits managers ("PBMs" or "PBM") and health insurance companies generally expressed concern over the rule. One comment from a group representing benefit administrators expressed neither support nor concern, but suggested a clarification. The comments are attached and individually addressed below.

The Mountain Health Network, which administers Cabell Huntington Hospital and St. Mary's Medical Center, indicated general support for the rule and specifically praised the rule's provisions offering protection for the federal 340B Prescription Drug Program. The West Virginia Hospital Association likewise expressed general support and applauded the support for the 340B Program. The West Virginia Pharmacists Association also generally voiced support for the rule.

Three owners or operators of independent pharmacies (J. Scott Boyd, Jason Turner, and John Hickman) submitted comments that generally announced support for the proposed rule. Two other independent pharmacy owners (Ali Gregg and Fred Gregg) also expressed support and commented that the rule could be improved if it included an anti-steering provision (*i.e.*, a provision prohibiting PBMs and insurance affiliates from "steering" patients to certain pharmacies). Ali Gregg also questioned whether the OIC could address the practice known as spread pricing. Without addressing the merits of "anti-steering" legislation passed in other states or the merits of prohibiting the practice of "spread pricing," the OIC notes that the *Pharmacy Audit Integrity Act*, W.Va. Code § 33-51-1 *et seq.*, does not prohibit these practices, so they were not prohibited in the rule. However, "steering" is prohibited in regard to 340B entities.

A comment offered by EHiM, a pharmacy benefit management company, requested that language be inserted into the rule providing for an exemption for self-insured plans subject to the federal Employee Retirement Income Security Act of 1974 ("ERISA"). In response to this comment, the OIC states that the *Pharmacy Audit Integrity Act* already provides for such an exemption. More specifically, W. Va. Code § 33-51-8(f) states: "The requirements of this section, and any rules promulgated by the Insurance Commissioner pursuant to §33-51-9(f) of this code, do not apply to the coverage of prescription drugs under a plan that is subject to [ERISA] or any information relating to such coverage." The OIC believes that the statutory language is sufficient to exempt ERISA plans from the rule's applicability, and no amendment to the rule is necessary.

The West Virginia Primary Care Association provided a comment suggesting that the definition of "340B entity" include vendors who contract with pharmacies to assist in the administration of the 340B Program. The OIC responds that the definition which appears in the rule mirrors the definition contained in the *Pharmacy Audit Integrity Act.* Thus, the OIC believes that any difference between the statute and rule may cause confusion. Moreover, the OIC believes that the protections afforded to a 340B entity under the federal 340B Prescription Drug Program would be applicable to any vendor that would contract with a 340B entity. The association also voiced its concern that "healthcare insurer" and "third party," as those terms are defined in the rule, are not expressly mentioned in the penalties section (§114-99-9) and thus the section could be interpreted as not being applicable to those entities. Pursuant to another comment, discussed below, the definition of "healthcare insurer" has been removed from the rule. Also, the OIC responds that the penalties section of the rule is applicable to the entities subject to the *Pharmacy Audit Integrity Act* as defined and set forth therein. Specifically, W.Va. Code § 33-51-4 sets forth the procedures for conducting audits and those procedures are applicable to an entity conducting an audit. The term "auditing entity" is defined in W.Va. Code § 33-51-3, as well as the rule. Likewise, W.Va. Code §§ 33-51-8 and 9 apply to "pharmacy benefit managers" as that term is defined in W.Va. Code § 33-51-3, as well as the rule.

EPIC Pharmacies, which purportedly has twenty-five pharmacy stores in West Virginia, indicated support for the rule and offered several changes to bolster the regulatory oversight of PBMs. It was first suggested that the rule provision prohibiting PBMs from requiring their network pharmacists to not inform consumers about lower cost drug alternatives, commonly described as "gag clauses," be strengthened. To do so, EPIC proposed that the rule direct a PBM to provide a statement during the licensure process describing how the PBM is in compliance with the rule's anti-gag clause provision. The OIC believes that the addition of such language is unnecessary since the licensing process requires a PBM to submit a copy of its standard, generic contract template, provider manual or other items incorporated by reference which it uses for contracts entered into with pharmacists, pharmacies or pharmacy services administrative organizations. The OIC can review the template to ensure compliance.

EPIC also recommended rule language requiring a PBM to submit a 30-day notice to an in-network pharmacy and the OIC with respect to amendments made to either the network contract

or pharmacy user manual that is provided by the PBM to the pharmacy. The OIC believes that such a requirement is better left to the discretion and negotiation of the contracting parties.

Concerning network adequacy, EPIC urges that a PBM be required to specify the mix of mail-order benefits to physical stores in the state that may be utilized by the PBM to ensure that a PBM is not unreasonably skewing the ratio towards its mail-order pharmacies. The OIC responds by stating that the rule already requires a PBM to submit to the OIC, upon application for licensure and upon request, a network report which describes the mix of mail-order benefits and physical stores. It was further advocated by EPIC that the phrases "reasonable distance from a patient's residence" and "adequate and accessible network" be clarified. The OIC believes that specifying what would comprise a "reasonable distance from a patient's residence" could lead to situations in which PBMs would be unable to comply with such a mandate given the rural nature of the state. What is a "reasonable distance" for someone living in Charleston compared with a person residing in a more rural county would likely be considerably different. Likewise, a clarification as to what constitutes an "adequate and accessible network" may not consider all of the situations that may be unique with respect to particular PBMs. Thus, the OIC believes that clarifying the subject phrases may result in unintended consequences and accordingly will not make any rule changes as a result of EPIC's comments about this issue. However, to clarify a PBM's reporting obligations, the OIC has added paragraph 4.5.a.4 to state that a PBM's failure to provide the Commissioner with its network report may result in the suspension or revocation of its license pursuant to W.Va. Code §33-51-8(d)(2) and (3).

EPIC finally recommends that "healthcare insurer" and "third party" be explicitly made applicable to the penalties section of the rule. As stated, pursuant to another comment discussed below, the definition of "healthcare insurer" has been removed from the rule. Again, the penalties section of the rule is applicable to the entities subject to the *Pharmacy Audit Integrity Act* as defined and set forth therein. W.Va. Code § 33-51-4 sets forth the procedures for conducting audits and those procedures are applicable to an entity conducting an audit. The term "auditing entity" is defined in W.Va. Code § 33-51-3, as well as the rule. Likewise, W.Va. Code §§ 33-51-8 and 9 apply to PBMs as that term is defined in W.Va. Code § 33-51-3, as well as the rule.

The West Virginia Independent Pharmacy Association ("WVIPA") signaled strong support for the rule and provided suggestions to further heighten the regulation of PBM activities. It was recommended by the WVIPA that a PBM be required to indicate in its licensure application whether it has been sanctioned, fined, or penalized for any reason by a state or federal entity. The OIC believes that the addition of such language would be useful and has amended the rule to reflect the addition of this language. The WVIPA also proposed the addition of new language to the rule that would require healthcare insurers to monitor, on an annual basis, the number of claims paid to pharmacies that were below the national average drug acquisition cost ("NADAC"). According to the WVIPA, the NADAC generally represents the actual acquisition cost ("AAC") of prescription drugs. The WVIPA advocates that all pharmacy claims be paid at the minimum AAC plus a professional dispensing fee so that PBMs are not allowed to consistently reimburse pharmacies below AAC and thus threaten the viability of the state's pharmacies. Without

addressing the merits of legislation passed in other states setting minimum pricing for reimbursement, the OIC notes that the *Pharmacy Audit Integrity Act* does not set minimum pricing for reimbursement, so this was not addressed in the rule. Additionally, the introduced version of Senate Bill 489 (2019) did include language regarding reimbursement minimums, but this language was removed from the bill before final passage. Accordingly, the OIC will not make any amendments to the rule in response to this comment.

It is further recommended by the WVIPA that the rule contain a provision prohibiting a PBM from providing a higher pharmacy claim reimbursement amount to a pharmacy owned by, or affiliated with, the PBM. WVIPA asserts that such a practice is not equitable and puts network adequacy at risk. Without addressing the merits of this proposal by WVIPA, the OIC notes that that the *Pharmacy Audit Integrity Act* does not prohibit this practice so this practice was not prohibited in the rule. Additionally, the introduced version of Senate Bill 489 (2019) did include language prohibiting this practice, but that prohibition was removed from the bill before final passage. Thus, the OIC will not revise the rule in response to this comment.

WVIPA also proposes that the terms "healthcare insurer" and "third party" appear in the penalties section of the rule so that these entities are expressly made subject to the state's regulatory scheme regarding PBMs. As previously stated, the definition of "healthcare insurer" has been removed from the rule. Again, the penalties section of the rule is applicable to the entities subject to the *Pharmacy Audit Integrity Act* as defined and set forth therein. W.Va. Code § 33-51-4 sets forth the procedures for conducting audits and those procedures are applicable to an entity conducting an audit. The term "auditing entity" is defined in W.Va. Code § 33-51-3, as well as the rule. Likewise, W.Va. Code §§ 33-51-8 and 9 apply to PBMs as that term is defined in W.Va. Code § 33-51-3, as well as the rule.

The National Association of Chain Drug Stores ("NACDS") submitted a comment letter in support of the rule and proposed changes for "additional protections against harmful PBM audit practices." It is first recommended by the NACDS that the word "properly" be removed in the following language of §114-99-5.2.c: "A claim for pharmacist services shall not be retroactively denied or reduced after adjudication of the claim by a PBM acting as an auditing entity unless: ... [t]he pharmacist services were not *properly* rendered by the pharmacy or pharmacist." (Emphasis added.) NACDS argues that inclusion of "properly" in the provision would allow a PBM to solely determine whether a service is appropriately rendered and that PBMs may exploit this discretion "to deny pharmacy claims based on potentially species criteria." This comment is persuasive. In response thereto, as well as in response to the Pharmaceutical Care Management Association's comment regarding subsection 5.2, the OIC believes that it would be less confusing and less problematic if the language in 5.2 was more closely reflective of the specific language in W.Va. Code § 33-51-4(a)(12) and (13) regarding fees, charge-backs, recoupments, or other adjustments for a dispensed product. Accordingly, the OIC will revise subsection 5.2 of the rule.

NACDS also suggested the following changes: (1) Prohibit PBMs from conducting an audit of a pharmacy more than once per year; (2) Require that audits use the same standards and

parameters as similarly situated pharmacies audited by the PBM, with all audits being conducted in accordance with generally accepted accounting principles and by a person with the requisite expertise in pharmacy practice; (3) Provide that any unintentional clerical or record-keeping error shall not constitute fraud or be subject to criminal penalties unless there is proof of intent to commit fraud; (4) Prohibit a PBM from assessing any chargebacks when unintentional errors have no financial harm to the patient or plan; (5) Prohibit PBMs from invalidating any pharmacy claim that is compliant with current Board of Pharmacy rules and have been positively adjudicated upon claim submission by the PBM (except for situations of fraud, duplicate claim, or service not rendered); and (6) Prohibit PBMs from requiring pharmacies to agree to recoupments against future remittances. Without addressing the merits of these suggestions, the OIC notes that that the *Pharmacy Audit Integrity Act*, specifically W.Va. Code § 33-51-4, already sets forth explicit procedures for conducting pharmacy audits and prohibits certain practices. Thus, the OIC will not propose amendments to the rule in response to these suggestions by the NACDS.

A health insurer association, America's Health Insurance Plans ("AHIP"), generally expressed concern over the rule, stating it believes that many of the rule provisions "go well beyond the authority of the OIC granted by the statute and are contrary to legislative intent." The OIC disagrees with this comment. The *Pharmacy Audit Integrity Act* provides rulemaking authority to the OIC in three separate sections. W.Va. Code § 33-51-8(a)(4) provides that the Insurance Commissioner shall promulgate and set forth a legislative rule providing for any information the OIC considers necessary and appropriate to establish the qualifications of a PBM to receive a license and to complete the licensure process. W.Va. Code § 33-51-8(c)(1) provides that the Insurance Commissioner shall propose legislative rules establishing the licensing, fees, application, financial standards, and reporting requirements of PBMs. W.Va. Code § 33-51-10 states broadly that the OIC may propose rules for legislative approval that are necessary to effectuate the provisions of this article. In promulgating this rule and the terms therein, the OIC is not attempting to act beyond its authority, but is instead acting to fulfill the mandate of the Legislature. To clarify the OIC's rulemaking authority, the OIC has proposed an amendment to § 114-99-1.2 to add W.Va. Code § 33-51-8, in addition to W.Va. Code §§ 33-51-10 and 33-2-10.

More specific to the individual rule provisions, AHIP comments that the term "healthcare insurer" is not defined in the enabling statute and that another, synonymous term, "covered entities," is already defined and utilized in the rule. Thus, AHIP opines that there is no need for the term "healthcare insurer." As previously stated, the term "healthcare insurer" has been removed from section 6 of the rule. Specifically, the removal of section 6 makes the rationale to define "healthcare insurer" moot.

AHIP also requests that the rebate reporting provisions set forth in §114-99-7.3 be removed. The association argues that such provisions are outside the scope of the *Pharmacy Audit Integrity Act*, would be operationally difficult, and do nothing to assist in controlling the cost of drugs and drug benefit plans. The OIC disagrees in part, and agrees in part, with this comment. W.Va. Code § 33-51-8(c)(1) provides that the Insurance Commissioner shall propose legislative rules establishing the reporting requirements of PBMs. Additionally, the OIC has the regulatory

responsibility to approve or disapprove premium rate charges for individual and group accident and sickness insurance and is statutorily obligated to ensure the health insurance premium rates are reasonable in relation to the benefits provided. The rise in prescription drug costs is one of the price drivers for health insurance and prescription drugs account for a significant portion of a health insurer's annual expenditures. The subject rebate reporting provisions will not only assist the OIC in ensuring that PBMs are properly adhering to W.Va. Code § 33-51-9, but will also assist the OIC in evaluating premium rates for accident and sickness insurance. However, the OIC does agree that handling such a large amount of data on a quarterly basis could be operationally difficult for this agency. Thus, in response to this comment and a comment from PCMA discussed herein below, the OIC has agreed to amend subsection 7.3, now subsection 6.3, to provide that the reporting be submitted by the PBM to the OIC upon request, as opposed to quarterly. This change will allow the OIC to target its reporting requirements to its regulatory responsibilities and will be less operationally burdensome on the OIC and PBMs.

