STATE OF WEST VIRGINIA
Offices of the Insurance Commissioner

James A. Dodrill
Insurance Commissioner

July 23, 2021

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 numerous stakeholders, including the National Association of Chain Drug Stores, National Community Pharmacists Association, Fruth Pharmacy, Mitchell International, Consumer Action, CareSource, Highmark West Virginia, Coalition of State Rheumatology Organizations, West Virginia Independent Pharmacy Association, Pharmaceutical Care Management Association, Pharmaceutical Research and Manufacturers of America, and medical provider associations. Most of the 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.

Nine entities (West Virginia Primary Care Association, West Virginia Hospital Association, Charleston Area Medical Center/CAMC Health System, Mountain Health Network, West Virginia University Health System, Marshall Health, Marshall Pharmacy, Partners in Health Network Inc., West Virginia Pharmacists Association) jointly submitted comments. In addition to their supportive comments, these entities proposed two modifications to subsection 6.1.3 of the rule, which provides: "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." First, it was proposed that this provision could be interpreted as only requiring data on pharmacists and pharmacies who/that have terminated with the covered entity but not the reverse – pharmacists and pharmacies who/that have been terminated from the network by the covered entity. Second, the entities noted that pharmacy services administration organizations

("PSAOs") contract with pharmacists and pharmacies to assist with third-party payer interactions and other administrative services. The entities suggested that subsection 6.1.3 include PSAOs. The OIC agrees that the subsection should be modified as proposed. Accordingly, the OIC will change the subsection to read as follows: "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, pharmacies and pharmacy services administration organizations that have either terminated their network participation with the covered entity or have had their network participation terminated by the covered entity."

The West Virginia Independent Pharmacy Association (WVIPA) offers two revisions to section 1.6 of the rule in light of the evolving law with respect to ERISA health plans and affiliated PBMs. First, the WVIPA suggests that the word "rates" be included in the following sentence of section 1.6: "However, certain sections of this rule that only affect costs, pricing, ***rates*** or alter incentives for ERISA plans are not preempted by ERISA and are accordingly applicable." The OIC declines to make this revision considering it believes the language as drafted more closely adheres to the decision in *Rutledge v. Pharmaceutical Care Management Assn.*, 592 U.S. ___, 141 S. Ct. 474, 208 L. Ed. 2d 327 (2020). The second recommendation of WVIPA regarding section 1.6 is to add the following sentence: "This section does not limit the applicability of other sections to ERISA plans should federal law or judicial decisions afford the state authority to regulate." The OIC agrees that the additional sentence would ensure that the rule is valid and enforceable in the event of future changes to the law. Thus, the OIC will add the following sentence to section 1.6: "This section does not limit the applicability of other sections to ERISA plans should federal statutory or common law afford the state authority to regulate."

WVIPA next requests clarification of subsection 9.3.1 of the rule, which provides:

> If a health benefit plan restricts pharmacy participation through a network, the covered entity providing the health benefit plan shall notify, in writing, all pharmacies within the geographic coverage area of the health benefit plan and offer those pharmacies the opportunity to participate in the health benefit plan's network. Notification shall be provided at least 60 days prior to the effective date of the health benefit plan's network.

It is posited by WVIPA that this provision could be interpreted as being applicable to only those health benefit plans that begin restricting a network prior to the effective date of the network, and not applicable to plans that already have a restricted network in place when the rule becomes effective. The OIC agrees that this may lead to such an interpretation and further finds that subsection 9.3.1 does not agree with its companion statute, W. Va. Code § 33-51-11(b). The OIC will accordingly propose the following revision to the subsection to more closely track the statute, which should ameliorate the concerns of WVIPA:

> If a health benefit plan restricts pharmacy participation through a network, the covered entity providing the health benefit plan shall notify, in writing, all pharmacies within the geographic

> coverage area of the health benefit plan and offer those pharmacies the opportunity to participate in the health benefit plan's network. Notification shall be provided at least 60 days prior to the effective date of the health benefit plan, or, if the plan is in effect at the time this rule becomes effective, at least 60 days prior to the plan's renewal.

A comment offered by Fruth Pharmacy suggests that the rule clarify that the reimbursement methodology set forth in section 5.9 of the rule (*i.e.*, prescription drug or pharmacy service is to be paid in an amount no less than the national average drug acquisition cost for the prescription drug or pharmacy service at the time the drug is administered or dispensed plus a dispensing fee of $10.49) is the minimum net reimbursement permitted after any fee charged by a PBM. The OIC declines to provide such a revision to the rule because it believes the enabling statute and proposed rule already clearly establish the "floor" or minimum for permissible reimbursement by a PBM.

Highmark West Virginia provided a comment requesting that section 6.5 of the rule, which pertains to the confidentiality of certain information submitted to the OIC, more closely conform to its corresponding statutory provision (W. Va. Code § 33-51-12(f)). The OIC acknowledges that section 6.5 unintentionally failed to exactly track the statute in that the rule provision is only applicable to PBMs while the statute applies to PBMs, health plans and covered entities. The OIC will accordingly revise section 6.5 to include health plans and covered entities.

Several comments were submitted by CareSource. It first recommended that "copays" be defined in the rule considering the definition of "defined cost sharing" may cause confusion due to the fact that some benefit designs include fixed copays in addition to or in lieu of deductibles or coinsurance. While the OIC believes that having a definition of copays is unnecessary, it will amend the definition of defined cost sharing at section 2.6 of the rule to clarify that copayments are not included. CareSource next suggests that the term "coinsurance" be included in the last sentence of subsection 5.13.3 of the rule to provide clarity. That subsection provides that a PBM shall not engage in any practice that "[d]erives any revenue from a pharmacy or insured in connection with performing pharmacy benefits management services. This prohibition shall not prohibit a PBM from receiving deductibles or co-payments." The OIC agrees that the Legislature did not intend for this subsection to prohibit a PBM from receiving coinsurance and will accordingly revise the subsection.

CareSource next takes issue with section 5.15 of the rule and its corresponding subsections. It is asserted by CareSource that the requirement for prescription drug rebates to be passed on to consumers at the point of sale fails to account for how pharmaceutical manufacturers actually pay rebates to employers and health plans based on a defined performance period and typically after drugs are dispensed. Thus, CareSource proposes that section 5.15 be revised to include the following emphasized language ". . . is reduced by an amount ***expected to be*** equal to at least 100% . . .." It is further suggested that the OIC consider a percentage of error in this section considering rebate pricing may not be exact at the point of sale and that language be included whereby a person's copay shall not exceed the price of the prescription drug that is reduced by an amount expected to be equal to at

least 100% of all applicable rebates received. And finally with respect to section 5.15, CareSource suggested that subsection 5.15.5 be revised as follows: ". . . covered individual's defined cost sharing ***or copay*** by an amount greater . . .." In response to these comments, the OIC believes that the suggested revisions would substantively depart from the enabling statute and the legislative intent of House Bill 2263. The OIC accordingly declines to propose any changes to section 5.15 as a result of these comments.

CareSource additionally inquires if standards will be forthcoming regarding the implementation of subsection 6.1.1 of the rule, which requires a PBM to maintain a reasonably adequate and accessible pharmacy network. OIC responds that such standards may be developed and set forth in an amendment to 114CSR100, Health Benefit Plan Network Access and Adequacy. CareSource also opines that subdivision 9.2.1.d of the rule will restrict the ability of a health benefit plan to do a "preferred pharmacy" type program and could contradict guidance from the federal Centers for Medicare and Medicaid Services that promotes value-based care and helping to direct members to lower costs of care. The OIC responds to this comment by noting that subdivision 9.2.1.d mirrors W. Va. Code § 33-51-11(a)(4) and thus is not a rule provision that can be substantively changed as suggested.

It is next suggested by CareSource that subdivision 9.2.1.g of the rule regarding reimbursement parity among mail order services and retail location services will raise implementation questions from an operational standpoint. In response, the OIC again states that this subdivision is a rule provision that precisely tracks the statutory language (W. Va. Code § 33-51-11(a)(7)) and accordingly is not a rule provision that the OIC can fundamentally modify.

CareSource finally comments that the notification requirements set forth in subsection 9.3.3 regarding changes in network participation by pharmacies would be costly and unduly burdensome on health benefit plans, as well as providing little to no benefit to insureds. The OIC agrees that the requirement for a health plan to notify its beneficiaries each time a pharmacy enters or leaves the network would be cumbersome to the health plan and could result in a situation where beneficiaries would be more likely to disregard notifications from the plan. Thus, the OIC agrees to modify subsection 9.3.3 as follows:

> A covered entity providing the health benefit plan shall inform the beneficiaries of the plan of the names and locations of pharmacies that are participating in the health benefit plan's network. Notification to beneficiaries should be provided through reasonable means, on a timely basis and at regular intervals. For purposes of this subsection, "reasonable means" may include written or electronic communications to beneficiaries by a health benefit plan, as well as publication on the health benefit plan's publicly available website. For purposes of this subsection, "regular intervals" should include notification to beneficiaries during a health benefit plan's open enrollment periods and at least on a quarterly basis.

A comment submitted by the Coalition of State Rheumatology Organizations ("CSRO") notes that a PBM may be unable to accurately predict the total amount of a rebate at the time of claim administration due to contractual incentives that are based on broader utilization beyond a single claim. According to CSRO, this could result in a discrepancy between the cost-sharing reduction at the time of claim administration and the total rebate received. It is recommended by CSRO that the OIC consider implementing additional reporting requirements that allow the agency to appropriately monitor PBM compliance with section 5.15 of the rule, which requires the pass-through of the "rebate received, ***or to be received***" to the covered individual. The OIC responds that it believes it has ample reporting requirements within the proposed rule to observe whether a PBM is adhering to section 5.15. However, should the OIC find that the requirements are insufficient in that regard, it will offer corrective amendments to the rule at a later date.

Consumer Action, which is purportedly an advocate for competitive health care markets, tendered a comment that supported the rule but also asserted that it did not go far enough in addressing what it calls a "rebate trap." According to this commentator, a rebate trap is when a drug manufacturer with dominant blockbuster drugs uses financial incentives in the form of conditional rebates to negotiate formulary access and exclude competing drugs, the end result being that patients are denied access to lower cost and more efficacious drugs. While Consumer Action's comment letter is very informative, the OIC believes that the rule under consideration is likely not the proper avenue to address so-called rebate traps. The OIC is tasked with proposing a rule that implements the provisions of House Bill 2263 (2021). Rebate traps were not addressed in this enabling legislation and thus the OIC is without authority to propose rule provisions on that subject.

A comment from Mitchell International opined that it did not believe the rule was applicable to workers' compensation and automobile insurance as a result of the definitions of "covered entity" and "health insurance policy." It is the OIC's position that "health insurance policy," which is broadly defined in W. Va. Code § 33-51-3 as "a policy, subscriber contract, certificate, or plan that provides prescription drug coverage," is sufficient for the rule to apply to workers' compensation insurance where there is prescription drug coverage under the policy. Although not directly on point, in further support of the OIC's position that the Legislature intended the rule and corresponding statutes to broadly apply, the OIC notes that "third party" is defined in the enabling statute as "any insurer, health benefit plan for employees which provides a pharmacy benefits plan, a participating public agency which provides a system of health insurance for public employees, their dependents and retirees, or any other insurer or organization that provides health coverage, benefits, or coverage of prescription drugs as part of workers' compensation insurance in accordance with state or federal law. The term does not include an insurer that provides coverage under a policy of casualty or property insurance." As such, despite the fact that workers' compensation insurers are generally licensed as casualty insurers, they were explicitly included within the definition of "third party," while other property and casualty insurers, such as automobile insurers, were excluded. To provide more clarity in this regard, the OIC will amend the last sentence of section 1.6 of the rule to read as follows: "This rule applies to PBMs that manage prescription drug coverage for workers' compensation insurers and employers who are self-insured for workers' compensation in this state

because workers' compensation insurers and self-insured employers are "covered entities" that provide pharmacy benefits under a "health insurance policy," as those terms are defined in W. Va. Code §33-51-3 and this rule."

