STATE OF WEST VIRGINIA
Offices *of the* Insurance Commissioner

Allan L. McVey
Insurance Commissioner

July 19, 2022

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 ("PBMs"), the Offices of the Insurance Commissioner ("OIC") of the Department of Revenue received comments from six stakeholders, including Epic Rx, Mountain Health Network, National Association of Chain Drug Stores, Pharmaceutical Care Management Association, West Virginia Independent Pharmacy Association, and West Virginia Primary Care Association. The majority of comments received were generally supportive of the rule. While all comments are attached hereto, for the sake of brevity, this letter does not summarize the supportive comments but instead addresses the comments indicating concerns with, or suggested revisions to, certain provisions of the rule. Moreover, this letter does not respond to substantially similar comments when the initial comment has already been addressed.

Four entities (Epic Rx, Mountain Health Network, West Virginia Independent Pharmacy Association, and West Virginia Primary Care Association) submitted comments in support of the modification of section 1.6 of the rule to clarify that House Bill 4112 (2022) applies to pharmacy reimbursements covered by the Employee Retirement Income Security Act of 1974 ("ERISA"). The entities further note support for the revisions to the various definitions under section 2 of the rule without proposing additional changes. As noted by the commenters, these proposed revisions were made to align the rule with the changes to the Pharmacy Audit Integrity Act made in House Bill 4112 (2022).

The West Virginia Primary Care Association ("WVPCA") comments that "it is important for 340B drug discounts or payments to remain explicitly excluded from any definition of 'rebate.'" The OIC agrees and notes the following existing, undisturbed rule language within subsection 2.22 of the rule: "The term 'rebate' does not include any discount or payment that may be provided to or made to any 340B entity through such program." Further, with respect to sections 5.6 and 5.7 of the rule, WVPCA requests the OIC assume regulatory responsibility for processing 340B-related complaints against PBMs that administer pharmacy benefits for the West Virginia Public Employee Insurance Agency ("PEIA"). Sections 5.6 and 5.7

of the proposed rule essentially mirror, respectively, W.Va. Code §33-51-9(c) and (d), which were amended by House Bill 4112 (2022) to make the subsections applicable to PEIA. While noting that the OIC is not the appropriate regulator of PEIA, WVPCA asserts that the intent of the Legislature was for the OIC to assume regulatory responsibility regarding 340B issues related to PEIA's contracted PBM. While the OIC agrees that the Legislative intent may be for PEIA to comply with these specific provisions of the *Pharmacy Audit Integrity Act*, PEIA is not an insurance company. PEIA is a fellow agency of state government and the OIC does not feel that it has inherent authority to regulate or take enforcement actions against the conduct of another state agency. However, the OIC is the designated regulator of PBMs and any PBM that violates these subject provisions may be subject to regulatory enforcement action by the OIC. In that regard, the OIC will accept complaints filed against PBMs for alleged violations of W.Va. Code §33-51-9(c) and (d) and the corresponding rules provisions. If, upon review and investigation, it appears the PBM is administering pharmacy benefits on behalf of PEIA in violation of W.Va. Code §33-51-9(c) and (d) and the corresponding rules provisions, the OIC will report the matter to PEIA.[1] The OIC may also take regulatory enforcement action against any PBM subject to W.Va. Code §33-51-9(c) and (d) and the corresponding rules provisions as is deemed necessary and appropriate.

The remaining comments from WVPCA are either supportive of the rule or proposed rule revisions or advocacy positions that do not require a specific response from the OIC.

The West Virginia Independent Pharmacy Association ("WVIPA") and Mountain Health Network submitted multiple supportive comments of the proposed rule, some of which require a substantive OIC response. The WVIPA and Mountain Health Network both aver that spread pricing "should be made explicitly unlawful in West Virginia." As set forth in the rule, "spread pricing" is a model of prescription drug pricing in which the PBM charges a health benefit plan a contracted price for prescription drugs although the contracted price may differ with the amount the PBM pays the pharmacy. The OIC responds to WVIPA's and Mountain Health Network's comment by stating that it is the province of the Legislature to prohibit spread pricing in this state and therefore is not something the OIC can initially address in a rule. However, PBMs are required to offer pass through pricing to health benefit plans and the OIC proposed the addition of subsection 4.2.18 and subdivision 4.4.1.d to the rule to ensure the required offer was being made and to sufficiently monitor the use of spread pricing in West Virginia.

WVIPA and Mountain Health Network also note their general support of the proposed new section 10 of the rule regarding specialty drug complaints, but state they are concerned that PBMs and/or health benefit plans will be permitted to "resolve" complaints under section 10.4 for one individual or entity to avoid applying the same standard consistently as would be the case if the Commissioner made a public ruling on the complaint. The OIC generally supports settlements or resolutions between consumers and regulated entities as beneficial public policy. However, the OIC agrees that avoidance of compliance with statutory mandates via subterfuge is not appropriate. As such, the OIC agrees to modify the rule to

[1] "Any plan established or administered by the Public Employees Insurance Agency pursuant to this article is exempt from the provisions of chapter 33 of this code unless explicitly stated. Notwithstanding any provision of this code to the contrary, the Public Employees Insurance Agency is not an insurer or engaged in the business of insurance as defined in chapter 33 of this code." See W. Va. Code § 5-16-22.

clarify that the OIC has the authority to review specialty drug complaints regarding how the subject drug should relate to all insureds:

> 10.4. If the specialty drug complaint is resolved before the time period for a response expires, the PBM and/or health benefit plan must advise the Commissioner in writing that the specialty drug complaint has been resolved and specifically advise the Commissioner of what steps or actions were taken to resolve the complaint. If the PBM and/or health benefit plan intends to take no action to resolve the complaint, the PBM and/or health benefit plan shall advise the Commissioner accordingly, in writing, and provide the Commissioner with a substantive response to the allegations in the specialty drug complaint. Nothing in this section in any way limits the authority of the Commissioner to investigate and take action against a PBM which the Commissioner has reason to believe has unreasonably designated a covered prescription drug as a specialty drug or limited a beneficiary's access to a specialty drug in violation of the provisions of W.Va. Code §33-51-11(a)(7) or (8) or subdivisions 9.2.1.g or 9.2.1.h of this rule, but thereafter has consistently resolved each specialty drug complaint prior to the final resolution thereof by the Commissioner in accordance with section 10.8 of this rule.

The remaining comments from WVIPA and Mountain Health Network are either expressions of general support for the rule or the proposed revisions to the rule or are advocacy positions that do not require a specific response from the OIC.

Epic Pharmacies ("EPIC Rx") submitted multiple supportive comments regarding the rule and the proposed changes thereto. Some of the comments made by EPIC Rx, specifically comments regarding sections 1.6 and 10.4 of the rule, have already been addressed by the OIC in response to comments made by WVPCA, WVIPA and Mountain Health Network. However, EPIC Rx commented that subsection 4.2.15 of the rule could be further amended to include the settlement of lawsuits by a PBM. The comment also footnotes to a lawsuit settlement between the Ohio Attorney General and a PBM regarding overbilling disputes with Ohio's Medicaid program. The OIC believes that the type of settlement noted in the footnote would be a required disclosure pursuant to 4.2.15, but agrees to modify this subsection of the rule as follows for additional clarity:

> 4.2.15. 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, 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 or entered into a monetary settlement for any reason by or with any state or federal entity, including but not limited to another state's department of insurance, department of health and human services or Medicaid program, attorney general's office, board of pharmacy or other similar regulatory agency;

Additionally, Epic Rx commented that the "OIC may want to consider requiring as part of any 'statement as to whether the PBM has restricted distribution of specialty drugs' an explanation from the PBM as to why a drug has been restricted in its distribution." The OIC agrees and modified the subsection as follows:

6.1.2. A PBM shall, upon licensure and upon further request by the Commissioner, provide a network report describing the PBM's network and the mix of mail-order to physical stores in this state and shall include a detailed description of any separate, sub-networks for specialty drugs. The detailed description should include a statement as to whether the PBM has restricted distribution of specialty drugs to mail-order specialty pharmacies or affiliate pharmacies, and if so, the reasons therefore, and further provide the names and addresses of any specialty pharmacies in the PBM's network that are not solely mail-order pharmacies or affiliate pharmacies and are located in West Virginia, or in an out-of-state county that is adjacent to West Virginia. This statement shall also include a list of all specialty drugs currently on restricted distribution to specialty pharmacies or affiliate pharmacies. Failure to provide a report may result in the suspension or revocation of a PBM's license by the Commissioner.