AHIP further suggests that the rule provision requiring a PBM to submit, during the initial licensure process, a copy of its "standard, generic contract template" that the PBM utilizes for contracts entered into by it with pharmacies be deleted. AHIP asserts that the enabling legislation does not require such a filing, the OIC does not have the authority to request or review provider contracts, and the provision of these contracts to the OIC would create an expectation that the OIC is authorized to alter such contracts or change contractual terms affecting rates paid to pharmacies. The OIC disagrees with this comment from AHIP and states that it does have authority to review the standard, generic contract templates. Additionally, the OIC is not requesting, reviewing or negotiating individual provider contracts, or the rates therein, but reviewing the PBM's standard, generic template to ensure that it does not contain terms that are prohibited by the *Pharmacy Audit Integrity Act*. Further, W.Va. Code § 33-51-8(e)(1) provides that the OIC can examine or audit the books and ***records*** of a PBM to determine whether it is in compliance with the *Act*. Further, W.Va. Code § 33-51-8(a)(4) generally provides that the PBM licensure application can request any information the Insurance Commissioner considers necessary and appropriate to establish the qualifications to receive a license as a PBM, as set forth by legislative rule, and W.Va. Code § 33-51-8(c)(1) also provides that the Insurance Commissioner shall propose legislative rules establishing the licensing, fees, application, financial standards, and reporting requirements of PBMs. Regardless, the OIC has agreed to add a clause to the end of this subsection to clarify that the OIC is reviewing the standard, generic contract template for the specific purpose of ensuring it does not violate W.Va. Code § 33-51-9.

AHIP next recommends that, instead of requiring PBMs to provide a description of their network service areas by county as set forth in subdivision 4.2.m of the rule, that this provision be revised to require a PBM to describe the type of networks offered to covered entities. AHIP also alleges that Qualified Health Plans ("QHP") must be accredited by NCQA or URAC, which includes meeting standards for network adequacy and access. The OIC disagrees with this comment from AHIP. The OIC is specifically tasked with enforcing W.Va. Code § 33-51-8(d) and is solely requesting information from the PBMs regarding network services areas by county and its pharmacy directory list for a covered entity to ensure compliance therewith. Additionally,

W.Va. Code § 33-51-8(d)(2) specifically provides that ***a PBM***, not a covered entity, shall provide its network report describing its network and mix of mail-order to physical stores in this state in a time and manner required by rule of the OIC. In order for the PBM to provide the OIC with a report detailing its "mix" of mail-order to physical stores, it would necessarily have to provide more information than a general description of the type of network offered to covered entities or health insurers. Moreover, NCQA and URAC are not state or federal regulatory entities, but are private, non-profit organizations. NCQA's network adequacy standards do not include pharmacy benefits. Upon information and belief, URAC does maintain a PBM accreditation program, but any network reports that may be provided by a PBM to URAC are not provided to the OIC. Additionally, the OIC does not receive the network reports that a covered entity provides to NCQA or URAC, but only receives a general certificate of accreditation from the covered entity. Accordingly, obtaining a network report from the PBM is not duplicative for the OIC and the *Pharmacy Audit Integrity Act* requires that the PBM, not a covered entity, provide its network report to the OIC.

AHIP requests that the rule provision pertaining to spread pricing be removed. §114-99-4.2.n provides: "If the PBM is engaged in spread pricing for a covered entity, an explanation regarding whether or not the PBM is assuming risk for the covered benefit, and how, for payment of the covered prescription benefits of health insurance policies[.]" AHIP posits that spread pricing is "not a matter of risk transfer, but the payment of a fee to the PBM for their services." Thus, AHIP argues that a PBM would be unable to explain a risk-assuming role. Initially, the OIC would note that the subsection provides that the PBM is only required to provide an explanation of whether or not the PBM is assuming risk for the covered benefit if it engages in spread pricing. If the PBM is not assuming risk for the covered benefit, then the PBM need not explain its risk assuming role. Further, W.Va. Code § 33-51-8(c)(1) provides that the Insurance Commissioner shall propose legislative rules establishing the financial standards and reporting requirements of PBMs. Additionally, as noted, the OIC has the regulatory responsibility of approving or disapproving premium rate charges for individual and group accident and sickness insurance and is statutorily obligated to ensure the premium rates for health insurance are reasonable in relation to the benefits provided. The subject spread pricing reporting provision will not only assist the OIC in ensuring that PBMs are properly adhering to W.Va. Code § 33-51-9, but will also assist the OIC in evaluating premium rates for accident and sickness insurance (health insurance). The information requested is not only relevant to the financial solvency of the PBM, but also relevant to the rate review process for insurers.

AHIP also suggests that subsection 5.8 of the rule be clarified. That subsection states: "Termination of a pharmacy or pharmacist from a PBM network shall not release the PBM from the obligation to make any payment due to the pharmacy or pharmacist for pharmacist services properly rendered." AHIP recommends that this provision be amended to note that any such payments must be "(1) authorized for payment under the terms and conditions of the contract, and (2) rendered prior to the termination of the pharmacy or pharmacist from the PBM network." The OIC responds to this comment by noting that use of the phrase "properly rendered" in the subject rule provision is indicative that the pharmacy claim must be in accordance with the PBM contract

and has occurred while the contractual relationship between the PBM and pharmacy was in effect. However, the OIC agrees to amend the subsection for clarity purposes as follows: "Termination of a pharmacy or pharmacist from a PBM network shall not release the PBM from the obligation to make any payment due to the pharmacy or pharmacist for pharmacist services that are authorized for payment under the terms and conditions of the contract and rendered prior to the termination of the pharmacy or pharmacist from the PBM network."

AHIP further urges that subdivisions 6.1.a and 6.1.b be removed. Those provisions are as follows:

> 6.1. For healthcare insurers using PBMs for administration of pharmacy benefits of its health benefit plans, a healthcare insurer shall:
>
> 6.1.a. Reasonably ensure that the reimbursement or compensation of pharmacists or pharmacies does not adversely impact participation of pharmacists or pharmacies in its health benefit plans.
>
> 6.1.b. Develop a mechanism or system with its PBM to track or monitor, on an annual basis, the number of pharmacists or pharmacies which terminated their network participation with the healthcare insurer or PBM network due to reduction in compensation[.]

It is argued by AHIP that health insurers and PBMs are not in a position to evaluate how a pharmacy may or may not be adversely impacted by their participation in a network. AHIP further asserts that a healthcare insurer has no mechanism by which it could determine if a pharmacy has terminated its network affiliation because of a reduction in compensation. In response to this comment, the OIC states that AHIP's assertions are persuasive. The OIC agrees that it could be difficult for an insurer to comply with section 6 of the rule if the insurer is not in a position to assess what does and does not adversely impact participating pharmacies or because the reason for the termination is not provided to the insurer. The two subdivisions addressed in AHIP's comments are essentially the only substantive provisions of that section. Thus, the OIC agrees to remove section 6 from the rule and renumber the subsequent sections. However, the OIC believes that having insurers report on the number of pharmacies terminating their network participation is valuable information with respect to the assessment of the PBM's network and whether premium rates are reasonable in relation to the benefits provided. Thus, the OIC will amend the rule to include the following new subsection in section 7 pertaining to network adequacy: "7.5. For covered entities using PBMs for administration of pharmacy benefits of its health benefit plans, the covered entity shall, upon request, provide the commissioner with the number of pharmacists or pharmacies that have terminated their network participation with the covered entity."

AHIP next takes issue with subdivision 4.1.b of the rule, which permits the OIC to use its discretion in fixing the initial term of a PBM's license. AHIP requests that the rule corresponds with the enabling statute by calling for a 2-year licensure term. The OIC responds to this comment

by stating that it would be more efficient for the OIC's tracking and processing of renewal applications if the renewal period for PBM licensure began on the same date each year. In other words, it would be administratively inefficient in terms of the OIC's workload for each PBM to have its own distinct licensing schedule. Other entities licensed by the OIC are on standardized renewal schedules. Thus, subdivision 4.1.b was included in the rule to permit the OIC to adjust the period of initial licensure so that the license issued to each PBM would expire on a certain month and day of the year, which would correspondingly cause the 2-year renewal period to begin on the day following expiration and standardize the renewal process/schedule over time. Pursuant to the rule, the term of the initial license may be slightly longer or slightly shorter than two years, but the renewal license for each PBM would be two years. The OIC believes the *Pharmacy Audit Integrity Act* supports the inclusion of this provision since W.Va. Code § 33-51-8(c)(1) provides that the Insurance Commissioner shall propose legislative rules establishing the licensing requirements of PBMs.

It is also asserted by AHIP that the rule provision prohibiting a PBM contract with a pharmacy from restricting disclosure of information to the OIC, law enforcement, or state and federal officials investigating a complaint is not supported by the *Pharmacy Audit Integrity Act* and could lead to the disclosure of proprietary information. AHIP requests that if the provision is to remain in the rule, any information provided should be expressly protected as confidential information and not subject to release under Chapter 29B of the West Virginia Code. In response, the OIC believes the subject rule provision is reasonable in that a PBM contract should not usurp the authority of a regulatory agency or law enforcement official with regard to obtaining information that is pertinent to the oversight responsibilities of the agency or official. The OIC further responds that any information provided to it by a PBM would be done so under sections 4, 7 or 8 of the rule, each of which contain a provision stating that any information provided pursuant to the respective section is confidential and protected from public disclosure. Additionally, persons engaged in the business of insurance are already subject to reporting requirements in the *Insurance Fraud Prevention Act*, Chapter 33, Article 41 of the *West Virginia Code*, that may be applicable. Thus, the OIC will offer no revisions to the rule as a result of this comment.

AHIP concludes its comments by noting that the penalties section of the rule does not set forth a process to appeal decisions issued by the OIC. The association suggests that a due process procedure be outlined in the rule. The OIC responds by stating that W.Va. Code §§ 33-2-13 and 33-2-14, as well as W.Va. Code R. § 114-13-1, *et seq.*, set forth the process and procedure for hearings before the OIC and judicial review of OIC orders. This review process applies to PBMs and provides them with the same level of due process provided to other entities regulated by the OIC.

The Pharmaceutical Care Management Association ("PCMA") submitted comments regarding many of the rule provisions. PCMA first commented generally that "the proposed rule goes well beyond the [Pharmacy Audit Integrity] Act, establishing new policies and requirements not contemplated by the Legislature or authorized by the statute." Again, the OIC disagrees with this comment. The *Pharmacy Audit Integrity Act* provides rulemaking authority to the OIC in

three separate sections. W.Va. Code § 33-51-8(a)(4) provides that the Insurance Commissioner shall promulgate and set forth a legislative rule providing for any information the OIC considers necessary and appropriate to establish the qualifications of a PBM to receive a license and to complete the licensure process. W.Va. Code § 33-51-8(c)(1) provides that the Insurance Commissioner shall propose legislative rules establishing the licensing, fees, application, financial standards, and reporting requirements of PBMs. Finally, W.Va. Code § 33-51-10 states broadly that the OIC may propose rules for legislative approval that are necessary to effectuate the provisions of this article. In promulgating this rule and the terms therein, the OIC is not acting beyond its authority, but is instead fulfilling the mandate of the Legislature.

PCMA begins its specific remarks by asserting that "healthcare insurer" is unnecessary considering the term "covered entity" is already defined and used within the proposed rule. As stated, the OIC has agreed to remove the definition of "healthcare insurer" in response to a comment provided by AHIP.

PCMA also expresses concern that the term "spread pricing" is defined, noting that the term is not used in the underlying statute and does not serve the legislative intent of the *Pharmacy Audit Integrity Act*. Thus, PCMA posits that the appearance of the term is outside the scope of the enabling statute. The OIC responds that the term "spread pricing" is defined in the rule because 4.2.n requires reporting by PBMs to the OIC regarding risk assumption and spread pricing and by reiterating that W.Va. Code § 33-51-8(c)(1) provides that the Insurance Commissioner shall propose legislative rules establishing the reporting requirements of PBMs. Additionally, the OIC has the regulatory authority to approve or disapprove premium rate charges for individual and group accident and sickness insurance and is statutorily obligated to ensure the health insurance premium rates are reasonable in relation to the benefits provided. As stated, the rise in prescription drug costs is one of the price drivers for health insurance and prescription drugs account for a significant portion of a health insurer's annual expenditures. The spread pricing reporting provision will not only assist the OIC in ensuring that PBMs are properly adhering to W.Va. Code § 33-51-9, but will also assist the OIC in evaluating premium rates for accident and sickness insurance (health insurance).

The rule provision allowing the OIC discretion with respect to the initial licensure term of a PBM is next addressed by PCMA. The association contends that any such term should be for a 2-year period to remain consistent with the *Pharmacy Audit Integrity Act*. A similar comment by AHIP was addressed above in which the OIC responded that it believed it had support in the *Pharmacy Audit Integrity Act* for the inclusion of this rule provision considering W.Va. Code § 33-51-8(c)(1) provides that the Insurance Commissioner shall propose legislative rules establishing the licensing requirements of PBMs, and this rule provision is only intended to standardize the renewal schedule of PBMs much the same as other regulated entities.

In discussing the rule's application filing fee provision, which permits the OIC to charge ***up to*** $10,000 to fund the OIC's regulatory responsibilities, PCMA states that $10,000 would be excessively high and not in conformity with what other states charge. PCMA suggests a fee of

$1,000 for the initial application and $500 for renewals. As previously stated, the OIC appreciates the input of the PCMA regarding its preference for low licensing fees and has independently researched the fees charged in other states. The fees from state to state vary widely depending on the state's registration or licensing and enforcement structure and the length of the licensure term. PCMA specifically notes that both Maryland and Kentucky have fees lower than $10,000. However, Maryland does not ***license*** PBMs, but ***registers*** PBMs. Also, the Maryland statute provides that the Maryland Insurance Administration sets the registration and renewal fee, much the same as the West Virginia statute does, but the Maryland state code does not set a fee cap. Thus, while it may be accurate to state that the Maryland Insurance Administration has currently set its registration fee at $250.00, it is inaccurate to infer that the Maryland Insurance Administration does not have the authority to raise or lower the fee as necessary. In Kentucky, PBMs are licensed with a $1,000 fee set forth in statute, but that is an annual fee as opposed to a biennial fee as West Virginia law provides. Additionally, however, Kentucky law provides that its Department of Insurance may impose a separate and additional fee upon PBMs to cover the costs of implementation and enforcement of its PBM legislation which can include the costs of salaries and benefits to department personnel, technology costs related to enforcement and education and training costs for enforcing personnel. Regardless of the differences in fees, the *Pharmacy Audit Integrity Act* was intended to be revenue neutral in that it specifically provides that the application fees and renewal application fees ***must be sufficient*** to cover the OIC's duties in relation thereto, but a single fee may not exceed $10,000. The OIC will endeavor to keep fees as low as possible, but it intends to set the initial fee and renewal fees in compliance with the *Act*.

PCMA proposes that the rule provisions regarding ways in which a PBM may prove the statutory requirement of having $1 million in financial responsibility be deleted. PCMA states that the rule unnecessarily expands upon the statutory language. The OIC disagrees with this comment from PCMA. W.Va. Code § 33-51-8(b)(4) requires a PBM application be accompanied by evidence of financial responsibility in the amount of $1 million. Further, W.Va. Code § 33-51-8(a)(4) generally provides that the PBM licensure application can request any information the Insurance Commissioner considers necessary and appropriate to establish the qualifications to receive a license as a PBM, as set forth by legislative rule and W.Va. Code § 33-51-8(c)(1) provides that the Insurance Commissioner shall propose legislative rules establishing the financial standards of PBMs. The OIC posits that subsection 4.2.e of the rule does not expand unnecessarily upon the statutory language, but merely sets forth acceptable ways in which a PBM may submit evidence of the required financial responsibility. The OIC believes that by enumerating the ways in which a PBM may demonstrate that it has $1 million in financial responsibility, the subject rule provisions support and clarify the underlying statutory provision.