Mitchell further comments that several of the rule provisions either conflict with the regulatory scheme relating to workers' compensation coverage or are inapplicable to how workers' compensation insurance is designed. The OIC responds that workers' compensation carriers and their PBMs should comply with the rule provisions where they are applicable to the coverage that is provided. With respect to the rule provisions conflicting with worker's compensation rules, the OIC opines that the subject rule provisions should control. This opinion is based on the fact that workers' compensation rules are "legislatively exempt" rules, meaning they are not formally approved by the Legislature, while the rule under consideration here is subject to ratification by the Legislature. The OIC further responds that it will provide guidance on which rule provisions are applicable to workers' compensation carriers on a case-by-case basis and/or through the issuance of an informational bulletin in the future. Furthermore, the OIC will undertake a review of its workers' compensation rules and attempt to eliminate any direct inconsistencies should any be identified.

The National Association of Chain Drug Stores (NACDS) provided a comment requesting the OIC to clarify how certain statutory provisions relating to drug reimbursements to a pharmacy by PBMs are to be implemented. More specifically, NACDS asks for clarification with respect to what fees would be permitted under W. Va. Code § 33-51-9(c)(1), which provides that a PBM "may only directly or indirectly charge or hold a pharmacy, a pharmacist, or a pharmacy technician responsible for a fee related to the adjudication of a claim if . . . [t]he total amount of the fee is identified, reported, and specifically explained for each line item on the remittance advice of the adjudicated claim." As noted by NACDS, PBMs are prohibited pursuant to W. Va. Code § 33-51-9(j)(2)(B) from imposing a "point-of-sale fee" or "retroactive fee," as those terms are defined in W. Va. Code § 33-51-3. Moreover, any fee would be prohibited if it has the effect of lowering the reimbursement "floor" set forth in W. Va. Code § 33-51-9(f). NACDS also suggests an additional subdivision be inserted into W. Va. Code § 33-51-9(c). Of course, the addition of a new statutory subsection can only be accomplished by the Legislature and thus the OIC must decline to substantively address this recommendation.

A comment submitted by the Pharmaceutical Research and Manufacturers of America ("PhRMA") recommends that the OIC require PBMs to submit an annual certification that they have complied with the requirements of House Bill 2263 relating to the calculation of patient cost sharing. The OIC appreciates this comment but declines to propose such a requirement. The OIC believes that the certification will do little to cause compliance with the rule. Further, the OIC has sufficient tools, such as periodic audits and targeted market conduct exams, to ensure compliance.

It is further requested by PhRMA that the language added to sections 5.7 and 5.8 of the rule be removed. Those provisions, including the proposed new language as underlined, is as follows:

5.7. A PBM or any other third party that reimburses a 340B entity for drugs that are subject to an agreement under 42 U.S.C. §256b shall not reimburse the 340B entity for pharmacy-dispensed drugs at a rate lower than that paid for the same drug to pharmacies similar in prescription volume that are not 340B entities, and shall not assess any fee, charge-back, or other adjustment upon the 340B entity on the basis that the 340B entity participates in the program set forth in 42 U.S.C. §256b. For purposes of this section, the term "other adjustment" includes placing any additional requirements, restrictions or unnecessary burdens upon the 340B entity that results in administrative costs or fees to the 340B entity that are not placed upon other pharmacies that do not participate in the 340B program, including affiliate pharmacies of the PBM, and further includes but is not limited to requiring a claim for a drug to include a modifier or be reprocessed or resubmitted to indicate that the drug is a 340B drug.

~~5.7.a.~~ 5.8. With respect to a patient eligible to receive drugs subject to an agreement under 42 U.S.C. §256b, a PBM or any other third party that makes payment for such drugs, shall not discriminate against a 340B entity in a manner that prevents or interferes with the patient's choice to receive such drugs from the 340B entity. For purposes of this ~~subsection~~ section, "third party" does not include the state Medicaid program when Medicaid is providing reimbursement for covered outpatient drugs, as that term is defined in 42 U.S.C. §1396r-8(k), on a fee-for-service basis; however, "third party" does include a Medicaid-managed care organization as described in 42 U.S.C. §1396b(m). For purposes of this section, it shall be considered a discriminatory practice that prevents or interferes with a patient's choice to receive drugs at a 340B entity if a PBM places additional requirements, restrictions or unnecessary burdens upon a 340B entity that results in administrative costs or fees to the 340B entity that are not placed upon other pharmacies that do not participate in the 340B program, including affiliate pharmacies of the PBM, and further includes but is not limited to requiring a claim for a drug to include a modifier or be reprocessed or resubmitted to indicate that the drug is a 340B drug.

PhRMA contends that the OIC's interpretation of "other adjustment" in section 5.7 is overly broad and not supported by the enabling statute. It is further asserted that the language creates bad policy considering the use of modifiers identifying 340B claims reduces the potential for duplicate claims and provides important data to manufacturers in cases of diversion, which occurs when a covered entity requests a 340B discount for someone who is not an eligible patient under federal law. With respect to the proposed language in section 5.8, PhRMA states that the purpose of the section is to prevent discriminatory practices which prevents or interferes with a patient's choice to receive drugs at a pharmacy that participates in the 340B program. The proffered language, PhRMA avers, fails to explain how a modifier

would impact an individual's choice of pharmacy, especially when considering that an individual has no way of knowing whether the pharmacy is a 340B entity. Thus, PhRMA maintains that the additional language of section 5.8 does not protect individuals from any "discriminatory practice," as well as not being supported by the corresponding statute. In response to PhRMA's comments regarding sections 5.7 and 5.8, the OIC states that during its monitoring of House Bill 2263 (2021) and Senate Bill 489 (2019) as they were being discussed in the Legislature prior to passage, it was clear that legislators wanted to ensure that 340B entities not have any impediments whatsoever regarding their participation in the federal program. The OIC believes that it was the Legislature's intent to ensure that 340B entities are not treated any differently, substantively, when it comes to drug reimbursement than how other types of pharmacies or entities are treated, and that includes placing additional administrative burdens or hurdles on 340B entities that are not applied to others, especially those that may result in higher expenses to a 340B entity or cause a 340B entity to become excluded from network participation, thus resulting in fewer choices for consumers. Additionally, the OIC has received multiple inquiries and/or consumer complaints from 340B entities about the lawfulness of modifiers and the OIC believes that clarity on the subject is needed. The OIC believes that the proposed language is consistent with this legislative intent and thus declines to remove the language as requested.

PhRMA next requests that the OIC define "aggregate" as it is used in section 6 of the rule so that it is clear that PBMs should not disclose individual drug information. The OIC believes that it is unnecessary to define the term given its common meaning (*i.e.*, to collect as a whole as opposed to individual parts). The final comment of PhRMA requests the revision of subdivision 6.2.1.c of the rule so that the reporting requirement expressed therein more closely aligns with section 5.15 of the rule. PhRMA asserts that it believes the intent of subdivision 6.2.1.c is to require PBMs to report the amount of the rebates that were used to decrease patient cost sharing in accordance with W. Va. Code § 33-51-9(*l*) and section 5.15 of the proposed rule. However, the language of subdivision 6.2.1.c does not precisely track the language of the statute and rule, which could cause confusion and ultimately result in inaccurate reporting. It is suggested that subdivision 6.2.1.c be revised as follows: "The aggregate amount of rebates used at the point of sale to reduce a covered individual's defined cost sharing in accordance with section 5.15 of this rule." The OIC agrees that the proposed language of subdivision 6.2.1.c does not adequately track that of W. Va. Code § 33-51-9(*l*) and section 5.15 of the rule and will accordingly revise the subdivision as requested.

The Pharmaceutical Care Management Association ("PCMA") offered comments regarding many of the proposed rule provisions. PCMA begins its comments by requesting that the rule clarify the effective date of House Bill 2263 due to conflicting information. The OIC believes that the legislation's internal effective date, despite its odd location, is sufficiently clear in that W. Va. Code § 33-51-9(*l*) provides, in part: "Notwithstanding any other effective date to the contrary, the amendments to this ***article*** enacted during the 2021 regular legislative session shall apply to all policies, contracts, plans, or agreements subject to this section that are delivered, executed, amended, adjusted, or renewed on or after January 1, 2022." Thus, the OIC declines to address the effective date of House Bill 2263 in the rule, as it is reasonably clear that the 2021 amendments to the entire article are effective on or after January 1, 2022.

PCMA asserts that many provisions of the law do not apply to self-funded plans based on the definition of "health benefit plan" because the definition does not include self-funded plans, and thus ERISA preemption is not an issue with respect to the rule provisions that apply to health benefit plans. The OIC believes the definition of "health benefit plan" is broad enough to encompass ERISA plans. W. Va. Code § 33-51-3 defines a health benefit plan or health plan as "a policy, contract, certificate, or agreement entered into, offered, or issued by a health carrier to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services." While the OIC acknowledges that the definition of health benefit plan or health plan does not specifically refer to a self-funded or ERISA plan, an ERISA plan is a contract or agreement entered into or offered to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care. The OIC does not believe the definition of health benefit plan or health plan must be read to be limited solely to contracts or agreements issued by health carriers. The Oxford or serial comma before "or issued by a health carrier" in the definition of health benefit plan or health plan in W. Va. Code § 33-51-3 indicates that "or issued by a health carrier" is the final item in a list of independent things and not a separate requirement in and of itself. As such, the OIC believes that a health benefit plan or health plan is a policy or contract or certificate or agreement that is entered into or offered or issued by a health carrier to provide or deliver or arrange for or pay for or reimburse any of the costs of health care services. If the Legislature intended that a policy, contract, certificate, or agreement was required to be issued by a health carrier in order to meet the definition of health benefit plan or health plan, it could have simply stated that a "health benefit plan or health plan means a policy, contract, certificate, or agreement entered into or offered by a health carrier to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services." Instead, it chose to place a comma before "or issued by a health carrier" and, thus, the OIC interprets that phrase as the final item in a list. The explicit usage of the comma before "or issued by a health carrier," combined with the actual removal of the ERISA exemptions from the applicability sections that were previously in W. Va. Code § 33-51-8(f)(2) and W. Va. Code § 33-51-9(f) provide clear legislative guidance to the OIC to include self-funded ERISA plans within the PBM regulatory scheme to the fullest extent permitted by federal law.

In its next comment, PCMA states that the sentence beginning with "However" in section 1.6 of the rule appears to conflict with the sentence immediately prior to it. Those sentences state:

> Additionally, certain sections of this rule may not be applicable to health benefit plans or health plans that are subject to the Employee Retirement Income Security Act of 1974 (ERISA) if the subject provision of the rule regulates a key facet or essential part of plan administration or design and is preempted by ERISA. However, certain sections of this rule that only affect costs, pricing or alter incentives for ERISA plans are not preempted by ERISA and may be applicable.

The OIC does not see a conflict between the two sentences. The first sentence expresses the view that if a rule provision pertains to plan administration or design, then it may be preempted by ERISA. The second sentence sets forth the position of the OIC that a rule

provision affecting cost, pricing or which alters incentives would not be preempted by ERISA. The OIC believes this agrees with the United States Supreme Court decision in *Rutledge*, *supra*.

PCMA comments that the terms as defined in the rule should be consistent with those found in House Bill 2263. While the OIC agrees that rule definitions should not significantly modify or usurp definitions set forth in the enabling statute, we do not believe this was done with the subject rule. An agency is afforded some latitude in proposing rule provisions in order to effectuate the corresponding statute(s), and this includes providing definitions for terms used in the rule although those terms may not be defined in the statute, as well as clarifying statutory definitions when necessary. The OIC believes all proposed definitions set forth in the rule are within the authority granted to it by the enabling legislation. Moreover, the OIC is proposing a legislative rule and the Legislature will have to explicitly approve any definitions used by the OIC therein.

PCMA further expresses its concern over subsection 4.2.17 of the rule, which requires a PBM to provide to the OIC its reimbursement methodologies. The subsection states:

> Any and all methodologies utilized by a PBM in connection with reimbursement shall be filed at initial licensure and all reimbursement methodologies must comply with the requirements set forth in Article 51, Chapter 33 of the West Virginia Code. If a PBM was initially licensed prior to the time methodologies were required to be filed, a PBM shall file any and all methodologies utilized by a PBM in connection with reimbursement at its first renewal after January 1, 2022. A PBM shall refile any and all methodologies utilized in connection with reimbursement at any time thereafter that a methodology is changed by the PBM for use in determining maximum allowable cost appeals. The methodologies are confidential and exempt from disclosure under the *West Virginia Freedom of Information Act*, W. Va. Code §29B-1-4(a)(1)[.]