Finally, EPIC Rx comments that the reports under sections 6.2 and 6.3 of the rule should be made public to the extent allowable by law. The OIC agrees that the quarterly reports required in section 6.3 are not subject to the confidentiality provisions in section 6.5 and will work towards making them available on the OIC's website. The OIC further responds that the information and data contained in the annual report, as required by section 6.2 of the rule, is expressly made confidential and not subject to public release pursuant to section 6.5.

The remaining general comments from EPIC Rx are either expressions of general support for the rule or the proposed revisions to the rule or are advocacy positions that do not require a specific response from the OIC.

Pharmaceutical Care Management Association ("PCMA") submitted several comments both specific to the proposed rule revisions and generally related to House Bill 4112 (2022), which is the underlying legislation upon which the proposed rule revisions are based. First, PCMA recommended that the information requested in subsection 6.1.2 of the rule be designated as exempted from disclosure under the *West Virginia Freedom of Information Act* (FOIA). The OIC responds that section 6.5 of the rule already provides that all information and data submitted in section 6 of the rule, except for the quarterly report noted in section 6.3, is considered confidential and exempt from disclosure under FOIA. Additionally, PCMA notes that information submitted under subsection 4.2.13 of the proposed rule should also be exempted from FOIA. Again, section 4.7 of the rule already provides a FOIA exemption for this information. The OIC accordingly declines to make any revisions to the rule as a result of this comment.

Additionally, PCMA requests a modification of the proposed language in section 10.3 of the rule, which reads, in part: "Upon receipt of a sufficiently complete specialty drug complaint, the Commissioner shall provide a copy to the PBM and health benefit plan. The PBM shall have 15 working days to respond." PCMA requests that the 15-working day requirement for responding to a specialty drug complaint be changed to a 30-working day requirement. As justification for the change, PCMA notes a 30-business day requirement in subsection 9.3.3 of the rule for pharmacies. The OIC does not agree with PCMA on this issue. First, the underlying subsection PCMA cites is a notice requirement regarding a contract or manual amendment with respect to a pharmacy and PBM relationship. It is simply irrelevant to the response time a regulated entity is permitted to have to respond to its regulator. Moreover, the OIC consistently and uniformly requires regulated entities to respond within 15-working days. *See* W.Va. Code R. §114-14-5.

Insurance companies, many of which will be health benefit plans subject to section 10 of the rule, are routinely required to respond to inquiries from the OIC within 15-working days. Insurance companies are also generally permitted only 15-working days to respond to or acknowledge claims or pertinent communications from their insureds or policyholders. It would be a deviation from existing standards to permit a PBM twice the amount of time to respond to inquiries from the OIC than is permitted to an insurance company or third-party administrator in the same circumstance. It could also cause inconsistency in response times and confusion depending on whether a specialty drug complaint was filed against a PBM or against a health benefit plan, including an insurer. However, this comment from PCMA did prompt the OIC to review section 10.3 and modify the language as follows:

> 10.3. Upon receipt of a sufficiently complete specialty drug complaint, the Commissioner shall provide a copy to the PBM and health benefit plan. The PBM shall have 15 working days to respond. A separate response may also be required of the health benefit plan. The Commissioner will advise a health benefit plan if it is required to respond separately from the PBM. A health benefit plan required to respond shall also have 15 working days to respond.

The OIC notes, however, that it will grant extensions to the 15-working day requirement on an as needed and appropriate basis.

In regard to section 10.5 of the rule, PCMA also objected to the language that, if the complaint remains unresolved, the "Commissioner shall send a copy of the specialty drug complaint, and the response(s) thereto, to the Board of Pharmacy..." and commented that the Board of Pharmacy should be removed as a reviewing and consulting entity because PCMA believes that the Board's membership are also pharmacists and active market participants in the occupation and that the Board's involvement "creates a regulatory scheme for self-dealing." In response, the OIC would direct PCMA's attention to W.Va. Code §33-51-11(a)(7), which specifically provides that "[a]ny beneficiary or pharmacy impacted by an alleged violation of this subsection may file a complaint with the Insurance Commissioner, who shall, in consultation with the West Virginia Board of Pharmacy, make a determination as to whether the covered prescription drug meets the definition of a specialty drug." As such, the Commissioner is expressly required to consult with the Board of Pharmacy regarding specialty drug complaints and the OIC does not agree that the Board's involvement regarding specialty drugs is inappropriate. The OIC accordingly declines to modify the language in 10.5 to remove the Board of Pharmacy as a reviewing and consulting entity.

PCMA is also concerned with the phrase "conveniency of access" in section 10.7 of the rule, which states:

> 10.7. The Commissioner may also obtain additional information from the PBM and/or health benefit plan regarding the circumstances surrounding the designation of the covered prescription drug as a specialty drug and whether access to a covered prescription drug is being limited in violation of W. Va. Code §33-51-11(7) and (8). Additional information may include, but is not limited to, an assessment of network adequacy and the availability or conveniency of access for West Virginia residents to obtain the covered prescription drug, the number of mail-order pharmacies and physical pharmacies located in West Virginia that are permitted to dispense the covered prescription drug, the special handling, administration and/or

provider care options or necessities that the PBM's specialty pharmacies offer that is not otherwise available at non-specialty pharmacies, and the circumstances surrounding the designation of the covered prescription drug as a specialty drug.

In response, the OIC notes that this section allows the Commissioner to obtain additional information necessary in making the determination as to whether a specific prescription drug should be classified as a specialty drug. The OIC does not share PCMA's concern that it would misconstrue "conveniency of access" to imply that any pharmacy can dispense a specialty drug. In considering whether a drug is properly classified as a specialty drug, the OIC understands that "conveniency of access" is within the context of how and which pharmacies are dispensing the drug in question. Accordingly, the OIC declines to modify this section.

Next, PCMA notes that there is no definition of "any party" in section 10.9 of the rule and questions which persons have the right to contest a decision on a specialty drug complaint. The OIC agrees that additional clarity would be desirable in section 10.9 and proposes to modify the section as follows:

10.9. Any party to an administrative proceeding regarding a specialty drug complaint has the right to contest the decision made pursuant to section 10.8 of this rule. If a decision is made pursuant to subsection 10.8.1 or 10.8.2 of this rule without hearing, any party may make a written demand for a hearing pursuant to the provisions of W. Va. Code §33-2-13. A hearing on a specialty drug complaint shall be scheduled to be held within 45 days from the date of the hearing request, unless continued by agreement of all parties or by the Commissioner and Board of Pharmacy for good cause. Good cause includes, but is not limited to, a determination by the Commissioner and Board of Pharmacy that additional investigation is necessary.

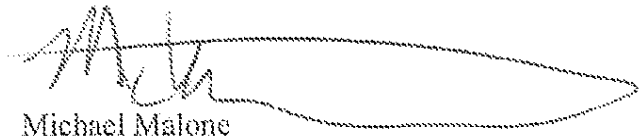
The OIC believes that a party to an administrative proceeding could be a covered individual, beneficiary, pharmacy, pharmacist, PBM or health benefit plan, including an insurer, as noted in sections 10.1 and 10.2 of the rule.