With respect to the rule's requirement that a PBM submit a standard, generic contract template it uses with a pharmacy, PCMA asserts that the enabling legislation does not contemplate the filing of such contracts as a condition of licensure and that such a requirement does not agree with the legislative intent of the *Pharmacy Audit Integrity Act*. As stated previously, the OIC disagrees with this comment and maintains that it has the authority to examine the records of a PBM and is reviewing the PBMs standard, generic template to ensure that it does not contain terms

that are prohibited by the *Pharmacy Audit Integrity Act*. W.Va. Code § 33-51-8(e)(1) provides that the OIC can examine or audit the books and records of a PBM to determine whether it is in compliance with the *Act*. Further, W.Va. Code § 33-51-8(a)(4) generally provides that the PBM licensure application can request any information the Insurance Commissioner considers necessary and appropriate to establish the qualifications to receive a license as a PBM, as set forth by legislative rule, and W.Va. Code § 33-51-8(c)(1) also provides that the Insurance Commissioner shall propose legislative rules establishing the licensing, fees, application, financial standards, and reporting requirements of PBMs. Regardless, as stated hereinabove, the OIC has agreed to add a clause for clarification on to the end of the relevant subsection.

It is suggested by PCMA that the rule provision concerning a PBM's submission of an audited financial statement be deleted because the underlying statute makes no mention of financial statements and a licensee need only produce evidence of $1 million in financial responsibility. The requirement to provide a financial statement is set forth at subdivision 4.2.k of the rule, which pertains to initial licensure, and at paragraph 4.4.a.2 of the rule, which concerns licensure renewal. PCMA states that if the OIC believes that these provisions should remain in the rule, then the provisions be amended to permit the submission of consolidated financial statements. The OIC disagrees with the comment from PCMA regarding removal of this provision of the rule and states that PBMs are currently licensed and regulated as Third-Party Administrators and are already required to provide audited financial statements as part of that process. However, the OIC agrees that consolidated financial statements are permissible if applicable. W.Va. Code § 33-51-8(a)(4) generally provides that the PBM licensure application can request any information the Insurance Commissioner considers necessary and appropriate to establish the qualifications to receive a license as a PBM, as set forth by legislative rule. Further, W.Va. Code § 33-51-8(c)(1) provides that the Insurance Commissioner shall propose legislative rules establishing the licensing, fees, application, financial standards, and reporting requirements of PBMs. Finally, W.Va. Code § 33-51-8(e)(1) provides that the OIC can examine or ***audit the books*** and records of a PBM to determine whether it is in compliance with the *Act*. The OIC believes that it presently has the authority to accept consolidated financial statements. However, the OIC will amend the rule to explicitly state that consolidated audited financial statements may be submitted, if applicable.

PCMA comments further that the requirement for a PBM to provide a description of the projected population of covered individuals to be administered by the PBM is duplicative given that covered entity filings would already contain such information, and the provision is outside the scope of the underlying statute. As discussed hereinabove, the filings of covered entities do not contain such information in regard specifically to PBM networks or pharmacy networks and, thus, it is not duplicative for the OIC. The OIC further responds by again asserting that W.Va. Code § 33-51-8(a)(4) generally provides that the PBM licensure application can request any information the Insurance Commissioner considers necessary and appropriate to establish the qualifications to receive a license as a PBM, as set forth by legislative rule. Moreover, W.Va. Code § 33-51-8(c)(1) provides that the Insurance Commissioner shall propose legislative rules establishing the application and reporting requirements of PBMs.

An amendment to subdivision 4.2.m of the rule is also recommended by PCMA. This subdivision, which requires a PBM to provide its network service areas by county and its pharmacy directory list for a covered entity, is, according to PCMA, beyond the scope of the law and unnecessary to determine compliance with the underlying statute. PCMA suggests that the subsection be changed to require a PBM to report on the types of networks it has (*i.e.*, mail order services and physical stores). The OIC disagrees with this comment from PCMA. The OIC is specifically tasked with enforcing W.Va. Code § 33-51-8(d) and is solely requesting information from the PBMs regarding network services areas by county and its pharmacy directory list for a covered entity to ensure compliance therewith. Additionally, as previously stated, W.Va. Code § 33-51-8(d)(2) specifically provides that a PBM shall provide its network report describing its network and mix of mail-order to physical stores in this state in a time and manner required by rule of the OIC. In order for the PBM to provide the OIC with a report detailing its "mix" of mail-order to physical stores, it would necessarily have to provide more information than a general description of the types of networks it has.

With respect to the requirement that PBMs engaged in spread pricing explain to the OIC if it is assuming risk for the covered benefit, PCMA asserts that the rule provision is beyond the scope of the law. PCMA also maintains that PBMs do not assume risk, stating that a "health insurer has already assumed its PBM costs into its financial solvency calculations in accordance with West Virginia law." As stated previously, the OIC disagrees with this comment. Again, the OIC would note that the subsection provides that the PBM is only required to provide an explanation of whether or not the PBM is assuming risk for the covered benefit if it engages in spread pricing. If the PBM is not assuming risk for the covered benefit, then the PBM need not explain its risk assuming role. Further, W.Va. Code § 33-51-8(c)(1) provides that the Insurance Commissioner shall propose legislative rules establishing the financial standards and reporting requirements of PBMs. Additionally, the OIC has the regulatory responsibility to approve or disapprove premium rate charges for individual and group accident and sickness insurance and is statutorily obligated to ensure the health insurance premium rates are reasonable in relation to the benefits provided. The subject spread pricing reporting provision will not only assist the OIC in ensuring that PBMs are properly adhering to W.Va. Code § 33-51-9, but will also assist the OIC in evaluating premium rates for accident and sickness insurance (health insurance).

PCMA suggests a revision to subdivision 4.2.p of the rule, which requires a PBM to inform the OIC whether it "had a business relationship with an insurance company terminated for any alleged fraudulent or illegal activities[.]" It is posited by PCMA that the use of the word "alleged" is not an appropriate standard and thus should be stricken and replaced with "legal finding or judgment of." The OIC agrees that the term "alleged" is problematic and will amend the subdivision as suggested. However, as noted, persons engaged in the business of insurance are already subject to reporting requirements in the *Insurance Fraud Prevention Act*, Chapter 33, Article 41 of the *West Virginia Code* that may be applicable.

It is further requested by PCMA that subdivision 4.2.q be amended. This subdivision mandates, in part, that a PBM provide information in which the OIC considers "necessary or appropriate . . . to establish the qualifications of the PBM to hold a license or to evaluate the financial condition of the PBM relative to the services it administers, or proposes to administer, for covered entities in this state." PCMA contends that the *Pharmacy Audit Integrity Act* solely establishes what the OIC should assess regarding a PBM's financial condition and that the statute clearly provides for it - the financial responsibility standard of $1 million. Thus, PCMA asserts that "[t]here is no additional need to evaluate that responsibility relative to the services [the PBM] administers." PCMA essentially provides the same comments and suggested revision with respect to the language of paragraph 4.4.a.5 of the rule, which concerns information required to be submitted to the OIC during the licensure renewal process. In response to this comment, the OIC states that, pursuant to W.Va. Code § 33-51-8(c)(1), it is specifically required to propose legislative rules to establish the licensing, fees, application, ***financial standards***, and reporting requirements of PBMs. Further, W.Va. Code § 33-51-8(a)(4) provides that the PBM licensure application can request any information the Insurance Commissioner considers necessary and appropriate to establish the ***qualifications to receive a license*** as a PBM, as set forth by legislative rule. However, PCMA's argument is persuasive in that the clause at the end of subdivision 4.2.q and paragraph 4.4.a.5 could be confusing and OIC believes the clause is generally unnecessary since the rule already provides that the OIC can seek any other information it deems necessary to evaluate the initial application and renewal application of the PBM and to establish the qualification of the PBM to hold a license. Accordingly, the OIC will amend 4.2.q and 4.4.a.5 by striking the final clause.

PCMA also recommends that the rule provision setting forth the timeframe by which the OIC has to review a PBM application be changed from ninety days to thirty days. PCMA argues that a review of a licensure application which is limited to the statutory requirements should not take three months and that such a timeframe will unnecessarily slow the business down with no clear consumer benefit. Similarly, PCMA suggests that the timeframe for licensure renewals be adjusted to a 15-day review, as opposed to a 30-day review, if the PBM provides a written attestation that there have been no material changes from the previous application. PCMA further recommends that the renewal filing fee be specifically set forth in the rule at $500. The OIC appreciates the input of the PCMA regarding its preference for quick licensure application review and renewal application review, as well as its preference for low application and renewal fees. However, given the responsibilities of the OIC and the workload of the agency, especially considering the marked reduction in agency employees over the past two years, the timeframes provided in the rule for application review and renewal are necessary. If the OIC is able, it will complete the application review and renewal process quicker than the maximum timeframe set forth. Additionally, W.Va. Code § 33-51-8(a) provides that PBMs currently registered may continue to do business in this state until the OIC completes this rule and have six months from completion of the final rule to submit a licensure application. Accordingly, the OIC believes that PBMs have ample time to prepare for licensure and application in a manner that will not unnecessarily slow down their business. Also, as previously stated, the *Pharmacy Audit Integrity Act* specifically provides that the application fees and renewal application fees ***must be sufficient***

to cover the OIC's duties in relation thereto, but a single fee may not exceed $10,000. As previously noted herein, the *Act* was intended to be revenue neutral. To set the renewal fee at $500.00 without knowing whether that fee is sufficient to fund the Commissioner's duties in relation to his or her responsibilities would contradict the statutory language of W.Va. Code § 33-51-8(b)(3).

PCMA next addresses the language of paragraph 4.5.a.1 of the rule, which states that the OIC may deny or not renew a PBM's license if it "operates, or proposes to operate, in a financially hazardous condition relative to its financial condition and the services it administers." The association objects to the use of the phrase "financially hazardous condition relative to its financial condition," arguing that this language is vague, overly broad, unnecessary, and not tethered to the underlying statute. PCMA further argues that there are no substantive requirements in the *Pharmacy Audit Integrity Act* on which the OIC can evaluate a PBM's financial condition other than ensuring that a PBM meets the $1 million financial responsibility standard. The OIC responds by first noting that W.Va. Code § 33-51-8(e)(1) provides that the OIC can examine or ***audit the books*** and records of a PBM to determine whether it is complying with the *Act*. Further, W.Va. Code § 33-51-8(a)(4) generally provides that the PBM licensure application can request any information the Insurance Commissioner considers necessary and appropriate to establish the qualifications to receive a license as a PBM, as set forth by legislative rule, and pursuant to W.Va. Code § 33-51-8(c)(1), the OIC is required to propose legislative rules to establish, among other things, the financial standards and reporting requirements of PBMs. The OIC believes that such a review is necessary for the protection of covered individuals. However, to clarify the rule, the OIC will amend this subsection to state that the Commission shall deny an initial application or renewal if "[t]he PBM operates, or proposes to operate, in a financially hazardous condition by failing to provide or maintain evidence of financial responsibility as noted under subdivision 4.2.e of this section."

PCMA additionally expresses concern with the use of the phrase "to the extent possible" in subsection 4.7, which protects against public disclosure of proprietary and confidential information submitted to the OIC by a PBM. PCMA asserts that the quoted language makes the protection conditional and should be struck from the rule. A similar comment and suggested revision were provided by PCMA with respect to subsection 7.4 of the rule, which pertains to network adequacy and reporting requirements. The OIC does not believe the phrase "to the extent possible" makes the confidentiality provision conditional and was not meant to equivocate the OIC's intention to protect the confidential and propriety information received from PBMs to the fullest extent permitted by law, as evidenced by the fact that the proposed rule contained three confidentiality provisions. However, since the phrase is superfluous, the OIC will agree to strike it from the rule in the affected subsections or subdivisions.

PCMA requests that subsections 5.1, 5.2., 5.7, and 5.8 be removed from the rule as they have the effect of amending the *Pharmacy Audit Integrity Act* "by adding whole new obligations completely unrelated to the provisions of SB 489." In regard to PCMA's comment concerning subsection 5.1, the OIC believes the subject provision is reasonable and furthers the goals of the

Pharmacy Audit Integrity Act by prohibiting PBMs that manage pharmacy claims for covered entities from knowingly engaging in unfair trade practices that the covered entities are themselves prohibited from engaging in regarding untrue, deceptive, or misleading advertisements, promotions, solicitations, representations, proposals or offers. These practices can harm covered individuals. Additionally, PBMs have been licensed in West Virginia as Third-Party Administrators since, at least, 2009 and Third-Party Administrators are required to use only advertising pertaining to the business underwritten by an insurer that has been approved in writing by the insurer in advance of its use. (*See* W.Va. Code § 33-46-6 and *West Virginia Informational Letter 166*, February 2009). Since 2013, the Insurance Commissioner has required all life and health insurer advertising to be filed for approval with the OIC's Rates & Forms Division. However, as previously noted, PCMA's comment regarding subsection 5.2 is persuasive. The OIC believes that it would be potentially less confusing and/or problematic if the language in 5.2 was more closely reflective of the specific language in W.Va. Code § 33-51-4(a)(12) and (13) regarding fees, charge-backs, recoupments, or other adjustments for a dispensed product and will revise this subdivision accordingly. In regard to PCMA's comments concerning subsection 5.7, as previously stated, the OIC believes the subject provision is reasonable in that a PBM contract should not be permitted to usurp the authority of a regulatory agency or law enforcement official with regard to obtaining information that is pertinent to the oversight responsibilities of the agency or official. The OIC further responds that any information provided to it by a PBM would be done so under sections 4, 7 or 8 of the rule, each of which contain a provision stating that any information provided pursuant to the respective section is confidential and protected from public disclosure. Additionally, persons engaged in the business of insurance are already subject to reporting requirements in the *Insurance Fraud Prevention Act*, Chapter 33, Article 41 of the *West Virginia Code* that may be applicable. Thus, the OIC will offer no revisions to the rule as a result of this comment. Finally, in response to PCMA's comment concerning subsection 5.8, as previously stated, the OIC agrees to amend the subsection for clarity purposes as follows: "Termination of a pharmacy or pharmacist from a PBM network shall not release the PBM from the obligation to make any payment due to the pharmacy or pharmacist for pharmacist services that are authorized for payment under the terms and conditions of the contract and rendered prior to the termination of the pharmacy or pharmacist from the PBM network."