It is asserted by PCMA that the reimbursement methodology that a PBM must follow is set forth in statute and therefore the disclosure requirement in subsection 4.2.17 could be read to require reporting of additional methodologies not mandated by law. The OIC believes that the rule provision is clear in that only the reimbursement methodologies as required by W. Va. Code § 33-51-1 *et seq.* are required to be filed, evidenced by the fact that "Article 51, Chapter 33 of the West Virginia Code" is cited in the provision.

PCMA offers a revision to section 5.14 of the rule, which provides:

> A PBM shall offer a health plan the option of pass-through pricing. However, pass-through pricing is required in regard to a PBM that performs pharmacy benefit management on behalf of a health benefit plan administered by or on behalf of the state or a political subdivision of the state.

PCMA requests that the phrase "performs pharmacy benefit management on behalf of" be replaced with "contracts with." The OIC agrees that the suggested language is more clear and will revise the rule accordingly.

PCMA comments that subsection 5.15.5 is not in the underlying law and the section within which the subsection resides pertains to PBMs, not insurers. In response, the OIC states that the language of subsection 5.15.5 almost mirrors that found in W. Va. Code § 33-51-9(*l*). The OIC further believes that a subsection can be properly contained within a section if there is a reasonable relationship between the two, which appears to exist with subsection 5.15.5 and section 5.15 considering both pertain to a covered individual's defined cost sharing.

PCMA asserts that subsection 6.1.3 of the rule, which contains a reporting requirement for covered entities relating to terminated networks, is not found in the enabling statute and is therefore outside the law. The OIC believes the subsection is consistent with the legislative intent regarding the enactment of House Bill 2263. Moreover, the exact same provision is found in section 6.4 of the current rule that was approved by the Legislature in 2020, but was simply moved to another location in the subject proposed rule amendments to better organize the rule. Thus, the Legislature has already approved of subsection 6.1.3 as being a valid rule-making exercise.

PCMA further asks for clarification regarding how subdivisions 6.2.1.c and 6.2.1.d differ from subsection 6.2.2. Those provisions state as follows:

> 6.2.1. ~~Upon request, a~~ A PBM shall report to the Commissioner on or before March 1 of each year, or more often as the Commissioner deems necessary, for each covered entity or health plan the following information:
>
> ~~6.3.c.~~ 6.2.1.c. The aggregate amount of rebates passed on to the enrollees of each covered entity or health plan at the point-of-sale that reduced the enrollees applicable deductible, copayment, coinsurance, or other cost sharing amount;
>
> ~~6.3.d.~~ 6.2.1.d. The individual and aggregate amount paid by the covered entity or health plan to the PBM for pharmacist services itemized by pharmacy, by product, and by goods and services; and
>
> 6.2.2. A PBM shall annually report in the aggregate to the Commissioner and to a health plan or covered entity the difference between the amount the PBM reimbursed a pharmacy and the amount the PBM charged a health plan or covered entity. The annual report required by this subsection shall be due on or before March 1 of each year.

The OIC agrees that, with respect to a report submitted to the OIC, the first sentence of subsection 6.2.2 is duplicative of subdivisions 6.2.1.c and 6.2.1d and will revise the sentence to read: "In regard to a PBM that contracts with a health plan or covered entity, the PBM shall annually report in the aggregate to the health plan or covered entity the difference between the amount the PBM reimbursed a pharmacy and the amount the PBM charged the health plan or covered entity."

PCMA next maintains that subsection 8.5.10 of the rule, which pertains to the OIC adding interest to an award of reimbursement, is new language not found in House Bill 2263 and thus outside the agency's jurisdiction. The OIC disagrees in light of the following language of W. Va. Code § 33-51-8(e)(2): "[r]ules adopted pursuant to this section shall set forth penalties and fines, including, without limitation, monetary fines, suspension of licensure, and revocation of licensure for violations of this chapter and the rules adopted pursuant to this section." Furthermore, W. Va. Code § 33-51-9(b) provides that the Commissioner "may order reimbursement to an insured, pharmacy, or dispenser who has incurred a monetary loss as a result of a violation of this article or legislative rules implemented pursuant to this article." The OIC routinely gets questions from regulated entities and consumers about the addition of interest to reimbursement awards and believes that it is clearer and more forthcoming to establish the process publicly through rulemaking. Thus, the OIC will not propose amendments to the rule in response to this comment.

PCMA avers that section 9.1 of the rule (with subsection 9.1.6 as a specific example) contains extraterritorial issues and that the scope of the section should be limited to West Virginia. The OIC believes subsection 9.1.1 already does what is being requested: "[s]ection 9 of this rule applies to all PBMs and health benefit plans providing pharmaceutical services or pharmacy benefits, including but not limited to prescription drugs, to any resident of West Virginia." Accordingly, the OIC will not propose any revisions to the rule as a result of this comment.

PCMA finally asserts that subsection 9.3.1 of the rule is inconsistent with subdivisions 9.2.1.a and 9.2.1.b of the rule. Those provisions state:

> 9.2.1. A PBM or health benefit plan may not:
>
> 9.2.1.a. Prohibit or limit any covered individual from selecting a pharmacy or pharmacist of his or her choice who has agreed to participate in the health benefit plan's network according to the terms offered by the health plan;
> 9.2.1.b. Deny a pharmacy or pharmacist the right to participate as a contract provider under the health insurance policy or health benefit plan's network if the pharmacy or pharmacist agrees to provide pharmacy services or benefits, including but not limited to prescription drugs, that meet the terms and requirements set forth by the insurer under the health insurance policy or health benefit plan's network and agrees to the terms of reimbursement set forth by the insurer[.]

> 9.3.1. If a health benefit plan restricts pharmacy participation through a network, the covered entity providing the health benefit plan shall notify, in writing, all pharmacies within the geographic coverage area of the health benefit plan and offer those pharmacies the opportunity to participate in the health benefit plan's network. Notification shall be provided at least 60 days prior to the effective date of the health benefit plan's network.

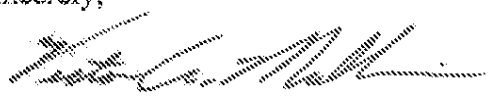
PCMA requests clarification as to whether subsection 9.3.1 intends to allow for restricted networks despite what subdivisions 9.2.1.a and 9.2.1.b state. The OIC first responds that in addressing another comment, it has agreed to revise subsection 9.3.1 as follows:

> If a health benefit plan restricts pharmacy participation through a network, the covered entity providing the health benefit plan shall notify, in writing, all pharmacies within the geographic coverage area of the health benefit plan and offer those pharmacies the opportunity to participate in the health benefit plan's network. Notification shall be provided at least 60 days prior to the effective date of the health benefit plan, or, if the plan is in effect at the time this rule becomes effective, at least 60 days prior to the plan's renewal.

The OIC further responds by stating it believes the provisions are compatible. Subsection 9.3.1 does not permit restricted networks but instead requires a health benefit plan to invite all pharmacies to become a member of the network should the pharmacy agree to the plan's network terms.

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

Sincerely,



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

Attachments

WVIPA
West Virginia Independent
Pharmacy Association

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

Victor Mullins
Associate Counsel
West Virginia Offices of the Insurance Commissioner
900 Pennsylvania Avenue
Charleston, WV 25302

June 23, 2021

Re: Comments on Proposed Rule 114-99

Dear Mr. Mullins:

On behalf of the West Virginia Independent Pharmacy Association ("WVIPA"), its 55 organizational members, and the 130 West Virginia pharmacies owned and operated by those members, we write to offer our comments on Proposed Rule 114-99: Pharmacy Auditing Entities and Pharmacy Benefit Managers. Thank you for this opportunity to offer comments. In our opinion, the West Virginia Offices of the Insurance Commissioner ("WVOIC") adhered to the legislative intent within the context of West Virginia Code §33-51 *et seq.* and applied a reasonable regulatory framework.

Additionally, we appreciate the WVOIC addressing challenges faced by our pharmacy members and patients by codifying relevant protections and specific duties and responsibilities of pharmacy benefit managers ("PBMs") and health insurers operating in West Virginia. Pharmacy issues are extraordinarily complex and important in terms of providing quality health care for patients while also containing 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.

Preventing PBM Fee Shifting and Fee Increases to Pharmacies

One purpose of House Bill 2263 and the proposed rule is to create a reimbursement floor of National Average Drug Acquisition Cost ("NADAC") plus a $10.49 dispensing fee for a prescription drug and pharmacy service. The WVIPA believes this is an equitable and reasonable reimbursement methodology, which is also used by West Virginia Medicaid. The WVIPA urges the WVOIC to protect the legislative intent that drove this policy change by closely monitoring PBM fees charged to pharmacies. The underlying policy decision to codify this reimbursement floor sets pharmacy reimbursement to easily accessible and nationally recognized benchmarks/ methodologies. It is important to note that while PBMs may charge fees to pharmacies, these fees should not be increased for the purpose of diverting pharmacy reimbursement dollars to PBMs. The clear intent is to reimburse pharmacies the cost of purchasing drugs plus a professional dispensing fee for services and related costs. Under 5.13, the proposed rule states that a "[a] PBM shall not engage in any practice that . . . [d]erives any revenue from a pharmacy or insured in connection with performing pharmacy benefits management services. This prohibition shall not prohibit a PBM from receiving deductibles or co-payments." The WVIPA respectfully requests that the WVOIC closely analyze PBM fees, especially new fees or fee increases, to pharmacies in the future. Further, if the WVOIC seeks to clarify and strengthen this position regarding fees, the WVIPA would be supportive.

Further, the WVIPA understands that according to W. Va. Code §33-51-9(c), PBMs may charge fees to pharmacies, but only if those fees are identified, reported, and specifically explained for each line item on the remittance advice of the adjudicated claim, or if the total amount of the fee is apparent at the point of sale and not adjusted between the point of sale and the issuance of the remittance advice. As mentioned above these fees must not be charged for the purposes of deriving revenue from a pharmacy or insured.

Proactively Addressing Federal Rulings/Actions on Employee Retirement Income Security Act of 1974 (ERISA) and Related Topics in Section 1.6

The WVIPA respectfully proposes two modifications to the WVOIC's changes in Section 1.6 of the proposed rule to ensure the rule is evergreen and applicable if future federal court decisions or actions occur.

To wit in 1.6:

> Certain sections of this rule may not apply to Medicare Part D plans or Medicare Advantage plans that offer prescription drug coverage as 42 U.S.C. §1395w–26(b)(3) and 42 U.S.C. §1395w–112(g) provide that standards established under 42 U.S.C. §1395w-101 *et seq.* and 42 U.S.C. §1395w-21 *et seq.* shall supersede any state law or regulation, other than state licensing laws or state laws relating to plan solvency. PBMs that perform pharmacy benefits management for Medicare Part D plans and Medicare Advantage plans in this state must be appropriately licensed. Additionally, certain sections

> of this rule may not be applicable to health benefit plans or health plans that are subject to the Employee Retirement Income Security Act of 1974 (ERISA) if the subject provision of the rule regulates a key facet or essential part of plan administration or design and is preempted by ERISA. However, certain sections of this rule that only affect costs, pricing or alter incentives for ERISA plans are not preempted by ERISA and are accordingly applicable. PBMs that perform pharmacy benefits management for ERISA plans in this state must be appropriately licensed. A PBM that performs pharmacy benefit management for workers' compensation insurers or self-insured employers must be licensed to operate in this state if it manages prescription drug coverage for 'covered entities,' as that term is defined in W. Va. Code §33-51-3 and this rule.

The ability of states to regulate PBMs operating through ERISA plans is a developing area of the law, most recently established through the decision in *Rutledge v. Pharmaceutical Care Management Association* issued by the Supreme Court of the United States.[1] There is likely to be additional litigation during the next five years—the term of this proposed rule—to clarify this decision, as well as other areas not yet clearly decided. Therefore, the applicability section of the proposed rule could be written to allow maximum flexibility for the WVOIC to regulate ERISA-covered health plans and affiliated PBMs, per evolving federal judicial decisions or actions.