Finally, PCMA's remaining comments concern the underlying language of House Bill 4112 (2022) and 340B Pricing Adjustments. PCMA provides a brief history of the 340B program and discusses the use of "modifiers" in relation to the federal program. These comments are generally advocacy positions. The OIC is a regulatory agency and will not take an advocacy position regarding the federal 340B drug program. However, in regard to PCMA's concerns about Medicaid, the OIC would note that West Virginia's Medicaid program does not currently utilize the services of a PBM and that language in both statute and rule provides that nothing therein shall be construed to prohibit the Medicaid program or a Medicaid managed care organization as described in 42 U.S.C. § 1396b(m) from preventing duplicate discounts as described in 42 U.S.C. 256b(a)(5)(A)(i). *See* W.Va. Code 33-51-9(c) and (d) and W.Va. Code R. §114-99-5.6 and 5.7.

The National Association of Chain Drug Stores also submitted public comments in regard to the proposed changes to this rule. The OIC acknowledges receipt of the comments and notes that the comments are either supportive of the rule or the proposed revisions to the rule or are advocacy positions that do not require a specific response from the OIC.

The OIC thanks all commenters and appreciates being able to review different perspectives on these important matters. All attention to, and time spent on, this matter is greatly appreciated.

Sincerely,



Michael Malone
Associate General Counsel
West Virginia Offices of the Insurance Commissioner

Attachments

June 28, 2022

Mr. Michael Malone
West Virginia Offices of the Insurance Commissioner
900 Pennsylvania Ave., 8th Floor
Charleston, WV 25302
Email: michael.n.malone@wv.gov

RE: Public Comment on Proposed Rule 114 CSR 99

Dear Mr. Malone,

On behalf of EPIC Pharmacies, which includes thirty-eight stores in its West Virginia Network, I write you today to provide public comment on the West Virginia Offices of the Insurance Commissioner's ("OIC") proposed legislative rule, WV CSR §114-99-1, *et seq.*, regulating "Pharmacy Audit Entities and Pharmacy Benefit Managers."

Over the past several years, EPIC Pharmacies has played an important role in the crafting of the Pharmacy Audit Integrity Act (the "Act"), as contained within W.Va. Code § 33-51-1, *et seq.*, including most recently with the West Virginia Legislature's passage of H.B. 4112 during the 2022 Regular Session. We have worked closely with many stakeholders, including the OIC, to ensure that West Virginia consumers are able to maintain their access to pharmacy care throughout the State of West Virginia.

For many West Virginians, their local pharmacy is oftentimes the first point of contact for needed health care decisions. Pharmacists play a critical role in West Virginia's health care delivery system, as most recently evinced during the COVID-19 pandemic when the state's network of independent pharmacists were at the forefront of West Virginia's successful vaccine rollout.[1]

The provisions of the Pharmacy Audit Integrity Act, and the OIC's corresponding legislative rule, are quite critical to the survival of West Virginia's local pharmacies and the continued care of those in our communities. Through a series of mergers and acquisitions, a distinct handful of pharmacy benefit managers ("PBMs") now control approximately 80% of the nation's prescription drug market. This nearly monopolistic system has created opaqueness in the prescription drug market, while also

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[1] *See* "'Little old West Virginia' emerges as national leader in COVID-19 vaccinations per capita," *The Associated Press*, Jan. 17, 2021. https://www.post-gazette.com/news/nation/2021/01/17/West-Virginia-COVID-19-coronavirus-vaccine-vaccination-when-can-I-get-Griffith-and-Hoh-Drug-Jim-Justice-pharmacies/stories/202101170104

placing West Virginia consumers and their local pharmacists at the mercy of abusive PBM business practices. Concern over the practices of PBMs have prompted lawsuits by state attorneys general, legislative action by the various state legislatures and the U.S. Congress, and most recently an announced inquiry into PBM practices by the Federal Trade Commission.[2]

EPIC Pharmacies is appreciative of the OIC's efforts to enforce the provisions of the Pharmacy Audit Integrity Act, as passed by the Legislature, in order to ensure a level playing field for all West Virginians with respect to the delivery of prescription drugs. West Virginia has been a national leader when it comes to the regulation of PBMs, and OIC's proposed changes to 114 CSR 99 will continue to put our state at the forefront of protecting consumer choice for pharmacy benefits. EPIC Pharmacies supports OIC's proposed legislative rule, WV CSR §114-99-1, *et seq.*, as written and offers the following additional comments for your consideration.

Section 1.6 – Applicability

As an initial matter, we applaud OIC's efforts to clarify the applicability of the legislative rule to PBMs administering ERISA plans through its amendments to Section 1.6. It was the clear intent of the West Virginia Legislature, in the wake of the United States Supreme Court's recent decision in *Rutledge v. Pharmaceutical Care Management Association,* to apply provisions of the Act to PBMs as allowed by federal law. Moving forward, enforcement of these and other provisions contained within the legislative rule will be critical, as we regularly hear from EPIC Pharmacies members about non-compliance by PBMs.

Section 4.2.15 – Licensure of PBMs

As part of the established licensure process, OIC requires PBMs to provide whether it "has been sanctioned, fined or penalized for any reason by any state or federal entity, including another state's department of insurance." Given the increasing number of lawsuits filed by states against PBMs for the overcharging of medications, the OIC may want to consider including in Section 4.2.15 language that would also require the disclosure of any state lawsuit settlements entered into by a PBM.[3]

Section 6.1.2 – Restricting Distribution of Specialty Drugs

One of the key goals of H.B. 4112 was to put an end to the unreasonable designation of "specialty drugs" by PBMs. To that end, the proposed amendments to Section 6.1.2 should be helpful in identifying efforts by a PBM to restrict distribution of drugs to mail-order or affiliate pharmacies. To ensure even greater transparency, OIC may want to consider requiring as part of any "statement as to whether the PBM has restricted distribution of specialty drugs" an explanation from the PBM as to why a drug has been restricted in its distribution. This would hopefully provide further clarity as PBMs restrict distribution to either mail-order specialty pharmacies or their own affiliates.

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[2] *See* "FTC Launches Inquiry Into Prescription Drug Middlemen Industry," June 7, 2022 at https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry; *see also* "PBM reform bill that boosts FTC powers inches closer to passage in the Senate," June 22, 2022 at https://www.fiercehealthcare.com/payers/pbm-reform-bill-boosts-ftc-powers-inches-closer-passage-senate.

[3] For instance, Ohio Attorney General David Yost obtained $88 million in settlement over disputes of overcharging with respect to Ohio's Medicaid program. https://www.healthcaredive.com/news/centene-shells-out-143m-to-settle-pbm-disputes-in-ohio-medicaid-lawsuit/601773/

Sections 6.2 and 6.3 – Reporting Requirements

There is undoubtably a need for greater transparency among PBMs, as the lack of clarity with respect to pricing allows for prescription drug costs to continue to rise. Understanding that the OIC is prohibited from disclosing much of the pricing information reported to it by a PBM under the "trade secrets" protections of the West Virginia Code, we would still encourage OIC to be as transparent as possible in publicly reporting what information it can on the OIC's web site. West Virginia consumers, pharmacists and health care payors alike deserve to know more about the spread pricing that takes place in the prescription drug industry. To the extent that the OIC can make such information publicly available, it should absolutely do so. At a bare minimum, the OIC should post the PBM Quarterly Reports required by Section 6.3 on the "Reports" section of its web site, as such documents are explicitly preserved as public.[4]

Section 10.4 – Specialty Drug Complaints

The specialty drug complaint process created in Section 10 is an extremely important addition to 114 CSR 99. Such a process will hopefully stem the practice of PBMs restricting access to and distribution of prescription drugs through an opaque specialty drug designation process. Section 10.4 provides that a PBM or health benefit plan must advise the Insurance Commissioner in writing if a specialty drug complaint filed with the OIC "has been resolved." The OIC should consider amending this provision to require some sort of written explanation from the PBM or health benefit plan as to what actions were taken to resolve any such complaint. Furthermore, the OIC should consider ways in which it might be able to formalize any such complaint resolutions with respect to unreasonable specialty drug designations. Absent such requirements, our fear is that PBMs will continue their practice of unreasonably designating specialty drugs, and simply resolve any such designations the instant a complaint is filed. This would effectively subvert the ability of the OIC and the Board of Pharmacy to make necessary determinations as to whether a covered prescription drug meets the definition of a specialty drug as provided for in state code.