Subsection 5.3 of the rule, which concerns prohibitions on "gag clauses" in PBM contracts, is next addressed by PCMA. The association remarks that the subsection is "impermissibly inconsistent with the Act" in that the statute "does not provide for a pharmacist to advise patients on the PBM regulatory structure or contractual matters." PCMA suggests striking a certain portion of the subsection. The OIC disagrees with this statement from PCMA and states that W.Va. Code § 33-51-9 specifically provides that neither a pharmacy, pharmacist or pharmacy technician may be penalized by a PBM for discussing information "***in this section,***" referring to information in W.Va. Code § 33-51-9 and the regulation of PBMs, or for selling a lower cost alternative to a covered individual without using a health insurance policy (emphasis added). However, in response to this comment, the OIC will revise subsection 5.3 of the proposed rule, now subsection 5.4, to clarify that a pharmacy, pharmacist or pharmacy technician shall not be penalized by a PBM

for discussing information in W.Va. Code § 33-51-9 of the *Pharmacy Audit Integrity Act* or the regulation of PBMs thereunder, or for selling a lower cost alternative, if one is available, without using a health insurance policy.

PCMA notes that subsection 5.6 and subdivision 5.6.a of the rule merely restate provisions of the *Pharmacy Audit Integrity Act* and are therefore unnecessary. The OIC responds by stating it believes the importance of the federal 340B drug discount program necessitates that the rule reiterate the prohibitions expressed in the subject subsection and subdivision.

It is further asserted by PCMA that subsection 5.9 of the rule, which requires pharmacy auditing entities and PBMs to comply with the statutory requirements regarding the procedures for conducting pharmacy audits, is unnecessary because auditing entities and PBMs already have an obligation to comply with applicable laws. The OIC agrees that the subsection is unnecessary and will remove it from the rule.

PCMA also announces its strong opposition to the inclusion of section 6 of the rule, stating that the provisions attempt to regulate contract reimbursement rates. PMCA asserts that such provisions were initially contained in Senate Bill 489 but were removed by the Legislature in the final version of the bill. Thus, PCMA argues that inclusion of section 6 is "a usurpation of legislative authority and runs contrary to the intent of the statute as passed." The OIC has agreed to remove section 6 in response to another comment due to potential difficulties in how the section could practically be adhered to by healthcare insurers. However, the OIC denies that the intended purpose of section 6 was to usurp legislative authority or regulate contract reimbursement rates. The rule does not mention contract reimbursement rates.

Concerning subsection 7.3 of the rule, which requires quarterly reports that contain information about the PBM's rebating practices and reimbursement rates, PCMA again asserts strong opposition. The association states that this was an area that the Legislature considered and rejected when it enacted the *Pharmacy Audit Integrity Act*. PCMA further claims that the information contained in such reports is confidential and proprietary. Any release of such information to the public, PCMA argues, would be anti-competitive and damaging to cost control efforts in the pharmacy benefit. Moreover, PCMA asserts that such reporting would be unreasonably costly, burdensome for the OIC to handle such a large amount of data, and would not benefit the consumer in any way. Accordingly, PMCA urges that the subsection be removed from the rule. The OIC generally disagrees with this comment, as noted herein above in response to a similar comment from AHIP. However, the OIC agrees that it could be burdensome for the OIC to handle such a large amount of data on a quarterly basis. W.Va. Code § 33-51-8(c)(1) provides that the Insurance Commissioner shall propose legislative rules establishing the reporting requirements of PBMs. Additionally, as noted, the OIC has the regulatory authority to approve or disapprove premium rate charges for individual and group accident and sickness insurance and is statutorily obligated to ensure that health insurance premium rates are reasonable in relation to the benefits provided. This rate review process benefits consumers and the subject rebate reporting provisions will assist the OIC in evaluating insurance premium rates for accident and sickness

insurance. However, due to the concerns regarding the burdensome nature of routinely handling such a large amount of data, the OIC has agreed to amend subsection 7.3, now subsection 6.3, to provide that the rebate reporting be submitted by the PBM to the OIC upon request, as opposed to quarterly. This will also allow the OIC to undertake targeted collection of the data when necessary to effectuate its regulatory responsibilities.

PCMA lastly comments that subsections 9.1 and 9.2 of the rule contain arbitrary and capricious language in that the penalty for an auditing entity who fails to comply with the rules is set at no more than $2,500 per violation while a potential penalty assessed against a PBM may be up to four times that amount ($10,000). PCMA suggests that the penalty amounts be set at no more than $2,500 per violation for both PBMs and auditing entities. It is also suggested that section 9 should contain language clearly outlining the notice and hearing rights for suspension or revocation of a PBM's license. The OIC believes that the difference in penalty amounts set forth for an auditing entity versus a PBM is not arbitrary and capricious, but consistent with the regulatory scheme set forth in the *Pharmacy Audit Integrity Act*. Auditing entities are merely registered, while PBMs are now licensed. Additionally, the Legislature noted this difference when it set the fee for PBM licensure at up to $10,000, but set the fee for auditing entity registration at up to $1,000. Further, W.Va. Code §§ 33-2-13 and 33-2-14, as well as W.Va. Code R. § 114-13-1 *et seq.*, set forth the process and procedure for hearings before the OIC and judicial review of OIC orders. This review process applies to PBMs and provides them with the same level of due process provided to other entities regulated by the OIC. It is unnecessary to restate the process in this Legislative Rule.

The OIC would like to thank all of the entities that submitted comments. Their attention and time spent on this matter is greatly appreciated.

Sincerely,

Victor A. Mullins
Associate Counsel
West Virginia Offices of the Insurance Commissioner

Attachments

Mullins, Victor A

From: Scott Boyd <jeffersonrx@hotmail.com>
Sent: Monday, October 14, 2019 2:58 PM
To: Mullins, Victor A
Subject: [External] Support Rule 114CSR99 - Pharmacy Auditing Entitites and Pharmacy Benefit Managers

CAUTION: External email. Do not click links or open attachments unless you verify sender.
I am requesting your support of Pharmacy Auditing Entities and Pharmacy Benefit Managers rule 114CSR99 now before your Insurance Commission. I also hope you will support the comments made by West Virginia Independent Pharmacy Association (WVIPA). This rule will help assure consumers receive appropriate prescription drug savings and assure pharmacies are adequately reimbursed for their services. Since implementation of the Dir Fees and Clawbacks over the last 3 years, the PBM's are taking back over $100,000 this year from Jefferson Pharmacy and $85,000 from South Berkeley Pharmacy. This number does not include the 15 to 20 prescriptions a day that I now lose money on just so I can keep long standing patients as customers. Five years ago, I never lost money on a insurance claim. Now it is common place. I can NOT withstand this much longer and will be forced to close. I have been in business for 37 years, I am asking for your support.

J. Scott Boyd, R.Ph., owner
Jefferson Pharmacy, Inc.
201 S. Preston St.
Ranson, WV 25438
304-725-6533

and

South Berkeley Pharmacy
5054 Gerrardstown Road
Inwood, WV 25420
304-229-2400

Mullins, Victor A

From: Fred Gregg <efgregg1@gmail.com>
Sent: Monday, October 14, 2019 3:38 PM
To: Mullins, Victor A
Subject: [External] Pharmacy Benefit Managers legislation

CAUTION: External email. Do not click links or open attachments unless you verify sender.

Sir,

You are requested to support Pharmacy Auditing Entities and Pharmacy Benefit Managers rule 114CSR99 now before your Insurance Commission. This rule will help assure consumers receive appropriate prescription drug savings and assure pharmacies are adequately reimbursed for their services.

I would also suggest that you consider adding language found in similar legislation in Georgia:

(a) This Code section shall be known and may be cited as the 'Pharmacy Anti-Steering and Transparency Act.' (b) The General Assembly finds that: (1) The referral of a patient to a pharmacy by an affiliate for pharmacy care represents a potential conflict of interest; and (2) These referral practices may limit or eliminate competitive alternatives in the health care services market, may result in overutilization of health care services, may increase costs to the health care system, may adversely affect the quality of health care, may disproportionately harm patients in rural and medically underserved areas of Georgia, and shall be against the public policy of this state. (c) As used in this Code section, the term: (1) 'Affiliate' means a person licensed under Title 33 which, either directly or indirectly through one or more intermediaries:
(A) Has an investment or ownership interest in a pharmacy licensed in or holding a nonresident pharmacy permit in Georgia; (B) Shares common ownership with a pharmacy licensed in or holding a nonresident pharmacy permit in Georgia; or (C) Has as an investor or ownership interest holder a pharmacy licensed in or holding a nonresident pharmacy permit in Georgia. (2) 'Referral' means: (A) Ordering of a patient to a pharmacy by an affiliate either orally or in writing, including online messaging; (B) Offering or implementing plan designs that require patients to utilize affiliated pharmacies; or (C) Patient or prospective patient specific advertising, marketing, or promotion of a pharmacy by an affiliate.

Thank you for your consideration in this matter.

Sincerely,

Fred Gregg
Owner

Gregg's Pharmacy
101 Gregg Memorial Drive
Terra Alta, WV 26764

Gregg's Pharmacy
20 North Third Street
Oakland, MD 21550

Mullins, Victor A

From: Ali Gregg <ali.robinson21@gmail.com>
Sent: Tuesday, October 15, 2019 8:47 AM
To: Mullins, Victor A
Subject: [External] PBM, Spread Pricing, and 114CSR99

CAUTION: External email. Do not click links or open attachments unless you verify sender.

Good morning,

You are requested to support Pharmacy Auditing Entities and Pharmacy Benefit Managers rule 114CSR99 now before your Insurance Commission. This rule will help assure consumers receive appropriate prescription drug savings and assure pharmacies are adequately reimbursed for their services.

Additionally, how can the insurance commission address spread pricing being conducted by PBM's? Has the state considered using the Affordable Care Act's model of 80/20 - only 20% of premium money collected may be used for administrative purposes, including salaries, while the other 80% must be used to provide health care services.

Also, Georgia has a really great bill addressing Anti-Steering with PBM's that own their own pharmacies (Humana, CVS Caremark, Express Scripts, Optum). The "discount" they give to use their own networks is hurting independent pharmacies and rural access to care. I believe there should not be networks for any health care service. Any person with any health care plan should be able to use whoever doctor and whatever pharmacy they desire. Forcing someone to go to a certain location because of a "discount" (or more cash in the insurance company pocket) hurts the consumer, and puts their own agenda ahead of the patient's health.

Thank you for considering my comments. I am a huge supporter of 114CSR99 and I believe it is a fantastic start to ending the monopoly PBM's are trying to achieve.

Sincerely,
Ali Gregg, PharmD
Proud third generation pharmacist at an independent pharmacy, Gregg's Pharmacy in Terra Alta, WV

Mullins, Victor A

From: JASONTURNER@MOUNDSVILLEPHARMACY.COM
Sent: Tuesday, October 15, 2019 10:51 AM
To: Mullins, Victor A
Cc: JASONTURNER@MOUNDSVILLEPHARMACY.COM
Subject: [External] Pharmacy Comments on Rule 114 CSR 99 - Pharmacy Auditing and PBM
Attachments: PA Pharmacy Auditing of PBMs.pdf

Mr. Mullins,

As a practicing pharmacist and an independent pharmacy owner in the state of West Virginia, I want to express my appreciation for your consideration and support of Rule 114CSR99 Pharmacy Auditing Entities and Pharmacy Benefit Managers. I believe the foundations of this rule will create an environment for third party insurances/PBMs to work with pharmacies to provide the HIGHEST level of care for patients AND to maintain fair business practices between the two entities.

Keep in mind, the state of West Virginia is made up of a strong network of independent "community pharmacies" AND patients throughout the state are depending on US to provide prescription services including home delivery, immunizations, disease state counseling, and advocacy for their better health!

Unfortunately, small business are not staffed with attorneys and legal teams to defend unfair business practices when they occur – so ultimately, WE ARE DEPENDING ON YOU to improve the rules between the third party PBM/insurance and the pharmacy – with fairness, and balance, and opportunity for both entities to remain successful serving the patients of West Virginia.

Thank you again for your consideration and support,

Jason Turner, PharmD
President, Pharmacole Inc
Moundsville Pharmacy
New Martinsville Pharmacy
Pine Grove Pharmacy
Sistersville Pharmacy
(304) 845-0390

Mullins, Victor A

From: jrh3@suddenlinkmail.com
Sent: Tuesday, October 15, 2019 4:28 PM
To: Mullins, Victor A
Subject: [External] Support rule 114CSR99

CAUTION: External email. Do not click links or open attachments unless you verify sender.

Mr. Victor Mullins
WV Insurance Commission
Charleston, WV 25305

Hickman's Pharmacy
John Hickman
Roger Hickman
199 12th St. Ext
Princeton, WV 24740
304-425-2188

Mr. Mullins,

As a small independent pharmacy serving the community of Princeton, WV since 1947, we express our support for the Pharmacy Auditing Entities and Pharmacy Benefit Mangers rule proposal. We look forward to this action in helping independent pharmacies to continue serving our patients in the future.

Thank You,

John Hickman

West Virginia Independent
Pharmacy Association

Charleston Office: 2017 Quarrier Street, Charleston, WV 25311
Barboursville Office: 650 Main Street, Barboursville, WV 25504
Phone: (304) 654-4214
Fax: (304) 733-6486
Web: www.WVIPA.org
Email: matt@walkerandstevens.com

October 14, 2019

West Virginia Offices of the Insurance Commissioner
Attention: Mr. Victor Mullins
P.O. Box 50540
Charleston, WV 25305
Email: victor.a.mullins@wv.gov

Dear Mr. Mullins:

Thank you for the opportunity to review and comment on the Title 114 - Series 99 "Pharmacy Audit Entities and Pharmacy Benefit Managers" legislative rule as proposed for public comment. The following comments are being submitted by the West Virginia Independent Pharmacy Association ("WVIPA") and its members.[1] There are approximately 200 independent community pharmacies in West Virginia which employ several thousand licensed professionals and proudly provide quality pharmacy services to hundreds of thousands of patients in the Mountain State.[2]

The WVIPA applauds the West Virginia Legislature and Governor Justice for demanding regulatory oversight of pharmacy benefit managers ("PBMs"), including minimum standards for licensure, regulation, and reporting. The West Virginia Offices of the Insurance Commissioner ("OIC") is the appropriate state agency under which PBMs should be licensed and regulated. A majority of states have implemented similar regulatory structures and processes to those found in these rules.[3][4] Decades ago, PBMs were created to assist health plans with processing complicated prescription drug claims. PBMs have since deviated from this intended function, and have become greedy middle-men, resulting in skyrocketing drugs prices and a lack of transparency. Many licensed pharmacies across the nation and in West Virginia have been forced to close their doors, partly due

[1] West Virginia Independent Pharmacy Association. "Official web site of the WVIPA." [www.wvipa.org]. Retrieved 23 Sept. 2019.
[2] West Virginia Board of Pharmacy. "Official web site." [www.wvbop.com]. Retrieved 24 Sept. 2019.
[3] PBM Watch. "Official web site." [www.pbmwatch.com]. Retrieved 24 Sept. 2019.
[4] National Community Pharmacists Association. "The Voice of the Community Pharmacist." [www.ncpanet.org] Retrieved 25 Sept. 2019.

to the predatory conduct of PBMs through audits, clawbacks, direct and indirect remuneration ("DIR") fees, and below-cost reimbursement.[5] The WVIPA seeks to reverse that trend and to protect the strong network of independent community pharmacies in the Mountain State.