We believe these suggested modifications ensure that the rule is valid and enforceable in the event of future decisions. This would reduce administrative burdens on the WVOIC and West Virginia Secretary of State's Office regarding rule drafting and the Legislature in the rulemaking process. The changes may also avoid future complaints by interested parties. The WVIPA respectfully proposes the following modifications, with suggested changes in bold and underlined text:

> Additionally, certain sections of this rule may not be applicable to health benefit plans or health plans that are subject to the Employee Retirement Income Security Act of 1974 (ERISA) if the subject provision of the rule regulates a key facet or essential part of plan administration or design and is preempted by ERISA. However, certain sections of this rule that only affect costs, pricing, **rates** or alter incentives for ERISA plans are not preempted by ERISA and are accordingly applicable. **This section does not limit the applicability of other sections to ERISA plans should federal law or judicial decisions afford the state authority to regulate**.

[1] The decision in *Rutledge v. Pharmaceutical Care Management Association* is available for download here: https://www.supremecourt.gov/opinions/20pdf/18-540_m64o.pdf.

Holding Pharmacists and Pharmacies Harmless for PBM or Health Insurer Miscalculation of a "Rebate" or "Defined Cost Sharing"

We strongly agree with the WVOIC's addition of 5.15.6 to the proposed rule, which would hold a pharmacist and pharmacy harmless if incorrect information is provided at the point-of-sale to calculate a patient's defined cost-sharing.

To wit in 5.15.6:

> A PBM or third-party shall be responsible for calculating a covered individual's defined cost sharing for each prescription drug. No PBM or third-party shall charge or deduct from a pharmacist or pharmacy any fee, recoupment, charge back, or other monetary penalty, amount or adjustment due to the PBM or third-party's miscalculation of a rebate or defined cost sharing amount.

The inclusion of 5.15.6 in the proposed rule reduces the fear among pharmacists and pharmacies that a PBM or health insurer will claw back or reduce future payments for the PBM or health insurer's failure or mistake in rebate or defined cost-sharing calculations. This is a well-founded fear, as PBMs and health insurers can and do adjust or modify claims well after they are adjudicated at the point-of-sale.

Clarifying Restricted Network Notification Process by Health Benefit Plans

The WVIPA respectfully requests clarification related to the WVOIC's addition of 9.3.1 in the proposed rule to spell out when notification is required for a health benefit plan that restricts or has restricted its network.

To wit in 9.3.1:

> If a health benefit plan restricts pharmacy participation through a network, the covered entity providing the health benefit plan shall notify, in writing, all pharmacies within the geographic coverage area of the health benefit plan and offer those pharmacies the opportunity to participate in the health benefit plan's network. Notification shall be provided at least 60 days prior to the effective date of the health benefit plan's network.

This provision could be interpreted as being triggered only by the health benefit plan *restricting* its network versus already *having a restricted* network. If a health benefit plan has a restricted network and is currently operating in West Virginia, is it required to notify pharmacies and offer the opportunity to participate in the network? The WVIPA believes that should be required for health benefit plans currently operating in West Virginia and required for health benefit plans entering West Virginia.

Payment Parity Addition in Section 5.10

The WVIPA strongly supports the inclusion of Section 5.10 in the proposed rule because it creates a level playing field for West Virginia pharmacies.

To wit in Section 5.10: "Payment Parity. A PBM may not reimburse a pharmacy or pharmacist for a prescription drug or pharmacy service in an amount less than the amount the PBM reimburses itself or one of its affiliates for the same prescription drug or pharmacy service."

Large retail pharmacies that also own and/or operate PBMs have an unfair advantage over independent and other pharmacies. The inclusion of this provision assures that all pharmacies receive the same reimbursement. West Virginia's independent pharmacies welcome the consistency and transparency provided by these rules.

Thank you for your time and consideration. Should you or your staff wish to discuss the comments in this letter, please do not hesitate to 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

Victor Mullins
Associate Counsel
West Virginia Offices of the Insurance Commissioner
900 Pennsylvania Ave
Charleston, WV 25302

June 23, 2021

Re: Comments on Proposed Rule 114-99 Regarding Pharmacy Auditing Entities and Pharmacy Benefit Managers

Dear Mr. Mullins:

On behalf of the organizations represented on page five of this letter, we write to offer our comments on Proposed Rule 114-99: Pharmacy Auditing Entities and Pharmacy Benefit Managers. We thank you for the opportunity to offer our collective comments. First and foremost, we wish to note our strong support for the rule as proposed. With this proposed rule, we believe the West Virginia Offices of the Insurance Commissioner (hereinafter "WVOIC") has captured the legislative intent of House Bill 2263 well and accurately within the context of West Virginia Code §33-51 *et seq.* Additionally, we applaud the WVOIC for striking a balance between patient and pharmacy protections and duties and responsibilities of pharmacy benefit managers (hereinafter "PBMs") and health insurers operating in West Virginia.

Finally, our comments highlight parts of the proposed rule that we feel are essential to protecting patients who rely on prescription drugs, 340B entities and contract/independent pharmacies. We offer four specific comments on the proposed rule for your consideration.

Comment One
Definition of "Rebate" in 2.24: 340B Program Clarification

We **strongly agree** with WVOIC's clarification that the definition of "rebate" in the proposed rule does not include 340B program discounts or payments.

To wit in 2.24: "the term 'rebate' does not include any discount or payment that may be provided to or made to any 340B entity through such program."

Per the 340B program's federal regulatory agency, the Health Resources & Services Administration, the program's purpose is "[...] to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[1] West Virginia's 340B entities rely on the program's savings to provide health care services that otherwise would not exist, including school-based health services, free/charity care to the underinsured and uninsured, discount/free prescription drugs to the underinsured and uninsured, to name but a few examples. If the definition of "rebate" is misconstrued, either willfully or unintentionally, it would violate the legislative intent of House Bill 2263 and conflict with the federal 340B statute.

We view this as a proactive clarification that could resolve ambiguity from a major change to the 340B program, if Congress enacts one. There have been proposals—heretofore unsuccessful and not supported by 340B entities generally—to change the program to a rebate model instead

[1] As noted on the Health Resources & Services Administration website: https://www.hrsa.gov/opa/

of an upfront drug discount-purchasing program.[2] We believe that including the 340B program clarification in the "rebate" definition would ensure the rule is valid even if such a change were to occur. In sum, this would reduce administrative burdens on the WVOIC and West Virginia Secretary of State's Office regarding rule drafting, as well as the legislature in the rule approval process. This change may also avert future complaints by 340B entities and other interested parties.

Comment Two
Prohibition of "Other Adjustment(s)" and Discriminatory Behavior Against 340B Entities

We **strongly agree** with WVOIC's additions in 5.7 and 5.8 of the proposed rule that prohibit "other adjustments," such as 340B modifiers and similar discriminatory practices against 340B entities, including contract and independent pharmacies.

To wit in 5.7:

> For purposes of this section, the term 'other adjustment' includes placing any additional requirements, restrictions or unnecessary burdens upon the 340B entity that results in administrative costs or fees to the 340B entity that are not placed upon other pharmacies that do not participate in the 340B program, including affiliate pharmacies of the PBM, and further includes but is not limited to requiring a claim for a drug to include a modifier or be reprocessed or resubmitted to indicate that the drug is a 340B drug.

To wit in 5.8:

> For purposes of this section, it shall be considered a discriminatory practice that prevents or interferes with a patient's choice to receive drugs at a 340B entity if a PBM places additional requirements, restrictions or unnecessary burdens upon a 340B entity that results in administrative costs or fees to the 340B entity that are not placed upon other pharmacies that do not participate in the 340B program, including affiliate pharmacies of the PBM, and further includes but is not limited to requiring a claim for a drug to include a modifier or be reprocessed or resubmitted to indicate that the drug is a 340B drug.

The legislative intent of House Bill 2263 and its preceding legislation, such as the *Pharmacy Audit Integrity Act*, was to protect pharmacists and pharmacies broadly from egregious, bad faith or discriminatory behavior by PBMs and health insurers. The WVOIC, through the proposed language in 5.7 and 5.8, guarantees just that. Moreover, the proposed language clearly defines acceptable behavior on the part of PBMs and health insurers, which continually place new, burdensome requirements on 340B entities to undermine the 340B program and prevent patients from accessing prescription drugs at pharmacies of their choice. One such example is a recent mandate by Express Scripts, Inc., one of the country's largest PBMs, to add a modifier to 340B claims. This mandate serves no functional or legal purpose under West Virginia law. Instead, it

[2] Please see here for background:
https://mckinley.house.gov/news/documentsingle.aspx?DocumentID=2924

increases costs, creates busywork for 340B entities and disproportionately affects contract pharmacies, especially small independent pharmacies.

Comment Three
Holding Pharmacists and Pharmacies Harmless for a PBM or Health Insurer Miscalculation of a "Rebate" or "Defined Cost Sharing"

We **strongly agree** with WVOIC's addition of 5.15.6 to the proposed rule, which would hold a pharmacist and pharmacy harmless if incorrect information is provided at the point-of-sale to calculate a patient's defined cost-sharing.

To wit in 5.15.6:

> A PBM or third-party shall be responsible for calculating a covered individual's defined cost sharing for each prescription drug. No PBM or third-party shall charge or deduct from a pharmacist or pharmacy any fee, recoupment, charge back, or other monetary penalty, amount or adjustment due to the PBM or third-party's miscalculation of a rebate or defined cost sharing amount.

The inclusion of 5.15.6 in the proposed rule reduces the fear among pharmacists and pharmacies that a PBM or health insurer will claw back or reduce future payments for **the PBM or health insurer's failure or mistake** in rebate or defined cost-sharing calculations. This is a well-founded fear, as PBMs and health insurers can and do adjust or modify claims well after they are adjudicated at the point-of-sale.

Comment Four
Clarifying Health Benefit Plan Network Reporting Obligations to the WVOIC

We **propose** two modifications to the WVOIC's addition of 6.1.3 to the proposed rule that will ensure certainty about what contract terminations and entities are required to submit network reporting data.

To wit in 6.1.3: "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."

This provision could be interpreted as **only requiring data on pharmacists and pharmacies who/that have terminated with the covered entity** but not the reverse (i.e., pharmacists and pharmacies who/that have been terminated from the network by the covered entity). If the WVOIC conducts investigations or examinations related to network adequacy (e.g., per 5.12; 6.1, *et seq.* and 9.3, *et seq.*) of the proposed rule, it will need to know if the covered entity has terminated pharmacists and pharmacies from its networks.

We also suggest WVOIC's proposed addition of 6.1.3 require covered entities to similarly disclose the number of pharmacy services administration organizations (hereinafter "PSAOs") that have either terminated their network participation with a covered entity or have had their network participation terminated by a covered entity. PSAOs contract with pharmacists and pharmacies to assist with third-party payer interactions and other administrative services. PSAOs' termination

from a network would be relevant for purposes of the proposed network adequacy reporting requirements.

* * *

Again, we thank you for your time and consideration of our collective comments. Should you or other WVOIC staff wish to discuss our comments on this proposed rule, please do not hesitate to contact Joshua Austin, Policy and Communications Director at the West Virginia Primary Care Association, at Joshua.Austin@wvpca.org or at 304.400.8300.

Respectfully submitted,

[See page five for signatories]

Comment Letter Signatories

Sherri P. Ferrell, CEO
West Virginia Primary Care Association

M. James "Jim" Kaufman, President & CEO
West Virginia Hospital Association

David L. Ramsey, President & CEO
Charleston Area Medical Center/CAMC Health System

Paul Smith, Interim President & CEO
Mountain Health Network

Albert Wright, Jr., President & CEO
West Virginia University Health System

Beth L. Hammers, CEO
Marshall Health

Jeffrey A. Fenerty, Director of Pharmacy Services
Marshall Pharmacy

Terry Cox, Executive Director
Partners In Health Network, Inc.

Katie Kacmarik, Board President
West Virginia Pharmacists Association

June 29, 2021

CareSource

Mr. Victor Mullins
West Virginia Offices of the Insurance Commissioner
900 Pennsylvania Ave
Charleston, WV 25302
Suite 100

Re: Comments to Proposed Rule 114 CSR 99 – Pharmacy Auditing and PBM

Dear Mr. Mullins,

Please accept these comments on behalf of CareSource. We appreciate 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.

We do acknowledge that with the passage of House Bill 2263 (2021), changes in this statute must be made. However, we respectfully have concerns on several items including Definitions, Point of Sale Rebates, and Notifications of Network Participation.

1. **§114-99-2. Definitions.**
    a. Section 2.6. "Defined Cost Sharing"
        i. Actuary: Some benefit designs also include fixed copays in addition to or in lieu of deductibles or coinsurance; we would recommend separately defining copays.