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,

Brittany LaPorta

Brittany LaPorta, Government Affairs Director
EPIC Pharmacies

[4] It would be extremely beneficial for the public at large to have a section on pharmacy pricing reports included here: http://www.wvinsurance.gov/Consumers_Reports.

MOUNTAIN HEALTH NETWORK 1340 Hal Greer Blvd. • Huntington, WV 25701 • www.mountainhealthnetwork.org

Mr. Michael Malone
West Virginia Offices of the Insurance Commissioner
900 Pennsylvania Avenue, 8th Floor
Charleston, WV 25302 Email: michael.a.malone@wv.gov

July 5, 2022

Re: Comments on Proposed Rule 114 CSR 99

Dear Mr. Malone:

On behalf of Mountain Health Network, a not-for-profit health delivery system comprised of Cabell Huntington Hospital, St. Mary's Medical Center, Hoops Family Children's Hospital, HIMG, and a management agreement with Pleasant Valley Hospital. We are committed to improving the health and well-being of over one million children and adults in 23 counties in West Virginia, southern Ohio and eastern Kentucky, we respectfully offer our comments on *Proposed Rule 114 CSR 99: Pharmacy Auditing Entities and Pharmacy Benefit Managers.* Thank you for the opportunity to offer comments.

Mountain Health Network is appreciative of the West Virginia Legislature and WVOIC leadership focused on protecting West Virginia patients by updating and amending relevant protections and specific duties and responsibilities of pharmacy benefit managers ("PBMs") operating in West Virginia. These pharmacy issues are extraordinarily complex and important in terms of providing quality healthcare for patients, while also containing rising healthcare costs. Increasing transparency and offering additional patient protections has established West Virginia as a national leader in this area. With these comments, we look to highlight and support provisions of the proposed rule and suggest modifications to further strengthen or clarify the proposed rule.

Applicability of Pharmacy Audit Integrity Act ("Act") to ERISA Plans

One purpose of House Bill 4112 (2022) and HB 2263 (2021) was to apply pharmacy reimbursement requirements of the Act to Employee Retirement Income Security Act of 1974 ("ERISA") Plans, including the reimbursement floor of National Average Drug Acquisition Cost ("NADAC") plus a $10.49 professional dispensing fee for prescription drug and pharmacy services. While HB 2263 originally established this reimbursement methodology, the addition of the more comprehensive defined terms "healthcare payor" and "payor," and the deletion of terms "covered entity," "health carrier," and "third party," provides clarity to the law/rule, without making substantive changes to the 2021 law.

We believe this is appropriate under court decisions throughout the country, including the Supreme Court of the United States' decision in *Rutledge v. PCMA*. Clearly, the West Virginia Legislature, Governor's Office, Department of Health and Human Resources ("DHHR") and its Medicaid operations, and the WVOIC, agree that this methodology is the most equitable.

reliable, and transparent model by which to reimburse pharmacies. This methodology is now used across various healthcare programs and plans (Medicaid, fully insured, ERISA, etc.) in West Virginia. Mountain Health Network urges the WVOIC to protect and further this legislative intent by closely monitoring PBM conduct across these various programs and plan types. We further urge the WVOIC to immediately apply fines, sanctions, licensure suspension/revocation for PBM noncompliance.

Spread Pricing / Pass Through Pricing & Drug Manufacturer Rebates

Although the issue may not be explicitly prohibited in current West Virginia law or this proposed rule, we firmly believe that "spread pricing" should be made explicitly unlawful in West Virginia. PBMs often charge employer-based health benefit plans more for the price of drugs than what is paid to dispensing pharmacies, without informing plans about this "spread pricing." This leads to confusion for plans and plan beneficiaries, ultimately resulting in increased drug costs and healthcare costs in general, not to mention unjust enrichment to the benefit of the PBM. PBMs have gone from plans to help reduce costs for patients to capturing their rebates as profit to affect dispensing habit. We believe PBMs should charge plans the same amounts for drugs that the PBMs reimburse pharmacies for those drugs. This transparency is important, and at the very least, if spread pricing does occur, PBMs should clearly notify plans and plan beneficiaries beforehand.

Rule Sections 4.2.18 and 4.4.1.d attempt to address this issue by requiring attestations that the PBM has offered health benefit plans the option of pass-through pricing. We anticipate that PBMs will refuse to comply with this provision related to ERISA plans. If this offer is clearly made from PBM to plans, we believe that most, if not all, health benefit plans will elect for pass-through pricing. If they do not, these plans will have been provided adequate transparency and fair opportunities to remedy the "spread pricing" issue.

Additionally, West Virginia laws and rules state that patients are to receive drug manufacturer rebates at the point of sale to reduce defined cost sharing. To date, we have not received information, instructions, or processing requests to effectuate this process. We ask the WVOIC to closely examine this process and the parties involved, with the understanding that pharmacies, providers and their patients are not harmed or held responsible for these obligations.

Defining "Specialty Drug" and the Protecting Patient Access to Specialty Drugs

In recent years, patient access to drugs has been unreasonably limited by PBMs. Specifically, the list of drugs defined as "specialty drugs" by PBMs, insurance companies, and drug manufacturers has grown significantly, as have the costs associated with these drugs. Often, drugs are defined or classified as "specialty drugs" because of their expensive prices and lucrative drug manufacturer rebates, not necessarily because they are used to treat rare or chronic and complex medical conditions, or because they require special handling or administration, provider care coordination, or patient education that cannot be provided by a non-specialty pharmacy or pharmacist. It has become common practice for PBMs to force patients to receive their medications via mail order pharmacies, leaving patients without choice to receive timely medications from trusted local independent community pharmacies and pharmacists.

Furthermore, many so-called "specialty pharmacies" do not report their pricing data to the NADAC survey. This leaves community pharmacies, providers, patients, policymakers, and regulators in the dark as to the true cost of medications.

Explaining this issue to patients can be difficult, and often leads to confusion, frustration, and sometimes strained relationships between patients and pharmacies. PBMs often make the hollow argument that "specialty drugs" must be mailed to patients due to safety concerns, as if mailing a medication to a patient's home without pharmacist interaction is somehow safer and more clinically adequate than a patient receiving their medication face to face and receiving counseling from a trusted pharmacist in their local community. This argument is flawed, and has been summarily rejected by policymakers and regulators in West Virginia. We are very grateful that this barrier to patient access has been removed under West Virginia law and this rule, giving patients the pharmacy access they deserve and desire.

The specific language found in 4.2.13 will be important to provide transparency related to separate sub-networks for specialty drugs, which are not accessible to most pharmacies. Clearly, the West Virginia Legislature intends for PBMs to provide increased transparency and access for patients related to their prescriptions. Further, the creation of processes giving beneficiaries access to drugs from the pharmacies and pharmacists of choice will improve access. We believe the WVOIC and the West Virginia Board of Pharmacy ("WVBP") are the appropriate agencies for making the determination as to whether drugs meet the definition of a "specialty drug." While some drugs truly are appropriately designated as "specialty drugs," and should be handled differently than other medications, customary PBM processes unreasonably limit patient access and create unfair practices that benefit PBMs and affiliated pharmacies, not patients.

"Specialty Drug" Complaints

We support the rule's language related to specialty drug complaints. The process, form, and requirements seem to be sensible, fair, and efficient. One concern is the ability of a PBM and/or health benefit plan to "resolve" a specific specialty drug complaint, formally or informally, for one individual or entity, to avoid applying the same standard consistently each time the specific drug is covered. Therefore, we support consistent application of determinations made related to specific drugs – whether made informally by a PBM or health benefit plan or made formally by the WVOIC and WVBP.