Under the authority granted to the OIC under *W.V. Code §33-51-10* and *W.V. Code §33-2-10*, the WVIPA firmly believes these proposed rules will properly effectuate current West Virginia law under the Pharmacy Audit Integrity Act. The WVIPA respectfully proposes the following:

Addition of the Terms "Healthcare insurer" and Third party" to *Penalties (§114-99-9)*

Relating to *Penalties (§114-99-9)*, the WVIPA respectfully proposes the addition of the terms "Healthcare insurer" and "Third party" throughout this section as those terms are defined under *Definitions (§114-99-2)*. Without this addition, there seems to be no penalty provision for non-PBMs in violation of certain provisions of this rule. For example, if a healthcare insurer or third party were to violate the certain provisions of this rule, there would be no penalty, since those organizations may not be included under the PBM definition. The addition of both terms throughout this section is essential to comply with legislative intent of the Pharmacy Audit Integrity Act.

Disclosure of Sanctions, Fines, or Penalties by States or Federal Entities

Relating to *Licensure of Pharmacy Benefit Managers (§114-99-4)*, the WVIPA respectfully proposes the following change:

> *4.2.o. A statement of whether the applicant has been refused a registration, license or certification to act as (or provide the services of) a PBM or third party administrator, ~~or~~ has any registration, license or certification to act as such been denied, suspended, revoked or non-renewed for any reason by any state or federal entity, or has been sanctioned, fined, or penalized for any reason by any state or federal entity;*

This change is necessary to provide the OIC with relevant information about sanctions, fines, or penalties from other states or federal entities which are relevant to PBM conduct in West Virginia. Nationally, several states and other entities have sanctioned, fined, or penalized PBMs in recent years for their conduct.[6] PBMs must also be held accountable for their conduct in West Virginia.

Disclosure of Below Cost Reimbursement

Relating to *Duties of healthcare insurers (§114-99-6)*, the WVIPA respectfully proposes the addition of a new provision *6.1.d* which states: "Develop a mechanism or system with its PBM to track or monitor, on an annual basis, the number of claims paid to pharmacists or pharmacies below

---

[5] Pharmacy & Healthcare Communications, LLC. "White Paper: DIR Fees Simply Explained." Pharmacy Times. [https://www.pharmacytimes.com/news/white-paper-dir-fees-simply-explained] Retrieved 11 Oct. 2019.

[6] Barlas, Stephen. "Employers and Drugstores Press for PBM Transparency: A Labor Department Advisory Committee Has Recommended Changes." *P&T : a peer-reviewed journal for formulary management* vol. 40,3 (2015): 206-8 [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4357353] Retrieved 26 Sept. 2019.

the National Average Drug Acquisition Cost ("NADAC").[7] The NADAC is based on the retail price survey and focuses on the retail community pharmacy acquisition costs. The Centers for Medicare and Medicaid Services ("CMS") has mandated that Medicaid pharmacy programs reimburse the actual acquisition cost ("AAC") of drugs, plus a professional dispensing fee. The NADAC represents the AAC in most cases. This is the process utilized by West Virginia Medicaid to ensure consistency and transparency in pharmacy reimbursement.[8] West Virginia Medicaid enrolled pharmacies are instructed that if they are being reimbursed less than AAC, they may re-bill those claims for proper reimbursement.[9] The WVIPA advocates that all pharmacy claims should be paid at the minimum of AAC, plus a professional dispensing fee. PBMs operating in West Virginia consistently reimburse pharmacies below AAC, which is unreasonable, and threatens the viability of all West Virginia pharmacies.

Reimbursement Parity and Co-Pay Parity to Protect Network Adequacy

Relating to *Duties of healthcare insurers (§114-99-6)*, and *Network adequacy and reporting requirements (§114-99-7)*, the WVIPA respectfully proposes the addition of a new provison which states: A PBM shall not reimburse a pharmacist or pharmacy owned or affiliated with the PBM a higher amount than a pharmacist or pharmacy not owned or affiliated with the PBM, including mail order-pharmacies. This language may be most appropriately added under *Prohibited acts (§114-99-5)*.

Mail-order pharmacies are overwhelmingly run by PBMs. These mail-order pharmacies have the ability to set pricing for both themselves and competitors. This advantage is often abused by PBMs through paying their own pharmacies higher reimbursement than other pharmacies, and by setting lower patient co-pays for using PBM-owned or affiliated pharmacies (both retail and mail-order).[10] This practice is not equitable and puts West Virginia's independent community pharmacy network adequacy at risk.

Thank you for your time and consideration of these comments. Please contact the WVIPA if you would like to discuss these or other issues further.

Respectfully Submitted,

Matthew R. Walker, Executive Director
West Virginia Independent Pharmacy Association

---

[7] NADAC (National Average Drug Acquisition Cost). Centers for Medicare & Medicaid Services. [https://data.medicaid.gov/Drug-Pricing-and-Payment/NADAC-National-Average-Drug-Acquisition-Cost-/a4y5-998d] Retrieved 8 Oct. 2019.
[8] Chapter 518 Pharmacy Services. West Virginia Bureau for Medical Services. [https://dhhr.wv.gov/bms/Pages/Chapter-518-Pharmacy-Services.aspx]. Retrieved 7 Oct. 2019.
[9] "NADAC Pricing for Medicaid Pharmacy Claims. West Virginia Bureau for Medical Services. [https://dhhr.wv.gov/bms/News/Pages/NADAC-Pricing-for-Medicaid-Pharmacy-claims.aspx]. Retrieved 8 Oct. 2019.
[10] Schweers, Kevin. Vice President for Public Affairs, National Community Pharmacists Association (NCPA). "Community pharmacists hear mail order complaints; debunk PBM myths." The Hill. [https://thehill.com/blogs/congress-blog/healthcare/59593-community-pharmacists-hear-mail-order-complaints-debunk-pbm-myths]. Retrieved 13 Oct. 2019.

October 15, 2019

West Virginia Offices of the Insurance Commissioner
Attention: Mr. Victor Mullins
P.O. Box 50540
Charleston, WV 25305
Email: victor.a.mullins@wv.gov

RE: Public Comment for Proposed Rule 114 CSR 99

Dear Mr. Mullins,

On behalf of EPIC Pharmacies, which includes twenty-five stores in its West Virginia Network, I write you today regarding the proposed legislative rule, WV CSR §114-99-1, *et seq.*, regulating "Pharmacy Audit Entities and Pharmacy Benefit Managers." As a general matter, EPIC Pharmacies is supportive of the West Virginia Offices of the Insurance Commissioner's ("OIC") efforts to implement the legislative rule-making requirements of SB 489.

As enacted by the West Virginia Legislature, and signed into law by Governor Jim Justice, SB 489 provides for much-needed transparency and regulatory oversight over pharmacy benefit managers ("PBMs"), which heretofore have operated without oversight or regulation in West Virginia. PBM practices in recent years have been harmful for both West Virginia's independent pharmacists, as well as the West Virginians seeking to fill their prescriptions at their local pharmacy. We think that the proposed legislative rule is a positive step towards reining in such abusive behavior. In addition to the provisions currently included in the legislative rule proposed by OIC, we respectfully propose herein several improvements to 114 CSR 99.

Prohibited Acts

As an initial matter, we would suggest two changes to WV CSR §114-99-5, which sets forth the "prohibited acts" for a PBM doing business in the state. First, WV CSR §114-99-5.3 reinforces the West Virginia Pharmacy Audit Integrity Act's prohibition on the use of "gag clauses," whereby a PBM prohibits its network pharmacists from informing consumers regarding available lower cost alternatives. We believe that this provision could be strengthened even further by requiring PBMs to include, as part of the licensure process, a description or statement as to how a PBM is in compliance with W.Va. Code provisions relating to such "gag clauses" in its contracts with pharmacists or pharmacies. Similar language is included in the Arkansas rule regulating the licensure of PBMs. Second, we would encourage the OIC to include language specifying a 30-day notification to

pharmacists and the OIC be incorporated regarding any PBM changes or amendments to either the contract or Pharmacy user/provider manuals that are provided by the PBM to pharmacy. This measure would provide greater transparency and ensure that PBMs are not skirting the prohibitions of the legislative rule through subsequent contract changes or policy amendments.

Network Adequacy

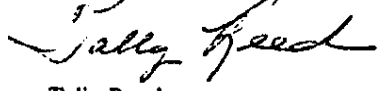
We would also suggest further clarification with respect to WV CSR §114-99-7, which sets forth a PBM's network adequacy and reporting requirements. Over the years, PBMs have been adept at changing their practices in a manner that effectively evades oversight and regulation. As such, we think that this section needs to be as specific as possible to ensure that West Virginians have access to adequate pharmacy networks. First, we think it would be beneficial to specify the mix of mail-order benefits to physical stores in state that may be utilized by a PBM. While our state law currently prohibits a PBM from relying exclusively on mail-order benefits, the rule as written would not appear to exclude a ratio that was unreasonably skewed towards a mail-order process. We think greater clarity on this front will benefit West Virginia pharmacies and patients alike. Second, the OIC should define, to the extent practicable, the term "reasonable distance from a patient's residence" as contained within §114-99-7.1. It is unclear under the proposed rule what exactly would constitute a reasonable distance, and further clarity on this front would be beneficial to West Virginians who currently lack adequate access to pharmacies.[1] It would also be beneficial to have clearer guidance as to what would constitute an "adequate and accessible" network for a PBM.

Penalties

Finally, we would recommend clarifying the penalties section of the proposed rule, §114-99-9, to clarify that the provisions would apply to a "Healthcare insurer or "Third party" as well. Otherwise, PBMs could continue to evade transparency and regulation in West Virginia through the violation of terms of the proposed rule and existing state law by either its healthcare insurer or other unregulated third parties.

We thank you for your time and consideration of these comments. To the extent that you have questions regarding any of these suggestions, or would like to discuss them further, please do not hesitate to contact me.

Respectfully Submitted,



Tally Reed
EPIC West Virginia PharmPac Chair

[1] Of note, a "rural pharmacy desert" is often defined as "any area within a 10-mile radius without ready access to a pharmacy (for those that have access to transportation)." *See* Zach Schladetsky, *Trend: What is a Pharmacy Desert?*, TELEPHARM (APRIL 8, 2017).

WV
Primary Care Association

October 15, 2019

West Virginia Offices of the Insurance Commissioner
Attention: Mr. Victor Mullins
P.O. Box 50540
Charleston, WV 25305
Email: victor.a.mullins@wv.gov

Dear Mr. Mullins:

Thank you for the opportunity to comment on the Title 114, Series 99 "Pharmacy Audit Entities and Pharmacy Benefit Managers" legislative rule, as proposed for public comment. The following comments are being submitted by the West Virginia Primary Care Association (WVPCA) and its 32-community health center organization members, including Federally Qualified Health Centers (FQHCs), FQHC Look-Alikes, and one Rural Health Clinic.[1] Community health centers provide medical homes to more than 467,000 patients, and approximately one in four West Virginians. Community health centers offer a broad range of services, including primary care, behavioral health, dental, vision, school-based health, social services, access to low-cost medications (known as the 340B pharmacy program), and more. There are more than 360 community health center sites throughout the Mountain State, employing more than 3,500 individuals, and providing significant economic benefits to the communities they serve.

Pharmacy issues can be extraordinarily complex, but, such an important, expensive area of health care requires careful consideration and sometimes extensive regulation/oversight. The West Virginia Offices of the Insurance Commissioner (OIC) have obviously given great consideration to the licensure and regulation of pharmacy benefit managers (PBMs) with these proposed rules. Fundamental to an effective, fair, and transparent pharmacy system in West Virginia is the licensure and regulation of pharmacy auditing entities and PBMs.

Because the 340B Drug Pricing Program is essential to the survival of West Virginia's safety net providers, such as community health centers and hospitals (340B covered entities), these comments focus primarily on the 340B provisions of the rule. The 340B provisions found in the Pharmacy Audit Integrity Act and these rules are meant to protect against PBM overreach such as a 2018-2019 attempt by a PBM to unilaterally create a separate and lower reimbursement structure for 340B covered entity pharmacies. This attempt was contrary to the intent and spirit of the 340B program and had to be addressed immediately. States across the country are now looking to West Virginia as one of the first states to address 340B discriminatory reimbursement.

[1] West Virginia Primary Care Association. "Official Website." [https://www.wvpca.org]; Retrieved 8 Oct. 2019.

Many 340B covered entities choose to contract with other pharmacies. Hundreds of independent pharmacies in West Virginia are "contract pharmacies" with 340B covered entities. The 340B program enables 340B covered entities to stretch federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.[2] The ability of these 340B covered entities to purchase 340B discounted drugs enables the offering of valuable services to vulnerable West Virginia patients. This program and the services it supports must be protected at all costs. The provisions contained in the Pharmacy Audit Integrity Act and these rules are essential to the continued success of the 340B program, its covered entities, and their contract pharmacies.

Under *§114-99-2. Definitions*, the following addition would provide necessary and appropriate protection for 340B covered entities and their pharmacy programs:

> *2.1. "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, ~~of~~ pharmacies, and vendors contracted with the participating entity to dispense drugs purchased through such program.*

This change will protect the management systems and processing vendors necessary for 340B covered entities to effectively operate and manage their 340B systems. It is nearly impossible for 340B covered entities to operate and manage 340B pharmacy programs "in-house," without assistance, given the complexities of Health Resources & Services Administration (HRSA) requirements, digital product inventories, audits, real-time information sharing, claim adjudication, billing, etc.[3] 340B vendors effectively become a part of the covered entity's system, and they should be protected as such. A variety of lawsuits have been filed throughout the country, as PBMs seek to force 340B covered entity pharmacies to switch to and contract with vendors that PBMs own and/or control, instead of the 340B covered entity chosen vendors.[4] [5]

Under *§114-99-9. Penalties*, the WVPCA has concerns that organizations defined in the Pharmacy Audit Integrity Act and in these rules as "healthcare insurer" and "third party" will not be subject to these penalties unless both terms are added throughout this section. Given the mergers, acquisitions, and vertical integration throughout the U.S. health care system, omitting these terms from the *Penalties* section could render the Pharmacy Audit and Integrity Act and these rules ineffective.

---

[2] U.S. Health Resources & Services Administration. "340B Drug Pricing Program - Official web site of the U.S. Health Resources & Services Administration." [www.hrsa.gov]; Retrieved 25 Sept. 2019.
[3] U.S. Health Resources & Services Administration. "340B Drug Pricing Program - Official web site of the U.S. Health Resources & Services Administration." [www.hrsa.gov]; Retrieved 24 Sept. 2019.
[4] O'Brien, Jack. "Sentry Data Gets 'Major Concessions' from CVS in 340B Lawsuit." Health Leaders. [https://www.healthleadersmedia.com/finance/sentry-data-gets-major-concessions-cvs-340b-lawsuit]. Retrieved 13 Oct. 2019.
[5] Paavola, Alia. "CVS Forced Hospitals to Drop CaptureRx Services, Lawsuit Charges." Becker's Hospital Review. [https://www.beckershospitalreview.com/legal-regulatory-issues/cvs-forced-hospitals-to-drop-capturerx-services-lawsuit-charges.html]. Retrieved 14 Oct. 2019.