2. **§114-99-5. Responsibilities and Prohibited Acts.**
    a. Section 5.13.3.
        i. Product Management: Including the term "coinsurance" alongside "deductibles or co-payments" would provide needed clarity to this section.
    b. Sections 5.15(1-6)
        i. General Rx Comments: Point of Sale Rebates. The bill requires prescription drug rebates to be passed on to consumers at the point of sale. Whenever possible, health insurance providers and their PBM partners use competitive, market-based tools to aggressively negotiate with manufacturers to reduce the cost of high-priced drugs. Those savings – including rebates – are passed on to all enrollees through benefit improvements, premium reductions and/or lower out-of-pocket costs. Requiring rebates to be passed on to consumers at the point of sale fails to recognize how pharmaceutical manufacturers actually pay rebates to employers and health plans based on a defined performance period (e.g., quarterly, annually) and typically after drugs are dispensed. Recent Congressional Budget Office analyses of a similar federal proposal to require point-of-sale rebates in the Medicare prescription drug coverage program (Part D) that is now being delayed due to legal challenges found that consumers would pay higher premiums, government and taxpayers would face higher costs, and result in a multi-billion dollar windfall for Big Pharma. Moreover, point-of-sale rebates would only benefit consumers taking a limited subset drugs with

meaningful competition rather than passing the savings on to all consumers by their health plan or employer.

ii. Actuarial: We would like to suggest amending the language to *"…is reduced by an amount expected to be equal to at least 100%..."*.

iii. Actuarial: We would also like to suggest the consideration of a percentage of error in this section, like 98%, in aggregate, as rebate pricing may not be exact at point-of-sale.

iv. Actuarial: We would suggest adding a section, such as: *"A covered individual's defined copay for each prescription drug calculated at the point-of-sale shall not exceed the price of the prescription drug that is reduced by an amount expected to be equal to at least 100% of all applicable rebates received, or to be received, in connection with the dispensing or administration of the prescription drug."*

c. Section 6.15.5

i. Actuarial: We would suggest amending the language and adding "or copay" to this section: *"…covered individual's defined cost sharing or copay by an amount greater"*.

3. **§114-99-6. Network Adequacy and Reporting Requirements.**

a. Section 6.1.1.

i. Product Management: Will there be forthcoming standards for implementation of section 6.1.1?

4. **§114-99-8. Consumer Choice for Pharmacy Benefits.**

a. Section 9.2.1.d.

i. Product Management: We believe this section would restrict the ability to do a "preferred pharmacy" type program and could contradict guidance from CMS that promotes value-based care and helping to direct members to lower costs of care. Does section 9.2.1.d prohibit value-based care models?

b. Section 9.2.1.g.

i. Product Management: Does section 9.2.1.g require parity of cost-shares from mail order or retail locations? This would raise questions on implementation from an operational standpoint.

c. Sections 9.3.3. Notification.

i. General Rx Comments: Notifications of Network participation. This code requires written or electronic notification to beneficiaries, at regular intervals, of the names and locations of pharmacies in the network. This notification must be done in addition to publication of said list on the health plan's publicly available website. In accordance with regular business practices, a list of network pharmacies is readily available to members on the health plan's website. The additional requirement of sending written or electronic notification at regular intervals, and with the addition or subtraction of a network pharmacy, causes an undue and costly burden on the health plan. Additionally, there is little to no gained

CareSource

benefit to members who already have their pharmacy network available on the health plan's webpage. Currently, the member can access the webpage from any location and at any time. The member simply types in the desired location and can instantaneously view all network pharmacies in their desired location perimeters. A new requirement such as section 9.3.3 to send updates in writing/electronically would result in the health plan sending a flurry of written or electronic updates that may or may not impact each individual member at any given time. The member will have to sift through each notification to identify if the update is applicable to them. Each additional and unnecessary notification will make it less likely for members to read notifications of importance that have impact on them. This requirement creates an unnecessary and costly burden on health plans to create and disseminate these updates that will add no value or benefit to our members.

Thank you again for the opportunity to provide feedback on the proposed changes to this legislative rule. If you have any questions regarding any of these suggestions, or would like to discuss them further, please do not hesitate to contact me at (502) 297-4740 or by email Travis.Phillips@CareSource.com.

Sincerely,

Travis Phillips
Manager, Government & Regulatory Affairs
101 Enterprise Drive
Frankfort, KY 40601
p: 502.213.4700 | c: 502.297.4740
Travis.Phillips@CareSource.com

Victor Mullins
Associate Counsel
West Virginia Offices of the Insurance Commissioner
900 Pennsylvania Avenue
Charleston, WV 25302

June 29, 2021

Re: Comments on Proposed Rule 114-99

Dear Mr. Mullins:

On behalf of Fruth Inc. DBA Fruth Pharmacy, its 18 West Virginia locations headquartered in Point Pleasant West Virginia, and our 293 West Virginia employees, I am writing to offer our comments on Proposed Rule 114-99: Pharmacy Auditing Entities and Pharmacy Benefit Managers. Thank you for this opportunity to offer comments. In our opinion, the West Virginia Offices of the Insurance Commissioner ("WVOIC") adhered to the legislative intent within the context of West Virginia Code §33-51 *et seq.* and applied a reasonable regulatory framework.

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

Preventing PBM Fee Shifting and Fee Increases to Pharmacies

One purpose of House Bill 2263 and the proposed rule is to create a reimbursement floor of National Average Drug Acquisition Cost ("NADAC") plus a $10.49 dispensing fee for a prescription drug and pharmacy service. Fruth Pharmacy believes this is an equitable and reasonable reimbursement methodology, which is also used by West Virginia Medicaid. Fruth urges the WVOIC to protect the legislative intent that drove this policy change by closely monitoring PBM fees charged to pharmacies. The underlying policy decision to codify this reimbursement floor sets pharmacy reimbursement to easily accessible and nationally recognized benchmarks/ methodologies. It is important to note that while PBMs may charge fees to

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www.fruthpharmacy.com

pharmacies, these fees should not be increased for the purpose of diverting pharmacy reimbursement dollars to PBMs. The clear intent is to reimburse pharmacies the cost of purchasing drugs plus a professional dispensing fee for services and related costs. Under 5.13, the proposed rule states that a "[a] PBM shall not engage in any practice that . . . [d]erives any revenue from a pharmacy or insured in connection with performing pharmacy benefits management services. This prohibition shall not prohibit a PBM from receiving deductibles or co-payments." Fruth Pharmacy respectfully requests that the WVOIC closely analyze PBM fees, especially new fees or fee increases, to pharmacies in the future. Further, Fruth Pharmacy proposes the intended reimbursement floor of National Average Drug Acquisition Cost ("NADAC") plus a $10.49 dispensing fee for a prescription drug and pharmacy service be made clear as net reimbursement after any fee charged by the PBMs.

Proactively Addressing Federal Rulings/Actions on Employee Retirement Income Security Act of 1974 (ERISA) and Related Topics in Section 1.6

Fruth Pharmacy respectfully proposes two modifications to the WVOIC's changes in Section 1.6 of the proposed rule to ensure the rule is evergreen and applicable if future federal court decisions or actions occur.

To wit in 1.6:

> Certain sections of this rule may not apply to Medicare Part D plans or Medicare Advantage plans that offer prescription drug coverage as 42 U.S.C. §1395w-26(b)(3) and 42 U.S.C. §1395w-112(g) provide that standards established under 42 U.S.C. §1395w-101 *et seq.* and 42 U.S.C. §1395w-21 *et seq.* shall supersede any state law or regulation, other than state licensing laws or state laws relating to plan solvency. PBMs that perform pharmacy benefits management for Medicare Part D plans and Medicare Advantage plans in this state must be appropriately licensed. Additionally, certain sections of this rule may not be applicable to health benefit plans or health plans that are subject to the Employee Retirement Income Security Act of 1974 (ERISA) if the subject provision of the rule regulates a key facet or essential part of plan administration or design and is preempted by ERISA. However, certain sections of this rule that only affect costs, pricing or alter incentives for ERISA plans are not preempted by ERISA and are accordingly applicable. PBMs that perform pharmacy benefits management for ERISA plans in this state must be appropriately licensed. A PBM that performs pharmacy benefit management for workers' compensation insurers or self-insured employers must be licensed to operate in this state if it manages prescription drug coverage for 'covered entities,' as that term is defined in W. Va. Code §33-51-3 and this rule.

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The ability of states to regulate PBMs operating through ERISA plans is a developing area of the law, most recently established through the decision in *Rutledge v. Pharmaceutical Care Management Association* issued by the Supreme Court of the United States.[1] There is likely to be additional litigation during the next five years—the term of this proposed rule—to clarify this decision, as well as other areas possibly including Medicare part D not yet clearly decided. Therefore, the applicability section of the proposed rule could be written to allow maximum flexibility for the WVOIC to regulate ERISA covered health plans and affiliated PBMs, per evolving federal judicial decisions or actions.

We believe these suggested modifications ensure that the rule is valid and enforceable in the event of future decisions. This would reduce administrative burdens on the WVOIC and West Virginia Secretary of State's Office regarding rule drafting and the Legislature in the rulemaking process. The changes may also avoid future complaints by interested parties. Fruth respectfully proposes the following modifications, with suggested changes in bold and underlined text:

> Additionally, certain sections of this rule may not be applicable to health benefit plans or health plans that are subject to the Employee Retirement Income Security Act of 1974 (ERISA) if the subject provision of the rule regulates a key facet or essential part of plan administration or design and is preempted by ERISA. However, certain sections of this rule that only affect costs, pricing, **rates** or alter incentives for ERISA plans are not preempted by ERISA and are accordingly applicable. **This section does not limit the applicability of other sections to ERISA or Medicare Part D plans should federally law or judicial decisions afford the state authority to regulate.**

Clarifying Restricted Network Notification Process by Health Benefit Plans

[1] The decision in *Rutledge v. Pharmaceutical Care Management Association* is available for download here: https://www.supremecourt.gov/opinions/20pdf/18-540_m64o.pdf.

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Fruth Pharmacy respectfully requests clarification related to the WVOIC's addition of 9.3.1 in the proposed rule to spell out when notification is required for a health benefit plan that restricts or has restricted its network.

To wit in 9.3.1:

> If a health benefit plan restricts pharmacy participation through a network, the covered entity providing the health benefit plan shall notify, in writing, all pharmacies within the geographic coverage area of the health benefit plan and offer those pharmacies the opportunity to participate in the health benefit plan's network. Notification shall be provided at least 60 days prior to the effective date of the health benefit plan's network.

This provision could be interpreted as being triggered only by the health benefit plan *restricting* its network versus already *having a restricted* network. If a health benefit plan has a restricted network and is currently operating in West Virginia, is it required to notify pharmacies and offer the opportunity to participate in the network? Fruth Pharmacy believes that should be required for health benefit plans currently operating in West Virginia and required for health benefit plans entering West Virginia.

Prohibition of "Other Adjustment(s)" and Discriminatory Behavior Against 340B Entities

We **strongly agree** with WVOIC's additions in 5.7 and 5.8 that prohibit "other adjusments," such as 340B modifiers, and similar discriminatory practices against 340B entities, including contract and independent pharmacies.

To wit in 5.7:

> For purposes of this section, the term 'other adjustment' includes placing any additional requirements, restrictions or unnecessary burdens upon the 340B entity that results in administrative costs or fees to the 340B entity that are not placed upon other pharmacies that do not participate in the 340B program, including affiliate pharmacies of the PBM, and further includes but is not limited to requiring a claim for a drug to include a modifier or be reprocessed or resubmitted to indicate that the drug is a 340B drug.

To wit in 5.8:

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> For purposes of this section, it shall be considered a discriminatory practice that prevents or interferes with a patient's choice to receive drugs at a 340B entity if a PBM places additional requirements, restrictions or unnecessary burdens upon a 340B entity that results in administrative costs or fees to the 340B entity that are not placed upon other pharmacies that do not participate in the 340B program, including affiliate pharmacies of the PBM, and further includes but is not limited to requiring a claim for a drug to include a modifier or be reprocessed or resubmitted to indicate that the drug is a 340B drug.