PBM Disclosures and Filings

We support requiring PBM disclosure of whether the PBM applicant has been refused a registration, license, or certification to act as a PBM or third-party administrator, has any registration, license, or certification to act as such been denied, suspended, or 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, including another state's department of insurance or similar agency. It is appropriate for the WVOIC to prevent PBMs that have violated the laws/rules of other states from being licensed and active in West Virginia, to adequately protect patients.

We believe the requirement under 4.2.17 stating that all filed reimbursement methodologies comply with West Virginia law, and that all contracts provide for clear reimbursement term is welcomed and necessary. We want to ensure that PBM contracts proposed to us are in compliance with the state law. Unclear or misleading contract terms proposed by PBMs to pharmacies will lead to network vacancies, network inadequacy, and pharmacy access gaps for patients.

Prohibitions Against Required Mail-Order Pharmacy

Mountain Health Network supports all prohibitions against required use of mail-order pharmacy under 6.1. We do support mail-order pharmacy being made available as a choice for patients. Many patients within our health system have had delayed treatment due to PBM and plan actions related to required mail order. We believe the additions in this section of the rule will improve access, protect patients, and promote network adequacy in leased network situations.

Prohibitions Against Pharmacy and Pharmacist Conditions for Participation

Mountain Health Network supports the addition of section 9.2.1c which prohibits a PBM or health benefit plan from imposing upon a pharmacy or pharmacist a condition of participation that is more stringent than or in addition to state requirements for licensure or certification as provided for in W.Va. Code §30-5-1 et seq. and legislative rules of the Board of Pharmacy. This addition follows legislative intent and is necessary for freedom consumer choice for pharmacy.

PBM Penalties

We urge the WVOIC issue penalties in the amount of $10,000 per violation for violations of the Act and Rule. We find that PBMs have violated, and continue to violate, the Act and rules. These violations cause real harm to patients, pharmacies, and employers in West Virginia. If the per violation financial penalties are not effective in stopping these violations, we ask the WVOIC to order PBM licensure suspensions and/or revocations.

Again, we are appreciative of the WVOIC and West Virginia Legislature's leadership on this very important patient care and choice issue. If you may have questions regarding these comments, please contact our Director of Advocacy, Abby Reale at 304-526-4028 or abby.reale@mhnetwork.org.

Respectfully submitted,

Kevin W. Yingling, R.Ph., M.D., FACP
CEO, Mountain Health Network
President, Cabell Huntington Hospital & St. Mary's Medical Center

NATIONAL ASSOCIATION OF CHAIN DRUG STORES

June 30, 2022

Michael Malone
West Virginia Offices of the Insurance Commissioner
900 Pennsylvania Ave., 8th Floor
Charleston, WV 25302
Submitted via *michael.n.malone@wv.gov*

Re: Proposed Rule Changes under W. Va. Code R. § 114-99-1 et. seq.; Pharmacy Auditing Entities and Pharmacy Benefit Managers

Dear Mr. Malone,

On behalf of our members operating 344 chain pharmacies in the state of West Virginia, the National Association of Chain Drug Stores (NACDS) is writing in support of the proposed rule changes under W. Va. Code R. § 114-99-1 et. seq. to align regulations for pharmacy auditing entities and pharmacy benefit managers with the statutory changes enacted under HB 4112 (2022). Importantly, the recent changes to the law serve to enhance patient access to pharmacy services for underserved populations, improve patient access to specialty medications, and increase transparency into the practices of pharmacy benefit managers (PBMs).

NACDS supports the provisions in the enacted law and in the proposed rule that help ensure that West Virginians can obtain specialty medications from the pharmacy of their choice. By prohibiting any practice that would require patients to use only a specialty pharmacy for medications that can be provided by their local retail community pharmacy, the law and proposed rule language together create a clear standard protecting patients against this harmful practice. Additionally, by establishing a process wherein patients and pharmacies may seek redress through the Insurance Commissioner for any violation of this prohibition, the proposed rule would establish a needed enforcement process to protect against the practice.

NACDS further supports the new provisions in the law and in the proposed rule that increase the Insurance Commissioner's oversight of specialty pharmacy benefit networks and enhance all pharmacies' transparency into sometimes confusing and opaque PBM contractual provisions. This improved oversight and transparency should help preserve patients' access to the pharmacy of their choice.

Thank you for the opportunity to share our perspectives on this matter. We urge the Offices of the Insurance Commissioner to approve this important rule change which should help to protect West Virginians' access to pharmacy care from the pharmacy of their choice, including local retail community pharmacies and specialty medications. For questions or further discussion, please contact NACDS' Jill McCormack, Regional Director, State Government Affairs, at jmccormack@nacds.org or 717-525-8962.

Sincerely,

Steven C. Anderson, FASAE, CAE, IOM
President and Chief Executive Officer
National Association of Chain Drug Stores

PCMA

July 5, 2022

Michael Malone
West Virginia Offices of the Insurance Commissioner
900 Pennsylvania Ave., 8th Floor
Charleston, WV 25302
EMAIL: michael.n.malone@wv.gov

SENT VIA EMAIL

Re: PCMA Comments on 114CSR99 – Pharmacy Auditing Entities and Pharmacy Benefit Managers – Amendment to Existing Rule

Dear Mr. Malone:

The Pharmaceutical Care Management Association ("PCMA") appreciates the opportunity to comment on the proposed regulations ("Proposed Rule") published by the West Virginia Offices of the Insurance Commissioner's ("OIC") on June 2, 2022 titled "Pharmacy Auditing Entities and Pharmacy Benefit Managers." This Proposed Rule would amend existing rules under 114CSR99, thus implementing the language of House Bill (HB) 4112. HB 4112 was enacted during the 2022 Legislative Session. This new law makes changes to WV's existing Pharmacy Audit and Integrity Act ("Act").

PCMA is the national trade association representing PBMs. PCMA's member companies administer drug benefits for more than 266 million Americans, including most West Virginias, who have health insurance through employer-sponsored health plans, commercial health plans, union plans, Medicare Part D plans, managed Medicaid plans, the state employee health plan, and others.

Below are PCMA's comments, concerns, and recommendations regarding specific provisions in the Proposed Rule, as well as the language of the enacted HB 4112.

§114-99-6. Network Adequacy and Reporting Requirements.

6.1.2. – "...and shall include a detailed description of any separate, sub-networks for specialty drugs. The detailed description should include..."

- Due to the potential proprietary and confidential nature of the information required in this provision of the Proposed Rule, as well as the potential disclosure information in a competitive marketplace, this provision should be changed.
- PCMA recommends that the information required for any specialty drugs be exempt from disclosure under the *WV Freedom of Information Act*, W. Va. Code §29B-1-4(a)(1), as it already applied to reimbursement methodologies as detailed in provision 4.2.17 of the Proposed Rule.

- The confidentiality protections of the WV Freedom of Information Act should also apply to provision 4.2.13 of the Proposed Rule.

§114-99-10. Specialty Drug Complaints.

10.3. – "The PBM shall have 15 working days to respond.

- Allowing a PBM only 15 working days to respond is an unreasonable timeframe.
- Correspondingly, PCMA requests that a PBM be entitled to at least "30 business days" to respond.
- This is the timeframe afforded to a participating pharmacy under 9.3.3.

10.5. – "...the Commissioner shall send a copy of the specialty drug complaint, and the response(s) thereto, to the Board of Pharmacy to make a determination..."

- Currently, licensed pharmacists comprise a majority, as well as a controlling number, of the Board membership of the WV Board of Pharmacy.
- It would be inappropriate for the Board to be allowed to make determination "as to whether the covered prescription drug meets the definition of specialty drug."
- The fact that licensed pharmacists comprise a controlling number of the Board's membership and are also active market participants in the occupation the Board regulates creates a regulatory scheme for self-dealing.
- PCMA requests that the Board of Pharmacy be removed as a review and consulting entity under the provisions of this Proposed Rule, that also include these additional provisions: 10.6; 10.8; 10.9; and 10.12.