Thank you for your time and consideration of these comments. The WVPCA fully supports your efforts related to this important rule. Please contact us if you have questions.

Respectfully,

Sherri P. Ferrell,
Chief Executive Officer
West Virginia Primary Care Association

West Virginia PHARMACISTS Association

2016½ Kanawha Boulevard, East
Charleston, West Virginia 25311

(t) 304.344.5302
(f) 304.344.5316

wvrds@aol.com
wvpharmacy.org

Date: October 16, 2019

To: Victor A. Mullins, West Virginia Insurance Commission
victor.a.mullins@wv.gov

From: Richard Stevens, Executive Director
West Virginia Pharmacists Association

Subject: Pharmacy Auditing and PBM - Rule 114 CSR 99

Dear Mr. Mullins:

Representing independent pharmacies throughout our State, I respectfully request your support and approval of proposed Rule 114 SCR 99 relating to the Pharmacy Auditing Entities and Pharmacy Benefit Managers (PBMs). Supported by this Association, this proposed Rule is a product of Senate Bill 489, passed by the 2019 West Virginia Legislature.

Your approval and implementation of this Rule will improve relations between West Virginia pharmacies and the various PBMs. It will improve reporting requirements of PBMs, and prohibit them from providing a network comprised only of mail-order benefits.

Of major importance to your proposed Rule is 114-99-5 which identifies specific Prohibited Acts by a PBM including "spread pricing" which is contained in 114-99-2 of your Rule.

This Association is pleased to discuss this Rule with you and your staff if you wish. Thank you for your attention to this issue.

Mullins, Victor A

From: Erin TePastte <etepastte@ehimrx.com>
Sent: Wednesday, October 16, 2019 3:32 PM
To: Mullins, Victor A
Subject: [External] PBM Comments for new legislation- 2019 WV REG TEXT 534708 (NS)
Attachments: WV PBM Regulation Comment (20191015-ert) (002).pdf

Hi Mr. Mullins,

Please find attached our comments concerning the new PBM legislation that you indicated we could submit in October 2019 when we spoke by phone at the end of September. Please let me know if you have any questions. I welcome any feedback. Thanks,

Erin R. TePastte, Esq., CHPC

EHIM

Pharmacy Benefits, Managed.
Third Party Administration

26711 Northwestern Highway • Suite 400 • Southfield, MI 48033
248.948.9900 x399 • Direct: 248.204.6395
Email: etepastte@ehimrx.com • Web: www.ehimrx.com

Mr. Mullins,

I am submitting the following comment regarding the proposed West Virginia PBM regulations.

ERISA Exemption

Upon review of the proposed regulations is appears West Virginia has not incorporated an ERISA exemption for self-insured plans. EHIM proposes that West Virginia either: (1) incorporate specific ERISA exemption language into the regulations; or (2) amend the definition of "PBM" so that PBM's administering benefits exclusively to self-insured ERISA plans are deemed to not satisfy the definition of a PBM in West Virginia.

For your reference and consideration I have included the statutory ERISA exemption language from Rhode Island and South Dakota. In addition, I have provided a non-exhaustive list of states that provide that PBM's administering benefits exclusively on behalf of self-insured ERISA plans **do not** meet definition of PBM.

Statutory ERISA Exemption Examples:

> Rhode Island General Laws § 27-20.7-2(1) states:
>
> "Administrator" means a person who directly or indirectly solicits or effects coverage of underwrites, collects charges or premiums from, or adjusts or settles claims on residents of this state, or residents of another state from offices in this state, in connection with life or health insurance coverage or annuities, except any of the following:
>
> (xii) A person who acts solely as an administrator of one or more bona fide employee benefit plans established by an employer or an employee organization, or both, for which the insurance laws of this state are preempted pursuant to the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. § 1001 et seq. That person shall comply with the requirements of § 27-20.7-12(g);
>
> South Dakota Codified Laws § 58-29D-27 states:
>
> License not required for administrator exclusively servicing certain employee benefit plans. A person is not required to hold a license as an administrator in this state if the person exclusively provides services to one or more bona fide employee benefit plans each of which is established by an employer or an employee organization, or both, and for which the insurance laws of this state are preempted pursuant to the Employee Retirement Income Security Act of 1974. Such persons shall register with the director annually, verifying their status as herein described.

Definition of PBM by Exclusion of ERISA Plans:

1. Alaska;[1]
2. Arkansas;[2]
3. Maryland;[3]
4. South Carolina[4]

---

[1] AS 21.27.630(i). Alaska regulates PBMs through their TPA statute, which includes an ERISA exemption.
[2] Arkansas Rule 118 Pharmacy Benefit Manager Licensure Act. The rule states that ERISA plans do not meet the definition of PBM. In addition, Section 10(B) of Arkansas Rule 118 provides that self-funded plans are exempt from Act.
[3] Maryland Code § 15-1601(l)(1), and (o)(2). ERISA plans do not meet definition of PBM.
[4] PBMs regulated through TPA statute. South Carolina Department of Insurance's website indicates that regulations do not apply to self-funded ERISA plans. See https://doi.sc.gov/572/Third-Party-Administrators-TPAs (last assessed October 14, 2019).

Please let me know if you have any questions or wish to discuss further.

Kind Regards,

Erin R. TePastte, Esq., CHPC

Pharmacy Benefits Manager
Third Party Administrator

26711 Northwestern Highway • Suite 400 • Southfield, MI 48033
248.948.9900 x399 • Direct: 248.204.6395

Email: etepastte@ehimrx.com • Web: www.ehimrx.com

Mountain Health Network

October 16, 2019

West Virginia Offices of the Insurance Commissioner
Attention: Mr. Victor Mullins
Email: victor.a.mullins@wv.gov
P.O. Box 50540
Charleston, WV 25305

RE: Mountain Health Network comments in regards to the Office of the Insurance Commissioner Rules: Title 114- Series 99.

Dear Mr. Mullins,

Thank you for this opportunity to review and voice comments on the "Pharmacy Audit Entities and Pharmacy Benefits Managers" Legislative Rule, Title 114-Series 99, as proposed for public comment. The following comments are being submitted by the Mountain Health Network. Mountain Health was created in 2018 with Cabell Huntington Hospital's acquisition of St. Mary's Medical Center to oversee both hospitals. Mountain Health Network is one of the largest hospital systems in West Virginia and combined have 696 beds and provide healthcare services to over one million patients in a 23 county service area.

The 340B prescription drug program is a vital lifeline for safety-net providers like Mountain Health Network, which support critical health services to the most vulnerable of patients in our community. The program is narrowly tailored to reach only hospitals that provide a high level of services to low-income individuals or that serve isolated rural communities. Savings from the 340B program help hospitals meet the healthcare needs of vulnerable, underserved patients across the country and state. Cabell Huntington Hospital and St. Mary's have provided an estimated $64 million and $20 million respectively in uncompensated care for the last year. As a "covered entity," 340B savings have enabled us to provide critical services and programs to our community. A sampling of those added programs are: clinical pharmacists as part of clinic teams to provide and develop the most appropriate medication treatment program for their patients, and education that emphasizes medication adherence; the cash card program that allows patients who meet financial criteria to purchase their medication and allows those who would otherwise be unable to afford their prescriptions to get the medication they need; we are also able to provide a

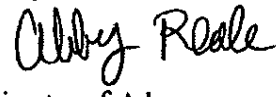
"meds to beds" program aimed at preventing re-hospitalization by ensuring patients have all prescribed medications prior to discharge; and medication assisted treatment and support to our mothers with substance use disorder through our MOMS Program and care for drug exposed babies in our neonatal therapeutic unit.

Mountain Health Network applauds the West Virginia Legislature and Governor Justice for their staunch support in demanding regulatory oversight of pharmacy benefit managers (PBMs), protection of the 340B program and all of the vulnerable West Virginians for whom the program serves! We believe the Offices of the Insurance Commissioner (OIC) is the appropriate agency under which PBMs should be regulated, licensed, and penalized, and we thank the OIC for their work to effectuate these rules and are in full support. PBMs have deviated from their intention of processing complicated prescription drug claims and have become predatory through direct and indirect remuneration "DIR fees," claw-backs and audits on the pharmacy industry and covered entities. There has been a continuous attack from PBMs and others to try and capture funds from the 340B program to pad their bottom line, without providing added services and increased access to patients. As a "covered" entity" we look forward to finally having an avenue of recourse when we come across the multitude of issues we face when dealing with PBMs.

Thank you for your work, time and consideration of our support. If you may have any questions or would like to discuss any other issues further, do not hesitate to contact us.

Respectfully submitted,

Abby Reale



Director of Advocacy
Mountain Health Network

WEST VIRGINIA HOSPITAL ASSOCIATION

100 Association Drive
Charleston, WV 25311-1571
Phone (304)344-9744
www.wvha.org

October 17, 2019

Victor Mullins
P.O. Box 50540
Charleston, WV 25305

Dear Mr. Mullins-

Re: LEGISLATIVE RULE 114CSR99, PHARMACY AUDITING ENTITIES AND PHARMACY BENEFIT MANAGERS

On behalf of the West Virginia Hospital Association and its 63 member hospitals and health systems, we respectfully submit this letter to provide public comments in support of the above referenced **Legislative Rule 114CSR99, Pharmacy Auditing Entities and Pharmacy Benefit Managers.**

This legislative rule is being promulgated because of the passage of **SB 489** during the 2019 Regular Session. The general purpose of SB489 was to provide for additional regulatory oversight of PBMs by requiring PBMs be licensed and regulated by the Offices of the Insurance Commissioner (OIC). The WVHA supports the promulgation of this rule, specifically the proposed language in **§114-99-4**, **§114-99-5**, and **§114-99-9**. We believe the regulations contained in these sections will go a long way in addressing the concerns our members have expressed relating to PBMs. These regulations will also support the continued administration and sustainability of the 340B Program, which has enabled more than 30 WVHA member hospitals and health systems to utilize the 340B Program to serve the needs of their communities.

We appreciate the opportunity to submit comments in support of this legislative rule, and we look forward to working with the OIC on this and other issues facing our hospitals.

If you have any questions or concerns, please contact me at (304) 353-9720.

Sincerely,

Brandon Hatfield
General Counsel

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

October 17, 2019

Victor Mullins
P.O. Box 50540
Charleston, WV 25305-0540

Via Email: victor.a.mullins@wv.gov

Re: West Virginia Office of Insurance Commission Proposed Rules for Pharmacy Auditing Entities and Pharmacy Benefit Managers

Dear Mr. Mullins:

On behalf of our members operating pharmacies in the state of West Virginia, the National Association of Chain Drug Stores ("NACDS") thanks the West Virginia Office of Insurance Commission ("Commission") for the opportunity to comment on proposed rules to implement the Pharmacy Audit Integrity Act ("Act").

We appreciate the Commission for acting swiftly to promulgate rules pursuant to the Act to rein in PBMs' questionable practices regarding pharmacy audits.

NACDS supports the provisions of the proposed rules, with one notable exception. Under §114-99-5.2.c, the Commission has proposed that a claim for pharmacist services may not be retroactively denied or reduced after adjudication unless the services "were not **properly** rendered by the pharmacy or pharmacist (emphasis added)." We have concerns that this language would allow a PBM to determine whether a service is properly rendered, thus giving the PBM sole decision-making authority over the practice of pharmacy and whether a pharmacy or pharmacist is properly practicing their profession; this is a determination that would be appropriate only by a person or persons with expertise in the pharmacy profession. Moreover, we fear that PBMs would essentially exploit this loophole to deny pharmacy claims based on potentially specious criteria, as has been our frequent experience.

To close this loophole and address our concerns about pharmacy practice determinations, we believe the language should be amended to delete the word "properly" so that the clause reads as "were not rendered by the pharmacy or pharmacist." Making this edit would remove PBMs' ability to deny claims based on questionable criteria and would impose a fact-based analysis, one that focuses on whether the service was actually rendered.

NACDS supports the provisions of the Act; however, we believe that the Commission could expand on some of the Act's provisions to better ensure appropriate oversight of PBM auditing practices. We provide the following recommendations for additional rulemaking based on our experiences dealing with PBMs over the years:

1. **Prohibit a PBM from conducting an audit of a pharmacy more than once per year.** This would end the abusive practice of constantly subjecting a pharmacy to audits, which are often disruptive to pharmacy operations and stress the pharmacy's ability to provide timely patient care.

2. **Require that audits use the same standards and parameters as similarly situated pharmacies audited by the PBM.** This would prevent PBMs from choosing winners and losers in the pharmacy marketplace, as it would help stop PBMs from using audit practices to punish or favor pharmacies. **Moreover, audits should be conducted in accordance with generally accepted accounting principles.**

3. To help ensure that audits are fair and accurate, **the Commission should require each audit be conducted by a field agent with the requisite expertise in pharmacy practice.**

4. To end the practice of PBMs punishing pharmacies for unintentional acts, the **Commission should state that any unintentional clerical or record-keeping error, such as a typographical error, scrivener's error, or computer error, shall not necessarily constitute fraud. Such claims may be subject to recoupment, but such claims shall not be subject to criminal penalties without proof of intent to commit fraud. In the case of errors which have no financial harm to the patient or plan, the PBM must not assess any chargebacks.**

5. PBMs commonly impose vague, arcane, or little-known requirements after-the-fact with respect to the question of whether a prescription is valid. They then use these criteria to recoup payments. Pharmacies should be able to rely on pharmacy regulations to determine whether a prescription is valid, not the vagaries of PBMs' *ex post facto* decisions. **To that end, prescriptions should be considered valid prescriptions if they are compliant with current Board of Pharmacy rules and regulations and have been positively adjudicated upon claim submission by the PBM (except for situations of fraud, duplicate claim, or service not rendered). Moreover, a PBM should not require more information than is required by state or federal law to be included in a prescription.**

6. **Finally, we recommend that the Commission prevent PBMs from requiring pharmacies to agree to recoupments against future remittances. Instead the PBM should invoice the pharmacy for any recoupment payments.** Allowing PBMs to recoup payments against future remittances places pharmacies in financial jeopardy, as pharmacies may be forced to operate without reimbursement sufficient to remain solvent.

As evidenced above, PBM audit practices place substantial financial and administrative burdens on pharmacies that often jeopardize pharmacies' abilities to remain in business. We support the vast majority of the Commission's proposed rules and we encourage the Commission to adopt additional protections against harmful PBM audit practices.

If you have any questions, please do not hesitate to contact Jill McCormack at jmccormack@nacds.org or 717-525-8962.