The legislative intent of House Bill 2263 and its preceding legislation, such as the *Pharmacy Audit Integrity Act*, was to protect pharmacists and pharmacies broadly from egregious, bad faith or discriminatory behavior by PBMs and health insurers. The WVOIC, through the proposed language in 5.7 and 5.8, ensures just that. Moreover, the proposed language clearly defines acceptable behavior on the part of PBMs and health insurers, which continually place new, burdensome requirements on 340B entities to undermine the 340B program and prevent patients from accessing prescription drugs at pharmacies of their choice. One such example is a recent mandate by Express Scripts, Inc., one of the country's largest PBMs, to add a modifier to 340B claims. This mandate serves no functional or legal purpose under West Virginia law. Instead, it increases costs, creates busywork for 340B entities and disproportionately affects contract pharmacies, especially small independent pharmacies.

Definition of "Rebate" in 2.24: 340B Program Clarification

We strongly agree with WVOIC's clarification that the definition of "rebate" does not include 340B program discounts or payments.

To wit, "the term 'rebate' does not include any discount or payment that may be provided to or made to any 340B entity through such program."

Per the 340B program's federal regulatory agency, the Health Resources & Services Administration, the program's purpose is "[…] to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[1] West Virginia's 340B entities rely on the program's savings to provide health care services that otherwise would not exist, including school-based health services, free/charity care to the underinsured and uninsured, discount/free prescription drugs to the underinsured and uninsured, to name but a few examples. If the definition of "rebate" is misconstrued, either willfully or unintentionally, it would violate the legislative intent of House Bill 2263 and conflict with the federal 340B statute.

[1] As noted on the Health Resources & Services Administration website: https://www.hrsa.gov/opa/.

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Furthermore, we view this as a proactive clarification that could help resolve ambiguity from a major change to the 340B program, if Congress enacts one. There have been proposals—heretofore unsuccessful and not supported by 340B entities generally—to change the program to a rebate model instead of an upfront drug discount-purchasing program.[1] We believe that including the 340B program clarification in the "rebate" definition would ensure the rule is valid even if such a change were to occur. In sum, this would reduce administrative burdens on the WVOIC and West Virginia Secretary of State's Office regarding rule drafting/commenting and the legislature in the rule approval process. This change may also avert future complaints by 340B entities and other interested parties.

Thank you for your time and consideration. Should you or your staff wish to discuss the comments in this letter, please do not hesitate me by email at lfruth@fruthpharmacy.com or by phone at (304) 593-1765.

Respectfully Submitted:

Lynne Fruth

Lynne Fruth, President and Chairman
Fruth Inc. DBA Fruth Pharmacy

[1] Please see here for background: https://mckinley.house.gov/news/documentsingle.aspx?DocumentID=2924.

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HIGHMARK WEST VIRGINIA

An Independent Licensee of the Blue Cross and Blue Shield Association

June 30, 2021

Victor Mullins, Associate Counsel
Legal Division
West Virginia Offices of the Insurance Commissioner
900 Pennsylvania Avenue
Charleston, WV 25302

Re: Proposed Rule 114CSR99, Pharmacy Auditing Entities and Pharmacy Benefit Managers

Dear Mr. Mullins:

I write today on behalf of Highmark West Virginia Inc. ("Highmark") to comment on the Office of the Commissioner of Insurance's proposed rule 114CSR99, Pharmacy Auditing Entities and Pharmacy Benefit Managers. Highmark has continuously focused on providing members with access to affordable comprehensive prescription drug coverage through a variety of approaches in the face of escalating drug costs and supports effective efforts designed to lower the cost of prescription drugs, improve the safety and health of members, and reduce fraud, waste and abuse. The opportunity to comment is much appreciated, as is your consideration of the comment below.

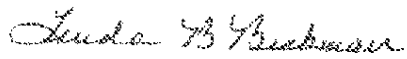
1. **Title 114-99-6 Network Adequacy and Reporting Requirements**

   Proposed rule 114-99-6.5 provides that "[w]ith the exception of the quarterly report noted in section 6.3 of this rule, 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 a "trade secret", is not open to public inspection, is not subject to subpoena, is not subject to discovery or admissible in evidence in any criminal, private civil or administrative action and is not subject to production pursuant to court order. The Commissioner is authorized to use the documents, materials, or other information in the furtherance of any regulatory or legal action brought as part of the Commissioner's official duties."

   Highmark respectfully requests that 114-99-6.5 be revised to more closely confirm to the statute by providing that the information and data submitted by a health plan or covered entity under such section also be protected to the same extent as the information and date submitted by a PBM. Section 33-51-12(f) provides that "[w]ith the exception of the quarterly report . . . all data and information provided by the pharmacy benefits manager, health plan, or covered entity pursuant to these reporting requirements shall be considered proprietary and confidential and exempt from disclosure under the West Virginia Freedom of Information Act §29B-1-4(a)(1) of this code." Proposed rule 114-99-6.2.3., as does Section 33-51-12(c), requires a health plan or covered entity to annually report specific information to the Commissioner. Therefore, we respectfully ask that the referenced protections in 114-99-6.5 be extended as stated under the mandate to health plans and covered entities.

Highmark West Virginia Inc. appreciates your consideration of the above comment and suggestion. Please do not hesitate to contact me at linda.beckman@highmark.com (412-352-9105) should you have any questions.

Sincerely,



Linda Beckman
VP Deputy General Counsel
Highmark West Virginia Inc.

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July 1, 2021

WV Offices of the Insurance Commissioner
Victor Mullins
900 Pennsylvania Ave
Charleston, WV, 25302

Delivered via email: victor.a.mullins@wv.gov

Re: W. Va. Rule 114CSR99

Dear Mr. Mullins,

We appreciate the opportunity to comment on the proposed amendments to West Virginia Code 33-51-8, 33-51-10, and 33-2-10. Mitchell International provides pharmacy benefit management for workers' compensation and automobile medical-payment insurers. We share the goal of West Virginia's workers' compensation program to "assist workers to return to work as soon as practicable after a compensable injury and to otherwise provide for high quality, cost effective medical care to injured workers" (§85-21-2).

Applicability
Section 1.6 outlines the applicability of the rule, stating, "A PBM that performs pharmacy benefit management services for workers' compensation insurers or self-insured employers must be licensed to operate in this state if it manages prescription drug coverage for "covered entities," as that term is defined in W. Va. Code 33-52-3 and this rule.

In 33-51-3, "Covered entity" means a contract holder or policy holder providing pharmacy benefits to a covered individual under a health insurance policy pursuant to a contract administered by a pharmacy benefits manager.

And "Health insurance policy" means a policy, subscriber contract, certificate, or plan that provides prescription drug coverage. The term includes both comprehensive and limited benefit health insurance policies.

Since workers' compensation and automobile insurance fall under the classification of property and casualty insurance, it is our understanding that services provided under those types of policies would fall outside the purview and requirements of this rule.

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However, if the Commissioner interprets these definitions differently, and workers' compensation and auto insurance activities would be considered included in this rule, we make the following comments regarding the proposed rule.

Reimbursement

As a worker's compensation PBM, one of the ways we achieve the goal of cost-containing and clinically effective controls is to utilize the tools outlined in 85 CSR 21. One of those important tools is allowing for contracted reimbursement rates. We recommend including language that allows contracted methodologies to reimbursement, for example:

114-99-5

5.18. Nothing in this section shall preclude a PBM, carrier, employer, or any other third party that makes payment for a prescription drug or pharmacy service from entering into an agreement with a provider for an agreed upon reimbursement methodology.

Responsibilities and Prohibited Acts

Workers' compensation PBMs and commercial PBMs are significantly different, please see the attached document entitled, *Pharmacy Benefit Management (PBM) Workers' Comp vs Commercial Health*. Section 5 of the rule contains provisions specific to practices in the health insurance arena and would not be applicable, or would be in conflict with the rules related to workers' compensation. For example, workers' compensation insurers do not have benefit designs (5.2.2) since injured workers are entitled to any medically necessary care reasonably required to cure their injury or sickness. Another example, injured workers are not required to participate in any cost-sharing (5.4, 5.5, 5.15, 5.15.3, 5.15.4, 5.15.5 & 5.15.6). Additionally, the federal provisions related to Medicare and Medicaid are not factors that are considered in the workers' compensation system when determining reimbursement (5.7, 5.8, 5.9, & 5.12). Our reimbursement is governed by the laws and rules for workers' compensation and auto insurance.

Reporting

As noted in the comments related to section 5, there are significant differences between workers' compensation and commercial health PBMs. Some of the reporting requirements in 114-99-6.2 through 6.5 would not have applicability in the workers' compensation or auto insurance systems. For example, injured workers are not required to pay a co-pay or deductible (6.2.1c).

It should also be noted that the workers' compensation system has an established process to resolve disputes between payers and providers and between injured workers and payers. We are concerned that some of the dispute and penalty provisions of this rule could conflict with

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the workers' compensation rules or subject a payer of pharmacy benefits to potential double jeopardy with disputes being pursued under both sets of rules.

Thank you for your consideration of our comments. If your interpretation is different than ours as outlined in the Applicability section of our comments above, please advise us as soon as possible. If you have any questions or need additional information on our business as a workers' compensation and automobile medical-payment PBM, please feel free to contact me at Brian.Allen@mitchell.com or at 801-903-5754.

Sincerely,

Brian Allen
Vice President Government Affairs

Pharmacy Benefit Management (PBM)

Workers' Comp vs Commercial Health

As states consider regulating the PBM industry, it is important to note that PBM services in the workers' compensation industry differ greatly from PBMs providing services to commercial health care. Some of the notable differences are:

No Cost to Injured Workers

Injured workers do not pay for services or medications (no co-pays, deductibles or cost-sharing)

Regulated by State Agencies

State workers' comp agencies and/or state laws regulate workers' comp PBMs and how they deliver and bill for pharmacy care to injured workers. An additional regulator may create confusion or conflict between regulatory bodies.

Pricing & Fees Based on State Fee Schedules

Workers' comp PBMs do not negotiate pricing with drug manufacturers or distributors, except as it relates to in-house mail-order medications.

For example, Mitchell's reimbursement is based on the state fee schedule. Reimbursement to the pharmacies in our network is typically a discounted rate from the maximum charge allowed by the fee schedule.

Workers' comp PBMs typically pay network pharmacies within 30-40 days of the prescription being processed. Additionally many states have prompt payment rules for workers' comp claims.

Workers' comp PBMs do not charge fees to pharmacies for processing prescriptions.

Workers' comp PBMs have the added complexity of coverage verification, including confirming details from the insurer about the eligibility of benefits, which medical care is compensable and for which injuries.

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Pharmacy Benefit Management

Workers' Comp vs Commercial Health

Pricing & Fees Based on State Fee Schedules (continued)

Manufacturers sometimes give administrative fees to PBMs or pharmacies for choosing their drugs over another. However, manufacturer fees do not exist in workers' comp because:

- Workers' comp volume is such a small percentage of overall prescription volume (less than 2%)
- Workers' comp PBMs are very limited in their ability to influence what is prescribed. For example, they request generic substitution (where allowed), ask if drugs are medically necessary or recommend an alternative, lower cost therapy to achieve the same clinical outcome as a prescribed brand medication.

Formularies

Workers' comp PBMs cannot use rebates to determine placement of a medication on a formulary.

- Unlike commercial insurance plans, workers compensation PBMs cannot limit a formulary to favor one drug manufacturer over another.
- Workers' compensation is primarily a generic drug preference system. Around 90% of the prescriptions used by injured workers are generic formulation and, thus, are not eligible for any rebate.
- If a rebate is available (in situations where there is no generic alternative or a treating physician instructs a brand may only be used), then the rebate is applied to reduce the cost of the drug to the insurer.

Workers' comp PBMs cannot control which manufacturer's drugs a physician prescribes based on a formulary design.

- Drugs prescribed to injured workers are based on whether the injury is compensable and whether the prescribed drugs are medically necessary to treat the covered injury as determined by state-established formularies, established medical treatment guidelines or other accepted medical evidence related to the specific injury.

Pharmacy Benefit Management

Workers' Comp vs Commercial Health

Networks

Typically, 90+% of the retail pharmacies in a state are included in a workers' comp PBM network. Workers' compensation prescriptions represent a small, single-digit percentage (usually less than 2%) of a retail pharmacy's business. As such, it is imperative to have as many pharmacies as possible willing to dispense medications to injured workers for maximum access to care.