10.7. – "...and the availability or convenience of access for West Virginia residents to obtain the covered prescription drug..."

- PCMA is concerned that this language may be misconstrued to imply that any pharmacy can dispense a specialty drug.
- The phrase "convenience of access" may be interpreted in an overly subjective manner, thus it is important to remember that patient safety and adherence lead to better health outcomes.
- This is why many specialty drugs are dispensed by specialty pharmacies with proper expertise.

10.9. – "Any party has the right to contest the decision made..."

- There is no definition as to what "any party" means. For example, is the term "any party" restricted to those entities and/or individuals with an interest in a complaint, such as the Commissioner, the PBM, the Board of Pharmacy, the complainant pharmacy etc?
- What about the plan sponsor, since this is the entity that may ultimately incur the cost burden of a decision made by the Commissioner and the Board of Pharmacy?

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325 7th Street, NW, 9th Floor
Washington, DC 20004
www.pcmanet.org

PCMA

Concerns with the underlying language of HB 4112

340B Pricing Adjustments

HB 4112 prohibits PBMs or any other third party from imposing any "other adjustments" on 340B claims that are not placed upon other pharmacies that do not participate in the 340B program. It's important to note that PBMs are already prohibited from paying 340B entities for drug costs below what the pay non-340B entities for the same drug under §33- 51-9(d) of this same statute.

Additionally, it's important to note that Medicaid and Medicare Part D programs require claim modifiers on 340B claims, the very thing HB 4112 is trying to prohibit. We want it understood that after the passage of HB 4112 as written, West Virginia pharmacist will still need to provide this information on the majority of the 340B claims they file.

The federal 340B Drug Pricing Program was created in 1992 to require that drug manufacturers provide outpatient drugs to eligible health care providers, known as "covered entities." In turn, these drugs are provided at significant discounts. The federal Health Resources and Services Administration (HRSA), part if the U.S. Department of Health and Human Services ("HHS") oversees the 340 Program. The intent of the program is to enable these eligible providers to serve the nation's most vulnerable patient populations.

When providing outpatient drugs to eligible providers, manufacturers must enter into a pharmaceutical pricing agreement ("PPA") with the HHS Secretary for the drugs to be covered under Medicaid and Medicare. Under the terms of the PPA, the manufacturer agrees to provide front-end discounts on covered outpatient drugs purchased by covered entities. These discounts average 30 percent (%) off the average manufacturer ("AMP") for brand-name drugs and 13 percent (%) for generic drugs. Historically, the Dept. of HHS has argued that it has broad statutory authority to adjust drug payments. It has also issued advisory opinions for industry guidance on the 340B Program.

Currently, 340B covered entities will typically create their own contract pharmacies. Covered entities then purchase a drug at about 70 percent (%) of the average wholesale price ("AWP") and supply it to their contract pharmacy for dispensing. In turn, PBMs reimburse a contract pharmacy for 100 percent (%) of the drug's AWP. The result is the contract pharmacy pocketing the 30 percent (%) reimbursement difference as profit.

Recent studies show that hospitals can earn substantial profits on specialty drugs, which as covered entities, they dispense to patient via their own contract pharmacies.[1] For example, 340B hospitals often earn mark-ups of 380 percent (%) over an oncology drug's acquisition cost. For some drugs, the mark-ups were ten times (10x) the acquisition costs. What's more,

[1] Aharon Gal, Ph.D. *Examining Hospital Price Transparency, Drug Profits, & the 340B Program* (September 2021), *available at* http://communityoncology.org/hospital-340b-drug-profits-report/

commercial health plans generally paid hospitals almost twice the WAC list price. Because of this, it is imperative that the federal 340B Program achieve a federal solution.

The 340B Program needs clarity from the federal government to sort out pending litigation, as well as proposed federal and state legislation that seeks to solve any problems related to the program. Medicaid currently requires claim modifiers on 340B claims. The very thing that the language of HB 4112 prohibits. Claims modifiers for 340B claims ensures that rebates are appropriately credited to Medicaid. By seeking to prohibit claims modifiers on 340B claims, the WV OIC is effectively endorsing the practice by which covered entities create an unmanaged health care system in establishing their own network of contract pharmacies. Unmanaged care is unaffordable care. It generates profits on the back of employers, patients, and payers.

For these reasons, we respectfully request that the WV OIC recognize that the savings generated by the federal 340B Program would not benefit patients without the use of claims modifiers. Instead, the language of HB 4112 bolsters the profits of covered entities and their contract pharmacies.

PCMA appreciates the opportunity to comment on the Proposed Rule. We look forward to a continued dialogue with the WV OIC regarding both the Proposed Rule and additional issues as they arise. Please feel free to contact me with any questions or for further discussion.

Sincerely,

Peter Fjelstad

Peter Fjelstad
Director, State Regulatory & Legal Affairs

Pharmaceutical Care Management Association
325 7th Street, NW, 9th Floor
Washington, DC 20004
www.pcmanet.org

WVIPA
West Virginia Independent Pharmacy Association

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Phone: (304) 654-4214
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Web: www.WVIPA.org
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Mr. Michael Malone
West Virginia Offices of the Insurance Commissioner
900 Pennsylvania Avenue, 8th Floor
Charleston, WV 25302
Email: michael.n.malone@wv.gov

June 24, 2022

Re: Comments on Proposed Rule 114 CSR 99

Dear Mr. Malone:

On behalf of the West Virginia Independent Pharmacy Association ("WVIPA"), its 72 organizational members, and the 130 West Virginia pharmacy sites owned and operated by those members, we respectfully offer our comments on Proposed Rule 114 CSR 99: Pharmacy Auditing Entities and Pharmacy Benefit Managers. Thank you for the opportunity to offer comments. In our opinion, the West Virginia Offices of the Insurance Commissioner ("WVOIC") continues to sufficiently and properly implement the legislative intent within the context of West Virginia Code §33-51 *et seq.*, following passage of House Bill 4112 during the 2022 Regular Legislative Session.

Additionally, the WVIPA appreciates the Legislature and WVOIC addressing the many challenges faced by pharmacies and their patients by updating and amending relevant protections and specific duties and responsibilities of pharmacy benefit managers ("PBMs") operating in West Virginia. Pharmacy issues are extraordinarily complex and important in terms of providing quality health care for patients, while also containing rising health care costs. Increasing transparency and offering additional patient protections establishes West Virginia as a national leader in this area. With these comments, we seek to highlight and support provisions of the proposed rule and suggest modifications to further strengthen or clarify the proposed rule.

Applicability of Pharmacy Audit Integrity Act ("Act") to ERISA Plans

One purpose of House Bill 4112 (2022) and HB 2263 (2021) was to apply pharmacy reimbursement requirements of the Act to Employee Retirement Income Security Act of 1974 ("ERISA") Plans, including the reimbursement floor of National Average Drug Acquisition Cost

("NADAC") plus a $10.49 professional dispensing fee for prescription drug and pharmacy services. While HB 2263 originally established this reimbursement methodology, the addition of the more comprehensive defined terms "healthcare payor" and "payor," and the deletion of terms "covered entity," "health carrier," and "third party," provides clarity to the law/rule, without making substantive changes to the 2021 law. Further, the WVIPA believes this is appropriate under court decisions throughout the country, including the Supreme Court of the United States' decision in *Rutledge v. PCMA*. Clearly, the West Virginia Legislature, Governor's Office, Department of Health and Human Resources ("DHHR") and its Medicaid operations, and the WVOIC, agree that this methodology is the most equitable, reliable, and transparent model by which to reimburse pharmacies, as this methodology is now used across various health care programs and plans (Medicaid, fully insured, ERISA, etc.) in the Mountain State. The WVIPA urges the WVOIC to protect and further this legislative intent by closely monitoring PBM conduct across these various programs and plan types, as WVIPA members have been informed by various licensed and unlicensed PBMs of instances of willful noncompliance. Further, the WVIPA urges the WVOIC to apply fines, sanctions, licensure suspension/revocation for PBM noncompliance immediately.