Regards,

Steven C. Anderson, IOM, CAE
President and Chief Executive Officer

America's Health Insurance Plans
601 Pennsylvania Avenue, NW
South Building, Suite Five Hundred
Washington, DC 20004

October 17, 2019

Victor Mullins
West Virginia Offices of the Insurance Commissioner
Post Office Box 50540
Charleston, West Virginia 25305-0540

Re: Proposed Rulemaking – Enrolled Senate Bill 489
Pharmacy Auditing Entities and Pharmacy Benefit Managers

Dear Mr. Mullins:

I write today on behalf of America's Health Insurance Plans[1] to share our concerns regarding the Offices of the Insurance Commissioner's (OIC) proposed rulemaking concerning pharmacy benefit managers (PBMs). As you know, this rulemaking is being made pursuant to the provisions of Enrolled Senate Bill 489, signed by Governor Justice on March 1, 2019, which provides for regulatory licensure and oversight of PBMs.

While we share your commitment to maintaining a fair and robust health insurance market in West Virginia, we believe that many provisions in the proposed rulemaking go well beyond the authority of the OIC granted by the statute and are contrary to legislative intent.

As health insurance providers, we are very concerned that the requirements mentioned below will have a significant impact on our ability to administer prescription drug benefits and lower drug spending for our enrollees. Moreover, we are concerned about the regulatory overreach of some of these provisions which we believe will place the OIC in a precarious position of having oversight into private provider negotiations or contractual agreements.

We respectfully recommend that the following provisions be deleted from or significantly revised in the rule.

- **In §114-99-2. Definitions, section 2.5** defines "healthcare insurer," a term that is not defined or used in the statute. The statute refers to "covered entities" and establishes a definition for this term which is also used multiple times in the proposed rule. There is no need for a new term "healthcare insurer" to be introduced in this rule.

- **§ 114-99-7.3. Rebate Reporting**. The requirements for PBMs to issue quarterly reports on rebates in this section are outside of the scope of the law. The proposed regulation includes requirements concerning aggregate rebates received by PBMs, the aggregate amount distributed to health plans, the amount passed on to enrollees at the point of sale, and the individual and aggregate amount paid by health care insurers to the PBM for pharmacist services itemized by the pharmacy, by product and by goods and services. The granular detail of the rebate reporting requirements itemized by pharmacy, product and goods and services would be operationally difficult and offer no meaningful information to consumers. More importantly, the information does not help control the costs of drugs and the cost of drug benefit plans.
- Rebates are in the agreements between health insurers and their respective PBM and are, therefore, outside the scope of Senate Bill 489. We recommend the rebate reporting provisions be deleted to align with the enabling statute.

[1] **America's Health Insurance Plans (AHIP)** is the national association whose members provide insurance coverage for health care and related services. Through these offerings, we improve and protect the health and financial security of consumers, families, businesses, communities and the nation. We are committed to market-based solutions and public-private partnerships that improve affordability, value, access and well-being for consumers.

- **In § 114-99-4. Licensure of Pharmacy Benefit Managers, section 4.2.j.** requires an initial licensure application to include "*A copy of the PBM's standard, generic contract template, provider manual or other appropriate items, incorporated by reference which it uses for contracts entered into by the PBM with pharmacists, pharmacies or pharmacy services administrative organizations in this state in administration of pharmacy benefits for covered entities;*"
    - Contracts between PBMs and their contracted providers are not required to be filed with the department under the enabling legislation. In fact, the OIC does not have the authority to request or review any provider contracts between health insurers or other downstream providers. These are private contracts that are negotiated in good faith between willing partners. Providing these contracts to the OIC creates an expectation that the OIC has the authority to alter such contracts or change contractual terms affecting rates paid to pharmacies or other providers – neither of which is authorized by law. This provision should be deleted.

- **§ 119-99-4.2m Licensure of Pharmacy Benefit Managers** requires a description of a PBM's network service areas by county. Currently, Qualified Health Plans (QHPs) must be accredited by NCQA or URAC which includes meeting standards for network adequacy and access. We recommend the regulation include a description of the type of networks offered to covered entities in the state and avoid unnecessary duplication of filing requirements.
- **In § 114-99-4. Licensure of Pharmacy Benefit Managers, section 4.2.n.** requires an initial licensure application to include "*If the PBM is engaged in spread pricing for a covered entity, an explanation regarding whether or not the PBM is assuming risk for the covered benefit, and how, for the payment of the covered prescription benefits of health insurance policies;*"
    - Spread pricing is a payment method negotiated between the insurer and the PBM that provides for pre-set pricing on a set of drugs that may have pricing variations throughout the contract. The "spread" that may result compensates the PBM for the services provided. This is not a matter of risk transfer, but the payment of a fee to the PBM for their services.
    - The "spread pricing" negotiations allow a health insurance provider to predict stable pricing for a set of drugs that help in evaluating drug spending assumptions in the premium setting process. It is unclear what kind of explanation of assumption of risk would qualify since each agreement includes the reimbursement to pharmacies along with a potential margin that helps alleviate the uncertainty of price changes in the market.
    - We believe this provision requires the PBM to explain a risk-assuming role, which is not accurate. If the preset prices for the drugs go up, the PBM is not fully compensated for its services. However, if the prices of the market basket of drugs go down, the PBM is compensated for its services. This is a service charge based on the PBMs ability to manage its costs and services effectively, it is not the unknown assumption of risk based on higher utilization in a manner that a health insurer assumes risk. Therefore, this provision should be deleted.

- **In § 114-99-5. Prohibited acts, section 5.8.** lists the following which is not provided for in the underlying statute, "*Termination of a pharmacy or pharmacist from a PBM network shall not release the PBM from the obligation to make any payment due to the pharmacy or pharmacist for pharmacist services properly rendered.*"
    - This section could require reimbursement for services provided that are not covered under the contract. Therefore, we request that this provision be clarified that the payments made would be (1) authorized for payment under the terms and conditions of the contract, and (2) rendered prior to the termination of the pharmacy or pharmacist from the PBM network.
    - Health insurance providers should not reimburse pharmacies for services that are not covered benefits, nor should reimbursement happen after the date of termination.

Further, reimbursement should follow the payment methodologies agreed to in the contract and should not be paid in some other non-contracted fashion.

- **In § 114-99-6. Duties of healthcare insurers, section 6.1.a.** requires healthcare insurers using PBMs for administration of pharmacy benefits to "*Reasonably ensure that the reimbursement or compensation of pharmacists does not adversely impact participation of pharmacists or pharmacies in its health benefit plans.*" **6.1.b.** requires these healthcare insurers to "*Develop a mechanism or system with its PBM to track or monitor, on an annual basis, the number of pharmacists or pharmacies which terminated their network participation with the healthcare insurer or PBM network due to reduction in compensation;*"
  - Health insurers are not in a position, nor is the PBM, to evaluate how a pharmacy may or may not be "adversely impacted" by their participation in a network. A pharmacy enters into privately negotiated contracts and are not mandated to enter into such contracts. If the pharmacy believes that it will be adversely impacted by the contract, it should not sign that contract or it should terminate its contract with its PSAO and/or PBM. No two pharmacies are the same, and what one may find advantageous, another may find adverse. It is inappropriate to put the health insurer in a role to make a determination of this sort on behalf of a pharmacist. Moreover, it is not authorized by the enabling statute that the health insurer take on such responsibility.
  - Through regular review of network adequacy, a health insurer monitors network participation across its network. There is no mechanism for a health insurer to evaluate that any given pharmacy terminated from the network solely due to a reduction in compensation. Again, this requirement is beyond the enabling statute and such intuition by a health insurer is an unreasonable expectation based on anecdote as opposed to real data.
  - These provisions should both be deleted.

- **In § 114-99-4. Licensure of Pharmacy Benefit Managers, section 4.1.b.** appears to grant the Commissioner authority to change the length of the term of a PBM's licensure in a manner inconsistent with the underlying statute. Senate Bill 489 states that "The term of registration shall be two years from the date of issuance" while the proposed rule would allow the Commissioner to, "in his or her discretion, fix the date of expiration regarding the initial license of a PBM in any manner as is considered by him or her to be advisable for an efficient distribution of the workload of his or her office, including fixing the date of expiration for the initial license of a PBM for a period less than or more than two years." We ask that the regulation correspond with the enabling statute by granting a two-year term.
- **§ 114-99-5.7. Prohibited acts** contains the following provision: "*A PBM's contract with a participating pharmacist or pharmacy shall not prohibit, restrict or limit disclosure of information to the Commissioner and law enforcement investigating or examining a complaint...*" This provision is not supported by the statute and could lead to the disclosure of proprietary and competitive information. We suggest that if this provision is to remain in the regulation the information needs to be protected by the confidentiality laws and exempt from disclosure pursuant to Chapter 29B of the West Virginia Code.
- **§ 114-99-9. Penalties** does not provide a process to appeal decisions by the Commissioner. We would request appropriate due process be outlined in the rule so that any issues can be adequately addressed. Health insurance providers cannot immediately cancel their contract with a PBM that were to lose its license or face significant penalties. We believe it is prudent to ensure a fair and balanced appeals process that would be given to any other licensee under the authority of the OIC.

Please do not hesitate to contact me at mhaffenbredl@ahip.org (202-413-9817) should you have any questions about these comments.

Sincerely,

Mary Haffenbredl

Mary Haffenbredl
Regional Director, State Affairs, AHIP

PCMA

October 17, 2019

Mr. Victor Mullins
West Virginia Insurance Commission
PO Box 50540
Charleston WV 25305-0540

Via email: victor.a.mullins@wv.gov

Re: Pharmacy Auditing Entities and Pharmacy Benefit Managers Rulemaking PCMA Comments

Dear Mr. Mullins:

I am writing to provide the Pharmaceutical Care Management Association (PCMA) comments on the West Virginia Insurance Commission's proposed rule implementing SB 489 (2019) and its changes to the Pharmacy Audit Integrity Act (the "Act"), enacted earlier this year. PCMA is the national trade association representing pharmacy benefit managers (PBMs), which manage prescription drug benefits for large and small employers, health insurance carriers, labor trusts, government programs, and other payers. We appreciate the opportunity to submit comments on the proposed rule and would be happy to discuss our comments further before the rule is finalized.

At the outset, we note that SB 489 established licensing requirements for pharmacy auditing entities and pharmacy benefit managers. The final enacted version of this bill was different than the bill that started in the legislative process. The Legislature opted to change the bill significantly during the session, signaling an intent to keep it to the limited licensing provisions that were enacted. The proposed rule, however, includes a number of provisions that fall out of scope of the law, are unnecessary to implement the law, and create new substantive provisions that the Legislature did not adopt.

While administrative agencies generally have the ability to provide clarity or further guidance to regulated entities through rulemaking, "the rules and regulations must be reasonable and conform to the laws enacted by the Legislature. *See Anderson & Anderson Contractors, Inc. v. Latimer*, 162 W. Va. 803, 807–08, 257 S.E.2d 878, 881 (1979). Indeed, "[t]o be valid, a regulation promulgated by an administrative agency must carry out the legislative intent of its governing statutes." *Moore v. K-Mart Corp.*, 234 W.Va. 658, 663, 769 S.E.2d 35, 40 (quoting *Hale v. W.Va. Office of Ins. Com'r*, 228 W.Va. at 785, 724 S.E.2d at 756 (2012)). Critically, rules and regulations will only be upheld if "they are reasonable and do not *enlarge*, amend or repeal substantive rights created by statute." *Hale*, 228 W.Va. at 786, 724 S.E.2d at 757 (quoting Syl. Pt. 4, *State ex rel. Callaghan v. W.Va. Civil Serv. Comm'n*, 166 W.Va. 117, 273 S.E.2d 72 (1980)) (emphasis added). Here, the proposed rule goes well beyond the Act, establishing new policies and requirements not contemplated by the Legislature or authorized by the statute. We note those areas in our comments below.

PCMA

Definitions - §114-99-2

1. Section 2.5 defines "healthcare insurer," but this term is not used in the statute (§33-51-3). The statute refers to "covered entities" and establishes a definition for this term. The term "covered entity" is used in a number of areas within the proposed rule. There is no need for a new term "healthcare insurer" to be introduced in this rule.

2. Section 2.18 defines "Spread pricing," which is not a term used in the underlying statute and does not serve the underlying legislative intent of SB 489 or the Act as a whole. This is out of the scope of the Act.

Licensure of Pharmacy Benefit Managers - §114-99-4

3. Section 4.1b grants the Commissioner authority to lessen or increase the length of licensure upon his or her discretion. The Act clearly states that the term of licensure "shall be two years from the date of issuance" (§33-51-8(1)). There are adequate procedures in place for the revocation or suspension of licenses in the rare case this may need to happen. However, the law does not provide discretion to shorten the term of the license.

   PCMA proposes the following amendment for consistency with the Act:

   4.1.b. The term of licensure shall be two years. ~~However, the Commissioner may, in his or her discretion, fix the date of expiration regarding the initial license of a PBM in any manner as is considered by him or her to be advisable for an efficient distribution of the workload of his or her office, including fixing the date of expiration for the initial license of a PBM for a period less than or more than two years.~~

4. Section 4.2.d requires a filing fee sufficient to fund the Commissioner's regulatory duties, not to exceed $10,000. PCMA suggests establishing a reasonable filing fee for licensure, and that $10,000 is exceedingly high. Most states have a filing fee of less than $1,000. While PCMA agrees that a fee should be sufficient for the purpose of enforcing the law, the limited scope of the law calls for a much lower fee than anything near $10,000. Neighboring states Kentucky and Maryland have licensing fees of $1,000 and $250, respectively, and their state laws are significantly more detailed than West Virginia's law. PCMA proposes a reasonable fee of $1,000 for initial application and $500 for renewals.

5. Section 4.2.e establishes ways PBMs may prove financial responsibility. The statute simply requires proof of $1 million financial responsibility (§33-51-8(b)(4)). There is no need to expand upon this requirement. PCMA suggests striking 4.2.e.1 through 4.2.e.5 for consistency with the Act.

6. Section 4.2.j requires that a PBM submit a standard contract template it uses with pharmacies or PSAOs. The Act, however, does not contemplate filing of contracts as a condition of licensure and such a requirement is untethered to any statement of

legislative intent in the statute. As a result, the proposed rule would impermissibly expand the burden placed on licensees.

7. Section 4.2.k requires an audited financial statement of the PBM. However, the Act makes no mention of financial statements and the statute is clear that a licensee need only produce evidence of $1 million in financial responsibility. Accordingly, PCMA suggests this requirement be removed. To the extent, however, the Commission believes financial statements are required by the Act, PCMA suggests that consolidated financial statements provide sufficient information to the Commissioner, and thus proposes that the language be amended to allow for the submission of consolidated financial statements.

   PCMA proposes the following language:

   4.2.k A copy of the most recent year-end audited consolidated financial statement of the PBM.

8. Section 4.2.*l* requires a PBM to provide a description of the projected population or numbers of covered individuals to be administered by the PBM, as well as the same information for the previous year. This requirement is outside the scope of the statute. Furthermore, this data request will not provide the Commission with valuable information. A PBM's state-regulated business falls under the regulatory umbrella of a covered entity. All of the covered individuals that a PBM would be reporting on are already accounted for through covered entity filings.. Requesting this information is duplicative, unnecessary, and outside of the scope of the Act.