- At Mitchell, if a pharmacy is not yet in our network, we will allow them in if they can abide by the contract terms.
- There is no requirement to, nor do we ask for, any additional accreditation or licensing requirements beyond that they are licensed in the state where they are located and in good standing.

Mitchell's pharmacy network performs random "desktop" audits of 3-5% of its pharmacies every year.

- The audit includes a random selection of 5% or less of their workers' compensation claims.
- On-site reviews are only conducted if the desktop review reveals any potential issues.
- All processes are designed to minimize the administrative burden on pharmacies. This is because it has been difficult to recruit pharmacies to accept workers' comp prescriptions due to the extra administrative requirements for processing a claim.

Workers' comp PBMs help by handling the claims processing and guaranteeing payment to the pharmacy for the prescription (even if it later turns out to be an non-compensable claim). Again, it is important that pharmacies are able to do business with PBMs so injured workers have convenient access to a local pharmacy.

Direction of Care

In most states, injured workers already have their choice of pharmacy unless the state workers' comp law allows for the direction of pharmacy care. Even in those cases, the injured worker can use any pharmacy included in the network (which is typically 90+% of in-state retail pharmacies).

If a state workers' comp system allows for direction of care to a pharmacy network, the workers' comp law or rules will already govern network adequacy.

Pharmacy Benefit Management

Workers' Comp vs Commercial Health

Mail Order

Workers' comp PBMs do offer a mail order option as a convenience for home-bound or remotely-located injured workers, but it must be agreed to by the injured worker. The workers' comp PBM does not and cannot require a mail-order option be used.

Step Therapy

Step therapy is used to recommend an equally effective drug or drug combination before moving to another drug. For example, Duexis is $2,900 per month, while its component drugs (Ibuprofen and Famotidine) are exactly the same, but cost $95 per month.

Step therapy may be used in the workers' compensation system but it is governed by treatment guidelines and other scientifically based evidence unique to the workers' compensation injury and industry.

Pharmacy Benefit Management

Workers' Comp vs Commercial Health

A Complex Industry

At Mitchell Pharmacy Solutions, we include price transparency options in our contracts and we support price transparency throughout the supply chain. Our marketplace is highly competitive and we are constantly seeking ways to lower costs for our customers. We are subject to extensive regulation by a given state's workers' compensation regulator and our delivery of necessary prescription medication is subject to that regulation and the performance expectations of the employers and insurers we serve.

In an already complex, highly regulated environment, we believe that adding multiple regulatory schemas will not benefit injured workers or provide better service to our customers. Rather, it will only add a layer of complexity, ambiguity and cost. Not only could it add unnecessary administrative costs, but it could result in violations of one agency to satisfy the rules of another.

In the past several years, some states have experienced excellent results when implementing sensible directed managed care regulations focused on providing quality managed pharmacy care to injured workers. This approach has proven to reduce opioid prescribing and save unnecessary costs while maintaining a positive experience and outcome for injured workers.

Mitchell helped drive a 56% reduction in unnecessary opioid prescriptions for Utah Workers' Comp Fund claimants. Learn More >

This kind of proven, managed care approach from state workers' comp bodies delivers positive outcomes and is the best defense against most of the fraudulent and abusive practices found in the workers' comp system, such as high-cost compound creams, high-cost physician dispensing and high-cost, out-of-state mail order solutions. These practices plague the workers' compensation industry and have no demonstrated efficacy in improving injured worker care or keeping them safe and on the road to recovery.

Our focus is on delivering safe, effective and high-quality pharmacy care. We believe that an additional layer of oversight will cause undue complexity, cost, and lead to delays in care. Instead, we recommend that the focus be on solutions that have proven, positive outcomes for injured workers so they may get back to work, their families and lives.

About Mitchell

Mitchell International, Inc. delivers smart technology solutions that simplify and accelerate claims handling and repair processes, driving more accurate, consistent and cost-effective resolutions. Mitchell integrates deep industry expertise into its workflow solutions, providing unparalleled access to data, advanced analytics and decision support tools. Mitchell's comprehensive solution portfolio and robust SaaS infrastructure connect its customers in ways that enable tens of millions of electronic transactions to be processed each month for more than 300 insurance companies, over 30,000 collision repair facilities and countless other Property & Casualty industry supply partners across the Americas and Europe. For more information, please visit mitchell.com.

Questions?

Please contact Brian Allen, VP of Government Affairs, at brian.allen@mitchell.com.

July 1, 2021

Victor Mullins, Esq.
West Virginia Offices of the Insurance Commissioner
900 Pennsylvania Ave.
Charleston, WV 25302

RE: NATIONAL COMMUNITY PHARMACISTS ASSOCIATION COMMENTS ON PROPOSED AMENDMENTS TO SERIES 114-99

Dear Mr. Mullins:

Thank you for the opportunity to provide comments on behalf of the National Community Pharmacists Association regarding the proposed amendments to series 114-99, "Pharmacy Auditing Entities and Pharmacy Benefit Managers." NCPA represents the interest of America's community pharmacists, including the owners of more than 21,000 independent community pharmacies across the United States and 227 independent community pharmacies in West Virginia. These West Virginia pharmacies filled over 13 million prescriptions last year, impacting the lives of thousands of patients in your state.

We appreciate the West Virginia Offices of the Insurance Commissioner's (WVIOC's) work to adopt regulations that will allow the agency to enforce HB 2263's provisions in a manner consistent with the Legislature's intent. To ensure the proposed rules align with the language, spirit, and intent of HB 2263, we request the following changes be added to the proposed amendments.

Pharmacy reimbursement transparency

> 5.9. A PBM may not reimburse a pharmacy or pharmacist for a prescription drug or pharmacy service in an a net amount less than the national average drug acquisition cost for the prescription drug or pharmacy service at the time the drug is administered or dispensed plus a dispensing fee of $10.49. The net amount is inclusive of all transaction fees, adjudication fees, price concessions, and all other revenue passing from the pharmacy to the PBM. If the national average drug acquisition cost is not available at the time a drug is administered or dispensed, a PBM may not reimburse in an a net amount that is less than the wholesale acquisition cost of the drug as defined in 42 U.S.C. §1395w-3a(c)(6)(B) plus a dispensing fee of $10.49.

HB 2263 requires that pharmacy reimbursements be tied to a benchmark of the national average drug acquisition cost (NADAC) and a dispensing fee of $10.49, and it prohibits a PBM from engaging in any practice that imposes a point-of-sale fee or retroactive fee or derives revenue from a pharmacy or insured in connection with performing pharmacy benefits management services. By enacting HB 2263, the West Virginia Legislature intended to bring transparency to pharmacy reimbursements so that insureds and insurers know how their money is being spent. By clarifying that the reimbursement amount must not be less than NADAC plus $10.49 net of any revenue passing from the pharmacy to the PBM, the rule would align with the Legislature's intent, and patients and insurers will have a better idea of where their healthcare dollars are going.

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Similarly, we ask WVIOC to monitor permissible fees that PBMs may charge to pharmacies once these rules take effect and are implemented. We are concerned that, without proper oversight, PBMs will increase the number and amount of permissible fees. We ask that WVIOC monitor and analyze these fees to ensure that they are not used in a manner that "derives revenue from a pharmacy or insured in connection with performing pharmacy benefits management services," in contravention of HB 2263 and the proposed rules.

ERISA applicability

> 1.6. Applicability. -- This rule applies to pharmacy benefit managers that perform pharmacy benefit management for covered entities, which may include health benefit plans, and persons or companies that perform pharmacy audits, as provided ~~by the Pharmacy Audit Integrity Act~~ in Article 51, Chapter 33, of the West Virginia Code. Certain sections of this rule may not apply to Medicare Part D plans or Medicare Advantage plans that offer prescription drug coverage as 42 U.S.C. §1395w-26(b)(3) and 42 U.S.C. §1395w-112(g) provide that standards established under 42 U.S.C. §1395w-101 *et seq.* and 42 U.S.C. §1395w-21 *et seq.* shall supersede any state law or regulation, other than state licensing laws or state laws relating to plan solvency. PBMs that perform pharmacy benefits management for Medicare Part D plans and Medicare Advantage plans in this state must be appropriately licensed. Additionally, certain sections of this rule may not be applicable to health benefit plans or health plans that are subject to the Employee Retirement Income Security Act of 1974 (ERISA) if the subject provision of the rule regulates a key facet or essential part of plan administration or design and is preempted by ERISA. However, certain sections of this rule that only affect costs, pricing or alter incentives for ERISA plans are not preempted by ERISA and are accordingly applicable. PBMs that perform pharmacy benefits management for ERISA plans in this state must be appropriately licensed, and all provisions of the rule that are not preempted by ERISA are applicable. A PBM that performs pharmacy benefit management for workers' compensation insurers or self-insured employers must be licensed to operate in this state if it manages prescription drug coverage for "covered entities," as that term is defined in W. Va. Code §33-51-3 and this rule.

We ask that WVIOC make this suggested change to provide the agency with more flexibility regarding ERISA preemption. In *Rutledge v. Pharmaceutical Care Management Association*, the U.S. Supreme Court ruled that ERISA does not preempt states from enforcing PBM regulations affecting drug costs and pricing. There is currently more litigation, such as *Wilke v. Pharmaceutical Care Management Association* in the Eight Circuit Court of Appeals, to further clarify a state's authority to regulate PBMs that serve ERISA plans. It is important that the rules provide WVIOC with the ability to adapt to future judicial decisions and changes to federal law.

I appreciate your consideration of our comments. If you have any questions about the information contained in this letter, please do not hesitate to contact me at matthew.magner@ncaa.org.

Sincerely,

Matthew Magner

Matthew Magner, JD

Director, State Government Affairs

July 1, 2021

Victor Mullins
900 Pennsylvania Ave
Charleston, WV 25302
Victor.a.mullins@wv.gov

Re: House Bill 2263 (2021) Amendment to Existing Rule: "Pharmacy Auditing Entities and Pharmacy Benefit Managers"

Dear Insurance Commissioner Dodrill:

Consumer Action is appreciative of the opportunity to comment on the proposed rule changes and is concerned about the high cost of prescription drugs, escalating healthcare costs, and lack of meaningful patient choice.[1] We write these comments in support West Virginia's efforts to lower drug prices for patients. We believe that the new law and its proposed rules requiring disclosure of prescription drug manufacturers' rebates to pharmacy benefit managers ("PBMs"), transparency, accountability, and pharmaceutical rebates to be provided to patients at the point of sale are a step in the right direction.

We also write these comments because we are concerned about the lack of meaningful patient choice resulting from drug manufacturers' use of anticompetitive contracting practices that restrict patients' access to new innovative therapies. Manufacturers with dominant blockbuster drugs use financial incentives in the form of conditional rebates to negotiate formulary access and exclude competing drugs. This contracting practice is known as a rebate wall or trap and results in patients being denied access to lower cost and more efficacious drugs.

The drug rebate system is broken.[2] Drug manufacturers provide rebates to PBMs for preferred placement on drug formularies, resulting in the escalation of list prices and sales of higher priced brand drugs over lower cost brand and generic alternatives.[3] Because patients' out of pocket costs are based on list prices, they end up paying more.[4] PBMs pass some of these rebate dollars back to plan sponsors, but often keep a substantial portion of these savings for themselves.[5] The lack of transparency in this process prevents patients that are generating rebates

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[1] Consumer Action is leading advocate for competitive markets, which benefit all consumers by maintaining lower prices and promoting innovation. It is an advocate for competitive health care markets and for consumers and patients who seek lower prescription drug prices.
[2] David Balto and Wayne Winegarden, America's Rebate System is Broken, The Hill, June 23, 2021.
[3] Stephanie Hedt, New Evidence Shows Prescription Drug Rebates Play a Role in Increasing List Prices, USC, February 11, 2020 available at https://healthpolicy.usc.edu/article/new-evidence-shows-prescription-drug-rebates-play-a-role-in-increasing-list-prices/.
[4] Benjamin Rome, William Feldman, and Rishi Desai, Correlation Between Changes in Brand Name Drug Prices and Patient Out of Pocket Costs, JAMA, May 4, 2021 available at https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2779442?utm_source=For_The_Media&utm_medium=referral&utm_campaign=ftm_links&utm_term=050421.
[5] Balto and Winegarden, *supra* note 2.

through their utilization from ever seeing the benefits of these rebates.[6] Even more troubling is how some drug manufacturers structure these rebates in their contracts with PBMs to foreclose rival prescription drug competition.[7] The rebate wall results in patients being denied access to lower cost and more efficacious drugs.[8]

We believe that the law and the proposed rules will lower the out-of-pocket costs of prescription medication to consumers in the state of West Virginia. House Bill 2263 and the proposed rule changes require that a covered individual's defined cost sharing for each prescription drug be calculated at the point-of-sale, based on a price that is reduced by an amount equal to at least 100% of all rebates received, or to be received, in connection with the dispensing or administration of the prescription drug. Any rebate over and above the defined cost sharing would then be passed on to the health plan to reduce premiums. Overall, this should have significant impact on lowering prescription drug costs for patients.