Spread Pricing / Pass Through Pricing & Drug Manufacturer Rebates

Although the issue may not be explicitly prohibited in current West Virginia law or this proposed rule, the WVIPA firmly believes that "spread pricing" should be made explicitly unlawful in West Virginia. WVIPA members are also employers that provide health benefits to many employees. WVIPA employers want their own health benefit plans to be affordable as well as the health benefit plans of other employers in their communities. For example, PBMs often charge employer-based health benefit plans more for the price of drugs than what is paid to dispensing pharmacies, without informing plans about this "spread pricing." This leads to confusion for plans and plan beneficiaries, ultimately resulting in increased drug costs and health care costs in general, not to mention unjust enrichment to the benefit of the PBM. The WVIPA believes PBMs should charge plans the same amounts for drugs that the PBMs reimburse pharmacies for those drugs. At the very least, if spread pricing does occur, PBMs should clearly notify plans and plan beneficiaries beforehand. This transparency is important.

For example, the WVIPA was recently made aware by an ERISA plan that a PBM had charged the plan a nearly a 100% mark-up on buprenorphine-naloxone, a drug used to help treat opioid dependence:

Drug NDC	Drug Name	Drug Strength	Quantity	Days of Supply	Rx Count	Plan Cost	NADAC Cost	Difference	Markup
47781035705	BUPRENORPHINE-NALOXONE	8 MG-2 MG	45.00	30	1	$ 289.77	$ 147.72	$ 142.05	96%
47781035705	BUPRENORPHINE-NALOXONE	8 MG-2 MG	28.00	14	1	$ 176.50	$ 92.21	$ 84.29	91%

Rule Sections 4.2.18 and 4.4.1.d attempt to address this issue by requiring attestations that the PBM has offered health benefit plans the option of pass-through pricing. The WVIPA anticipates that PBMs will refuse to comply with this provision related to ERISA plans. If this offer is clearly made from PBM to plans, the WVIPA believes that most, if not all, health benefit plans will elect for pass-through pricing. If they do not, these plans will have been provided adequate transparency and fair opportunities to remedy the "spread pricing" issue.

Additionally, West Virginia laws and rules state that patients are to receive drug manufacturer rebates at the point of sale to reduce defined cost sharing. To date, WVIPA members have not received information, instructions, or processing requests to effectuate this process. The WVIPA urges the WVOIC to closely examine this process and the parties involved, with the understanding that independent community pharmacies and their patients are not harmed or held responsible for these obligations.

Defining "Specialty Drug" and the Protecting Patient Access to Specialty Drugs

In recent years, patient access to drugs has been unreasonably limited by PBMs. Specifically, the list of drugs defined as "specialty drugs" by PBMs, insurance companies, and drug manufacturers has grown significantly, as have the costs associated with these drugs. Often, drugs are defined or classified as "specialty drugs" because of their expensive prices and lucrative drug manufacturer rebates, not necessarily because they are used to treat rare or chronic and complex medical conditions, or because they require special handling or administration, provider care coordination, or patient education that cannot be provided by a non-specialty pharmacy or pharmacist. It has become common practice for PBMs to force patients to receive their medications via mail order pharmacies, leaving patients without choice to receive medications from trusted local independent community pharmacies and pharmacists. Furthermore, many so-called "specialty pharmacies" do not report their pricing data to the NADAC survey. This leaves independent community pharmacies, patients, policymakers, and regulators in the dark as to the true cost of medications.

Thousands of patients have contacted WVIPA member pharmacies, confused as to why they cannot receive their medications at their pharmacy of choice. Explaining this issue is difficult, and often leads to confusion, frustration, and sometimes strained relationships between patients and pharmacists. PBMs often make the hollow argument that "specialty drugs" must be mailed to patients due to safety concerns, as if mailing a medication to a patient's home without pharmacist interaction is somehow safer and more clinically adequate than a patient receiving their medication face to face and receiving counseling from a trusted pharmacist in their local community. This argument is flawed, and has been summarily rejected by policymakers and regulators in West Virginia. Thankfully, this barrier to patient access has been removed under West Virginia law and this rule, giving patients the pharmacy access they deserve and desire.

The specific language found in 4.2.13 will be important to provide transparency related to separate sub-networks for specialty drugs, which are not accessible to most pharmacies. Clearly, the West Virginia Legislature intends for PBMs to provide increased transparency and access for patients related to their prescriptions. Further, the creation of processes giving beneficiaries access to drugs from the pharmacies and pharmacists of choice will improve access. The WVOIC and the West Virginia Board of Pharmacy ("WVBP") are the appropriate agencies for making the determination as to whether drugs meet the definition of a "specialty drug." While some drugs truly are appropriately designated as "specialty drugs," and should be handled differently than other medications, customary PBM processes unreasonably limit patient access and create unfair practices that benefit PBMs and affiliated pharmacies, not patients.

"Specialty Drug" Complaints

The WVIPA supports the rule's language related to specialty drug complaints. The process, form, and requirements seem to be reasonable, fair, and efficient. One concern the WVIPA has is the ability of a PBM and/or health benefit plan to "resolve" a specific specialty drug complaint, formally or informally, for one individual or entity, to avoid applying the same standard consistently each time the specific drug is covered, as would be the case if the Commissioner found that the drug does not meet the definition of a specialty drug and that a beneficiary's access is being prohibited or limited in violation of West Virginia law, and further ordered that the drug be removed from the PBM and/or health benefit plan's specialty drug list. Put simply, the WVIPA supports consistent application of determinations made related to specific drugs – whether made informally by a PBM or health benefit plan or made formally by the WVOIC and WVBP.

PBM Disclosures and Filings

The WVIPA supports requiring PBM disclosure of whether the PBM applicant has been refused a registration, license, or certification to act as a PBM or third-party administrator, has any registration, license, or certification to act as such been denied, suspended, or 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, including another state's department of insurance or similar agency. It is appropriate for the WVOIC to prevent PBMs that have violated the laws/rules of other states from being licensed and active in West Virginia, to adequately protect patients.

The WVIPA also supports the requirement under 4.2.17 stating that all filed reimbursement methodologies comply with West Virginia law, and that all contracts provide for clear reimbursement terms. Over the past year, various West Virginia pharmacies were confused by terms in proposed PBM contracts that did not comply with NADAC+$10.49 reimbursement, which may have led to these pharmacies not completing or rejecting the contracts, for fear of signing a contract that did not comply with West Virginia laws/rules. Unclear or misleading contract terms proposed by PBMs to pharmacies will lead to network vacancies, network inadequacy, and pharmacy access gaps for patients.

Prohibitions Against Required Mail-Order Pharmacy

As was mentioned above, the WVIPA supports all prohibitions against required use of mail-order pharmacy under 6.1. The WVIPA supports mail-order pharmacy being made available as a choice for patients. Additions in this section of the rule will improve access, protect patients, and promote network adequacy in leased network situations.

PBM Penalties

Again, the WVIPA urges the WVOIC to issue penalties in the amount of $10,000 per violation for violations of the Act and Rule. PBMs have violated, and continue to violate, the Act and rules. These violations cause real harm to patients, pharmacies, and employers in West Virginia. If the

per violation financial penalties are not effective in stopping these violations, the WVIPA urges the WVOIC to order PBM licensure suspensions and/or revocations.

Thank you for your time and consideration of these comments. Should you wish to discuss the comments in this letter, please contact Matthew Walker, WVIPA Executive Director, by email at matt@walkerandstevens.com or by phone at (304) 654-4214.