9. Section 4.2.m requires a PBM to provide its network service areas by county a list of the pharmacy directory for a covered entity. This information request is beyond the scope of the law and this level of detail is unnecessary to determine compliance with the statute.

   PCMA suggests the following amendment for consistency with the Act:

   4.2.m. A description of the PBM's types of networks utilized by covered entities it serves in the state to ensure that the networks include a mix of mail order services and physical stores~~. service areas by county in this state for a covered entity and the PBM's pharmacy provider directory list for a covered entity~~.

10. Section 4.2.n requires PBMs engaged in spread pricing to explain whether or not the PBM is assuming risk for the covered benefit. Far from "faithfully reflect[ing] the intention of the Legislature," the rule here again goes beyond the provisions of the Act in violation of well-established principles of administrative law. *See CNG Transmission Corp. v. Craig*, 211 W.Va. 170, 175, 564 S.E.2d 167, 172 (2002) (quoting Syl. Pt. 4, *Maikotter v. University of W.Va. Bd. of Trustees*, 206 W.Va. 691, 572 S.E.2d 802 (1999)). Furthermore, this provision misunderstands the role of PBM as a subcontracting administrator of a portion of the health care benefit. PBMs are not insurers and do not

PCMA

take insurance risk. PBM contracts are arms-length contracts with their health insurer clients, where—like all contracts—a set of rights, responsibilities and compensation terms are agreed upon. This arrangement between a PBM and a health insurer does not change the responsibility of an insurer to maintain sufficient capital to manage the insurance risk associated with accepting monthly premiums and covering a set of promised services to enrollees. A health insurer has already assumed its PBM costs into its financial solvency calculations in accordance with West Virginia law. Therefore, this should be stricken from the proposed rule.

11. Section 4.2.p requires a PBM to provide a description of whether the applicant had a "business relationship with an insurance company terminated for any *alleged* fraudulent or illegal activities..." (emphasis added). PCMA recognizes the importance of companies avoiding illegal or fraudulent behavior, but believe that an allegation is not an appropriate standard.

    PCMA suggests the following amendment:

    4.2.p A description of whether the applicant had a business relationship with an insurance company terminated for ~~any alleged~~ legal finding or judgment of fraudulent or illegal activities in connection with the administration of a pharmacy benefits plan; and

12. Section 4.2.q requires a PBM to provide "any other information deemed necessary by the Commissioner...to evaluate the financial condition of the PBM..." This section is vague, overly broad, and unnecessary. There are no underlying substantive requirements on which the Commissioner would evaluate a PBM for holding a license except those outlined in the Act. There is no assessment outlined in the statute relating to the financial condition of the PBM relative to the services it administers. The statute is clear that the financial responsibility standard is $1 million. There is no additional need to evaluate that responsibility relative to the services it administers.

    PCMA suggests the following amendment to clarify that the information requested is consistent with the Act:

    Any other relevant information which is deemed necessary by the Commissioner in evaluating the application to comply with the Pharmacy Audit Integrity Act ~~or requirements of this rule or deemed necessary or appropriate by the Commissioner to establish the qualifications of the PBM to hold a license or to evaluate the financial condition of the PBM relative to the services it administers or proposes to administer for covered entities in the state~~.

13. Section 4.3 requires the Commissioner to review a PBM licensure application and act within 90 days. PCMA understands that the Commissioner must have adequate time to review the license application but suggests that a PBM licensure application that is limited to the terms of the statute should not take three months to review. The license application should be limited to the basic information required in the statute—contact information and information about the organization, proof of $1 million of financial

responsibility, and the filing fee. PCMA member companies are concerned that a three-month review timeframe will unnecessarily slow the business down, with no clear consumer benefit. PCMA suggests that this review should be done within 30 days of receiving the filing.

14. Section 4.4 sets out the requirements for PBM license renewals and states that the application shall be deemed approved "after 45 days from the date of the receipt of the renewal application"... PCMA suggests that a faster timeline—15 days—be adopted if a PBM provides a written attestation that there have been no material changes from the previous application.

15. Section 4.4.a.1 establishes a renewal filing fee not to exceed $10,000. PCMA believes the potential of a $10,000 fee is excessive and a more appropriate, reasonable fee should be established in regulation. In most states, the renewal fee is less—typically half—of the cost of the initial filing fee. PCMA suggests a $500 renewal application fee, established in this rule.

16. Section 4.4.a.2 requires a PBM to submit audited financial statements. However, the Act makes no mention of financial statements and the statute is clear that a licensee need only produce evidence of $1 million in financial responsibility. Accordingly, PCMA suggests this requirement be removed. To the extent, however, the Commission believes financial statements are required by the Act, PCMA suggests that consolidated financial statements provide sufficient information to the Commissioner, and thus proposes that the language be amended to allow for the submission of consolidated financial statements.

    PCMA proposes the following language:

    4.4.a.2 A copy of the most recent year-end audited, consolidated financial statement of the PBM.

17. Section 4.4.a.5 requires a PBM to provide "any other information deemed necessary by the Commissioner..." This section is vague, overly broad, and unnecessary. In addition, it impermissibly operates as a grant of authority by the Commission to itself. Indeed, there are no underlying substantive requirements on which the Commissioner would evaluate a PBM for holding a license except those outlined in the statute. There is no assessment outlined in the statute relating to the financial condition of the PBM relative to the services it administers. The statute is clear that the financial responsibility standard is $1 million. There is no additional need to evaluate that responsibility relative to the services it administers.

    PCMA proposes the following amendment to clarify information requested is consistent with the Act:

    Any other relevant information which is deemed necessary by the Commissioner in evaluating the renewal application to ~~establish the continuing qualifications of the PBM~~

~~to hold a license or to evaluate the financial condition of the PBM relative to the services it administers, or proposes to administer, for covered entities in the state~~ comply with the Pharmacy Audit Integrity Act.

18. Section 4.5.a.1 establishes that the Commissioner may deny or not renew a PBM license if that "PBM operates, or proposes to operate, in a *financially hazardous condition relative to its financial condition* and the services it administers..." (emphasis added). PCMA objects to the terms "financially hazardous condition relative to its financial condition" used here and in earlier sections. This language is vague, overly broad, and unnecessary. There are no underlying substantive requirements on which the Commissioner would evaluate a PBM for holding a license except those outlined in the statute, nor has there been any demonstration that there are PBMs operating in financially hazardous conditions. There is no assessment outlined in the statute relating to the financial condition of the PBM *relative to the services it administers*. The statute is clear that the financial responsibility standard is $1 million.

19. Section 4.7 provides a protection—"to the extent possible"—against public disclosure of proprietary and confidential information submitted by a PBM. PCMA appreciates the acknowledgement that the information being supplied to the Commissioner by the PBM is trade secret and should be exempt from public disclosure. However, we remain concerned that the words "to the extent possible" make the protection conditional. If the condition is simply as allowed by law, there is no need to state it.

    PCMA proposes the following amendment:

    4.7 ~~To the extent possible,~~ Tthe information and data submitted by a PBM under this section shall be considered proprietary and confidential by law and privileged, and exempt from disclosure pursuant to Chapter 29B of the West Virginia Code as "trade secret"...

Prohibited acts -- §114-99-5

20. Many of the provisions in this section are new policies being proposed by the Commissioner and represent significant expansion of the Act. Specifically, sections 5.1, 5.2, 5.7, and 5.8 lack any basis in the statute and, therefore, should be stricken in their entirety. The Legislature had an opportunity to act on the issue of these types of "prohibited acts" and chose not to, and instead passed a licensure law. West Virginia law is clear that a "statute may not, under the guise of 'interpretation,' be modified, revised, amended or rewritten." Syl. Pt. 1, *Consumer Advocate Div'n v. Public Service Comm'n*, 182 W.Va. 152, 386 S.E.2d 650 (1989). While PCMA does not believe that was the Commission's intent here, the effect of this proposed provision is to amend the Act by adding whole new obligations completely unrelated to the provisions of SB 489.

PCMA

21. Section 5.3 refers to prohibitions on "gag clauses" in contracts. Although pharmacist-patient communications about lower cost options and cost share are concepts addressed in the underlying statute (§33-51-9(a)), the language in the proposed rule is impermissibly inconsistent with the Act. *See* Syl. Pt. 3 *Rowe v. W.Va. Dept. of Corrections*, 170 W.Va. 230, 292 S.E.2d 650 (1982) ("an administrative agency may not issue a regulation which is inconsistent with. . . its statutory authority.") Section 5.3 prohibits a PBM from penalizing a pharmacy for discussing *information in the Pharmacy Audit Integrity Act or the regulation of PBMs thereunder*. (emphasis added). The law does not provide for a pharmacist to advise patients on the PBM regulatory structure or contractual matters. The statutory language was intended to make sure consumers have access to information relating to medication options and costs at the pharmacy counter, so they can make informed decisions. It was not intended for pharmacists to advise patients on PBM regulatory structure or the law. While PCMA supports patients having information that helps them make informed decisions about their care and about their costs, and expects network pharmacies to have these valuable conversations, we do not support pharmacists sharing private contractual matters or providing what could be considered legal advice on PBM regulations.

    PCMA proposes the following amendment for consistency with the statute:

    5.3 To assist health care consumers in making informed decisions, so called "gag clauses" in contracts between pharmacies and PBMs are prohibited. A pharmacy, pharmacist or pharmacy technician shall have the right to provide a consumer information relating to lower cost alternatives and cost share for the covered individual, and a pharmacy, pharmacist or pharmacy technician shall not be penalized by a PBM ~~for discussing information in the Pharmacy Audit Integrity Act or the regulation of PBMs thereunder, or~~ for selling a lower cost alternative, if one is available, without using a health insurance policy.

22. Sections 5.6 and 5.6.a are provisions that restate the Act and are unnecessary. While consistency with the rule is important, there is no need for restatement of the Act's language. PCMA supports elimination of these sections from the rule.

23. Section 5.9 requires PBMs to comply with the statute on pharmacy audits. There is no need to establish a regulation that requires compliance with law. The requirement already exists. PCMA suggests striking this section.

Duties of healthcare insurers -- §114-99-6

24. This section relating to the duties of health insurers is completely new language, not contained in the statute. Here again, through its attempt to interpret the Act, the Commission's proposed rule is "rewriting" the Act. Syl. Pt. 1, *Consumer Advocate Div'n v. Public Service Comm'n*, 182 W.Va. 152, 386 S.E.2d 650 (1989). Not only are these new substantive requirements for health insurers, the terminology for insurers is different than that used in other areas of West Virginia insurance code (i.e., "healthcare insurers" vs. "covered entities," used in §33-51 and areas of these proposed rules). PCMA is very

concerned that the language in §114-99-6 is attempting to regulate contract reimbursement rates, which is a significant new policy decision outside the scope of the Commissioner's statutory authority. In fact, contract reimbursement rates were included in the introduced version of SB 489, but the legislature removed those provisions from the final version of the bill. Including this provision in the regulations is therefore a usurpation of legislative authority and runs contrary to the intent of the statute as passed. PCMA strongly opposes the inclusion of this section.

25. Section 7.3 proposes to require regular reports to the Commissioner with information relating to rebates and pharmacy reimbursement rates. PCMA strongly objects to the requirements of this section. Again, this is an area of regulation that the legislature considered but rejected in adopting the final version of SB 489. Not only is this a significant expansion of the statute, the type of information that would be contained in these reports is confidential, proprietary, and competitively sensitive, the public disclosure of which could be anti-competitive and would be damaging to cost control efforts in the pharmacy benefit. Government agencies—including the Congressional Budget Office (CBO) and the Federal Trade Commission (FTC)—have long cautioned that PBM disclosure mandates could raise costs. Estimates from Visante specifically quantify these potential costs at 4.3% increase over the next ten years.[1] The CBO has noted that disclosure requirements could allow firms to "observe the prices charged by their rivals, which could lead to reduced competition." According to CBO, the "disclosure of rebate data would probably cause the variation in rebates among purchasers to decline" leading to a "compression in rebates."[2] Similarly, the FTC has noted concern about rebate transparency and its impact on pricing. The FTC has warned that "whenever competitors know the actual prices charged by other firms, tacit collusion—and thus higher prices—may be more likely." FTC concluded that PBM disclosure mandates could "undermine the ability of some consumers to obtain the pharmaceuticals and health insurance they need at a price they can afford."[3]

    The West Virginia Legislature adopted a licensing structure for PBMs and restrictions on gag orders, fees, and audits, not on rebate reporting or exposure of confidential contract rates between pharmacies and PBMs. In addition, the reporting required would be unreasonably costly and burdensome for regulated entities and the state. PBMs process claims for millions of prescriptions. Section 7.3.e would require a PBM to report the amount paid for pharmacist services, itemized by pharmacy, by product, and by goods and services. The OIC is not equipped to deal with this colossal amount of data, nor would the OIC having access to this information benefit consumers in any way. There is no legal support for this entire 7.3 section and it should be stricken.

---

[1] "Increased Costs Associated With Proposed State Legislation Impacting PBM Tools," Visante, January 2019.
[2] Letter to Rep. Joe Barton and Rep Jim McCrery, U.S. House of Representatives, Congressional Budget Office, Mar. 12, 2007.
[3] Letter from FTC to Rep. Patrick T McHenry, U.S. Congress, July 15, 2005; Letter from FTC to Assemblyman Greg Aghazarian, California State Assembly, Sept. 3, 2004.

PCMA

Examinations - §114-99-8

26. Section 8.4 provides a protection—"to the extent possible"—against public disclosure of proprietary and confidential information obtained through an exam of a PBM. PCMA appreciates the acknowledgement that the information being supplied to the Commissioner by the PBM is trade secret and should be exempt from public disclosure. However, we remain concerned that the words "to the extent possible" make the protection conditional. If the condition is simply as allowed by law, there is no need to state it. PCMA suggests the following amendment:

    8.4 ~~To the extent possible, T~~the information and data submitted by a PBM under this section shall be considered proprietary and confidential by law and privileged, and exempt from disclosure pursuant to Chapter 29B of the West Virginia Code as "trade secret"...

Penalties – §114-99-9

27. Sections 9.1 and 9.2 set forth the potential penalties for failing to comply with the PBM licensure rules or the auditing entity rules. The penalty for an auditing entity is up to $2,500 per violation, but the penalty for the PBM may be up to four times that ($10,000). PCMA believes these amounts as well as their disparate nature are arbitrary and capricious and should be standardized at no more than $2,500 per violation for both PBMs and auditing entities. In addition, the rule should clearly outline notice and hearing rights for suspension or revocation of the license.

Thank you for the opportunity to provide feedback on the issues above. We look forward to working with you as this proposal is developed. Please contact me at 202-756-5743 or our local counsel, Hallie Mason, if you have any questions about our comments.

Sincerely,

April C. Alexander
Vice President, State Legislative and Regulatory Affairs