Respectfully Submitted:

Michael Rudge, Board President
West Virginia Independent Pharmacy Association

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

WV
Primary Care Association

One Mission. One Vision. One Voice.

Submitted Electronically

July 1, 2022

Mr. Michael Malone
West Virginia Offices of the Insurance Commissioner
900 Pennsylvania Avenue, 8th Floor
Charleston, WV 25302
Email: michael.n.malone@wv.gov

RE: Comments Related to 114 CSR 99

Dear Mr. Malone:

I am writing you on behalf of the West Virginia Primary Care Association, Inc. (hereinafter "WVPCA"). The WVPCA represents the state's 32 community health centers and one rural health clinic, which constitute the largest independent primary care network in the state. Community health centers and rural health clinics provide primary care services, and many offer additional services such as dental, behavioral health, school-based health, and pharmacy services at in-house and contract pharmacies. Services and prescriptions are provided to community health center patients regardless of their insurance status or ability to pay. More than 470,000 West Virginians receive health care services from a community health center—more than one out of every four citizens.

Thank you for this opportunity to comment on 114 CSR 99, the legislative rule relating to Pharmacy Auditing Entities and Pharmacy Benefits Managers. This rule is tremendously important to WVPCA members and their patients in terms of accessing quality pharmacy services. The WVPCA's comments will focus mainly on the rule's 340B Drug Pricing Program related provisions.

Over the past several years, pharmacy benefit managers (hereinafter "PBMs") have engaged in behavior that is harmful to safety net health care providers, especially those that participate in the federal 340B Drug Pricing Program. The purpose of the 340B Program, overseen by the U.S. Health Resources & Services Administration, is to allow participating entities to stretch scarce resources as far as possible to reach and serve additional patients and provide more comprehensive health care services. The 340B Program is especially important in a rural, underserved state like West Virginia.

As you know, the WVPCA and several other major health care associations/providers were involved in a PBM complaint through the West Virginia Offices of the Insurance Commissioner (hereinafter "WVOIC") following a PBM violation of the *Pharmacy Audit Integrity Act*. The WVOIC recently ruled that a PBM violated W.Va. Code §33-51-9(d) by requiring a post claim adjudication modifier to identify 340B drug claims. Per page 22 of the order: "It is recommended that the Complainants proved, by a preponderance of the evidence, that the Respondent's [ESI's] new submission policy is discriminatory and violates W.Va. Code §33-51-9(d) since the costs associated with this change will be assessed on 340B entities and not upon other similar entities." If left to their own devices, the WVPCA fears that PBMs will attempt the same or substantially similar attacks on 340B covered entity pharmacies in the future. The WVPCA supports this rule as written, and respectfully provides the following comments:

- In 1.6 and in other related sections of the rule, it is important to note that certain sections of the rule affecting pharmacy costs, pricing, and other issues are not preempted by the Employee Retirement Income Security Act of 1974 (hereinafter "ERISA"). It is the WVPCA's understanding that most, if not all, PBMs operating in West Virginia are willfully violating West Virginia's laws and rules related to ERISA pharmacy claims, such as NADAC + $10.49 reimbursement, pharmacy networks, basic patient pharmacy choice, and drug rebate sharing provisions. The WVPCA respectfully requests that the WVOIC enforce these laws/rules and hold PBMs accountable for these violations as soon as possible.

- In 2.7, the additions of "Health care payor" and "payor" are helpful in understanding the Legislative intent of House Bill 4112 and various pieces of legislation passed and signed into law before it. It is important to note that pharmacy reimbursement and other provisions were originally included in 2021's House Bill 2263, and have been in effect for some time.

- In 2.22, it is important for 340B drug discounts or payments to remain explicitly excluded from any definition of "rebate." 340B discounts are not rebates, and any effort to define them as such or transition the 340B Program from a discount program to a rebate program should be rejected.

- In 2.24 and 9.2.1.c, and in later rule provisions, such as §114-99-10, the WVPCA supports protecting patient choice of pharmacy at all times, including instances when certain drugs have been classified as "specialty" by PBMs and others in the past. The state of West Virgnia, WVOIC, and West Virginia Board of Pharmacy (hereinafter "WVBP") must continue to place special emphasis on protecting patient access to medications and patient choice of pharmacy. This is especially relevant to 340B entity pharmacies, as PBMs often attempt to implement barriers such as discriminatory reimbursement, claims modifiers/tags, reprocessing, and restrictive networking processes to limit patient choice and circumvent the purpose of the 340B Program related to "specialty" drugs, which are often expensive brand name drugs, as opposed to less expensive generic drugs. The WVPCA also supports a prohibition on PBMs imposing requirements inconsistent with or more stringent than the

WVBP for participation in health benefit plan networks . Further, the WVPCA supports the "Specialty Drug Complaints" process as written in this rule.

- Furthering the protection of patient pharmacy choice and ensuring reasonable opportunities for participation in all PBM networks for 340B entity pharmacies, the WVPCA respectfully requests that the WVOIC closely monitor several "specialty" drug issues. For background purposes, please note that the WVPCA and other pharmacy representatives participated in a Public Employees Insurance Agency (hereinafter "PEIA") PBM Transition Call on May 23 with PEIA and ESI representatives. During that call, ESI representatives stated that West Virginia pharmacies of various types (WVPCA members and other 340B contract pharmacies included) will be allowed to participate in ESI's specialty drug network as of 10/1/22. Most pharmacies have not been allowed to participate in this network in the past, which prevented FQHC pharmacies from being able to dispense PEIA prescriptions that were designated as "specialty." To participate, pharmacies must join ESI's "Specialty Precision Network." While the WVPCA appreciates this opportunity, the ability of WVPCA member in-house and contract pharmacies to meet additional any applicable certification/accreditation standards will determine whether this network is truly available to these pharmacies. As was mentioned above, imposing requirements for network participation that are reasonable and attainable by a variety of West Virginia pharmacies is essential. Imposing requirements for network participation that are not attainable is not reasonable, and will severely limit patient choice of 340B entity pharmacies across the state. ESI representatives also stated that they will solicit participation in this specialty network. To date, the WVPCA has not seen the contract terms for network participation, but we are eager to begin this process and provide education to members about the network and how to participate.

- In 4.2.17, it is important that all PBM filed methodologies comply with West Virginia law, and PBMs should make clear in their contracts that the NADAC + $10.49 reimbursement methodology will be applied correctly and consistently, including ERISA pharmacy claims.

- In 4.2.18, PBMs should be held to this transparent standard, by offering all health benefit plans the option of pass-through pricing as required by West Virginia law, followed by an attestation to the WVOIC. Requiring PBMs to offer health plan clients the option of pass-through pricing is important. Further, the WVPCA supports this provision being extended not only to commercial (fully insured) plans, but to the various types of ERISA plans (self-funded, partially self-funded, level funded, etc.) as well. This will increase transparency for plan sponsors and their beneficiaries in the Mountain State.

- As W.Va. Code §33-51-9-c and §33-51-9-d are applicable to PEIA, as well as under 5.6 and 5.7 of this rule, the WVPCA respectfully requests that the WVOIC assume the responsibility of fielding 340B related complaints against PBMs under these sections. The WVPCA recognizes that, in most instances, the WVOIC is not the appropriate regulator for PEIA. However, regarding 340B issues related to PEIA's contracted PBM, the Legislature clearly

intended the WVOIC to assume regulatory authority. Further, the Legislature intended the addition of an explanation that discriminatory 340B practices include actions that "prevents or interferes with a patient's choice to receive drugs at a 340B entity..." to not only include modifiers/tags or reprocessing/resubmitting mandates, but other actions as well. Clearly, protecting patients' rights to choose a 340B entity pharmacy are mandated to be protected.

Thank you for your consideration of our comments. If you have questions or wish to discuss this letter in detail, please do not hesitate to contact me at 304.346.0032 or at Sherri@wvpca.org.

Sincerely,

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