We also note that the new law and rules could potentially help deter pharmaceutical manufacturers and PBMs from entering exclusionary rebate walls, however, the proposed rules likely do not go far enough. The Insurance Commission should be aware of rebate walls and consider the impact of them.

I. The Current Rebate System Is Broken

Pharmaceutical manufacturers pay rebates to PBMs that incentivize them to give higher cost drugs preferred formulary placement. PBMs tend to recommend preferred status on the formulary for therapeutically comparable brand-name drugs that offer the highest rebates; this encourages drug manufacturers to focus on offering higher rebates to secure that preferred status. As Professor Robin Feldman puts it, "the system contains odd and perverse incentives, with the result that higher–priced drugs can receive more favorable health-plan coverage, channeling patients toward more expensive drugs."[9]

A. Rebate Walls Are Not Procompetitive Discounts

The rebate wall comes in many forms but what is important to understand is that it is not a procompetitive discount rather it is an exclusionary contracting practice limiting the ability of rivals from gaining preferred formulary access or getting on formulary at all.[10] A typical rebate wall occurs when manufacturers of blockbuster drugs tie the rebate to volume targets, and use retaliatory measures to claw back rebates if the PBM allows rival drugs on the formulary.[11] The potential loss of rebates incentivizes the PBMs to prefer the blockbuster drugs over branded drugs or generic alternatives.[12] In sum, rebate walls distort the workings of the free market,

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[6] Peter Sullivan, Gottlieb: Drug rebates not benefiting sicker patients, The Hill, March 6, 2019. Former Food and Drug Administration Commissioner Gottlieb candidly stated, "sick people aren't supposed to be subsidizing the healthy."
[7] Baito and Winegarden, *supra* note 2.
[8] *Id.*
[9] Robin Feldman, Why Prescription Drug Prices Have Skyrocketed?, Washington Post, November 26, 2018.
[10] Madelaine Feldman & Wayne Winegarden, Want to Lower Drug Costs? End Rebate Walls, Real Clear Health, April 9, 2021.
[11] Baito and Winegarden, *supra* note 2.
[12] *Id.*

result in higher drug prices, and reduce patients' access to lower-cost generic and biosimilar alternatives.

B. Rebate Walls Harm Patients

The foreclosure of rival drug competition[13] harms patients by increasing costs and restricting patient access to more effective and affordable prescription drugs.[14] Dr. Wayne Winegarden, director of Pacific Research Institute's ("PRI") Center for Medical Economics and Innovation, claims that rebate walls cause patients to suffer in the form of artificially inflated prices which results in higher coinsurance payments or out of pocket expenses that are usually a percentage of the list price as well as reduced choice.[15] For example, Dr. Winegarden calculates that ending rebate walls would save patients more than $6,000 of out of pocket savings for expensive biologics like AbbVie's Humira that run approximately $70,000 per year.[16] Importantly, rebate walls cause patients to miss out on obtaining more effective treatments sooner by having to step through older incumbent drugs prior to using new more effective treatments. This raises the costs for patients and health plans because patients need to try older drugs and fail before gaining access to more effective and affordable treatments from the beginning. For immunology drugs such as Humira, a patient may have to be on a drug for at least six months before being able to switch to a more effective drug.

C. Rebate Walls Have Attracted the Attention of the Federal Antitrust Enforcers and Policy Makers

While the Federal Trade Commission ("FTC") has not yet acted on rebate walls, the practice is on its radar.[17] On May 28, 2021, the FTC issued a report on rebate walls to Congress and committed to investigating exclusionary practices that "threaten to delay new entry" and "deny patients access to competing treatments."[18] In its report, the FTC noted that "a variety of

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[13] David Balto, *Drug Rebate Walls Should Be Dismantled by the FTC's Antitrust Arm*, Stat News, December 4, 2018 available at https://www.statnews.com/2018/12/04/ftc-dismantle-drug-rebate-walls/.

[14] Providers and patient groups have raised concerns about rebate walls. *See Let My Doctors Decide Announces Expanded Patient Centered Principles and Issues Call to Action to Drive Access and Affordability. Millions of Americans Face Health Insurance Coverage Barriers; Formulary Contracting Increasingly a Concern for Patients and Doctors*, November 6, 2020 (urging CMS, employers, insurers, and other decision-makers to adopt patient-centered principles that would eliminate rebate walls) available at https://www.businesswire.com/news/home/20201106005547/en/Let-My-Doctors-Decide-Announces-Expanded-Patient-Centered-Principles-and-Issues-Call-to-Action-to-Drive-Access-and-Affordability; *see also* Global Health Living Foundation's comments at the FTC/FDA Joint Biosimilars Workshop available at https://beta.regulations.gov/comment/FDA-2019-N-6050-0012.

[15] Wayne Winegarden, *Tearing Down Drug Rebate Walls Would Save Patients and Improve Healthcare Outcomes*, Pacific Research Institute, December 9, 2020 available at https://www.pacificresearch.org/new-brief-tearing-down-drug-rebate-walls-would-save-patients-improve-health-care-outcomes/.

[16] *Id.*

[17] The FTC currently has an ongoing investigation into Johnson & Johnson's use of rebate walls to exclude rivals and protect its blockbuster, Remicade. *See* Eric Sagonowski, *J&J boasted about defending Remicade from biosims. Now its under FTC investigation*, Fierce Pharma, July 30, 2019.

[18] Federal Trade Commission Report on Rebate Walls, FTC, May 28, 2021 available at https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-report-rebate-walls/federal_trade_commission_report_on_rebate_walls_.pdf.

stakeholders have identified rebate wall issues" and that "the Commission is closely attuned to pharmaceutical manufacturer contracting practices, including rebate strategies."[19] Both FTC Chairwoman Rebecca Slaughter and Commissioner Rohit Chopra issued their own statements noting that the FTC needs to give more attention to rebate walls, but that the normal FTC investigatory process would likely take too long to avoid competitive harm in the near term.[20] And, members of both parties have criticized these practices, including Senators Klobuchar (D), Blumenthal (D), Cornyn (R), and Grassley (R), the ranking member of the Senate Judiciary Committee.[21] On July 17, 2020, the U.S. House Committee on Appropriations included language in its report accompanying H.R. 7668 urging "the FTC to prioritize investigations into manufacturers that erect rebate walls to block competition from new branded therapies, biosimilars, generics, and other innovative products."[22] Both Alex Azar, former Secretary of Health & Human Services,[23] and Scott Gottlieb, the former Food and Drug Administration Commissioner, have also raised substantial concerns over the use of rebate walls.[24]

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[19] *Id.*

[20] Statement of Acting Chairwoman Rebecca Slaughter Regarding the Commission's Report to Congress on Rebate Walls, May 28, 2021 available at https://www.ftc.gov/system/files/documents/public_statements/1590532/statement_of_acting_chairwoman_slaughter_regarding_the_ftc_rebate_wall_report_to_congress.pdf; Statement of Commissioner Rohit Chopra Regarding the Commission's Report on Pharmacy Benefit Rebate Walls, May 28, 2021 available at https://www.ftc.gov/system/files/documents/public_statements/1590528/statement_of_commissioner_rohit_chopra_regarding_the_commissions_report_on_pharmacy_benefit_manager.pdf.

[21] Drug Pricing in America, A Prescription for Change, Part II, S. HRG. 116-39, February 26, 2019, at pg. 69-71 Senators Grassley and Cornyn ask questions on rebate walls available at https://www.finance.senate.gov/imo/media/doc/37143.pdf.; Senator Klobuchar News Release, *Klobuchar Leads Warning that Pharmaceutical Mergers May Threaten Drug Competition, Increase Prices and Reduce Patient Access*, September 17, 2019 available at https://www.klobuchar.senate.gov/public/index.cfm/2019/9/klobuchar-leads-letter-warning-that-pharmaceutical-mergers-may-threaten-drug-competition-increase-prices-and-reduce-patient-access-to-essential-medications; Senator Klobuchar News Release, *Klobuchar, Blumenthal, Cicilline, Jeffries Call on Government Accountability Office to Study Effects of "Rebate Traps" on Pharmaceutical Prices and Competition*, June 10, 2020 available at https://www.klobuchar.senate.gov/public/index.cfm/2020/6/klobuchar-blumenthal-cicilline-jeffries-call-on-government-accountability-office-to-study-effects-of-rebate-traps-on-pharmaceutical-prices-and-competition.

[22] FINANCIAL SERVICES AND GENERAL GOVERNMENT APPROPRIATIONS BILL, 2021 Report July 17, 2020, available at https://www.congress.gov/116/crpt/hrpt456/CRPT-116hrpt456.pdf.

[23] HHS Secretary Alex Azar Testimony to the Senate Health, Education, Labor and Pensions (HELP) Committee, June 12, 2018 ("I am very much aware that these rebate walls can prevent competition and new entrants into the system… I do not like that practice. I think it's using their market power in ways that are not appropriate.") available at https://www.c-span.org/video/?446791-1/secretary-azar-testifies-prescription-drug-pricing-plan.

[24] Scott Gottlieb *Don't Give Up on Biosimilars—Congress Can Give Them a Boost*, Wall Street Journal, August 24, 2019. Gottlieb argued to "stop branded drug companies from using "rebates" to squelch competition from biosimilars…If there's one situation where rebates are anticompetitive, it's when they're being used to block competition from a low-cost generic." Available at https://www.wsj.com/articles/dont-give-up-on-biosimilarscongress-can-give-them-a-boost-11566755042.

II. Implementation of the Proposed Rules Will Lower Patient's Out-of-pocket Costs

Under the current rebate system, the PBMs' and payors' incentives are not aligned with those of patients.[25] While patients taking prescription drugs for chronic illnesses generate the majority of manufacturer rebate payments, they currently receive little or no financial benefits from the rebates.[26] In fact, these rebate payments are used to offset total plan costs, not to offset the out-of-pocket costs incurred by the patients whose prescriptions are generating those rebates.[27] Patients with prescription drug deductibles and coinsurance face higher out-of-pocket costs because their coinsurance amounts and payments within the deductible phase are based on a drug's list price not the net price paid by the payor.[28]

Encouraging discounts at the point of sale will benefit patients by lowering their out-of-pocket costs and realizing substantial savings at the pharmacy. Drug manufacturers will now be under more direct scrutiny so they should be incentivized to lower list prices to reflect the actual transaction price of drugs, with perhaps additional discounts provided openly, at the point of sale. Patients' out-of-pocket costs should also subsequently decrease because their co-insurance and deductibles would now be based on a lower list price.

III. Implementation of the Proposed Rules Is Not Likely to Prevent Rebate Walls

Passing on discounts to patients at the point of sale and making sure that the rebates are passed on to payors will help address perverse incentives, increase transparency, and lower out-of-pocket costs to patients, but we do not believe that they will lower all the costs associated with an anticompetitive rebate wall. There still may be significant consumer harm if drug manufacturers of blockbuster drugs are still able to employ the rebate wall strategy. The rebate wall strategy does not disappear by passing on some of the rebates to the patient. As the rules are currently drafted, rebates not provided to the patient are to be passed on to the insurer to reduce premiums. Because some of the rebate will still go to the health insurance plan, the insurer will still have perverse incentives for it to have the PBM negotiate higher list prices so they can secure higher rebates – without regard to patient wellbeing.

If a drug manufacturer with a blockbuster drug is still able to foreclose rival drug competition through a rebate wall, the PBMs will still be able to make formulary decisions that are not based on a drug's superior efficacy and lower price. While the intent of the rule is to lower insurance premiums, we do not believe the implementation of the rule will do so. When rival drugs are left off of a formulary, patients' choices are reduced, and they miss out on the medicines that they need. In sum, patients' health will suffer.[29] One of the most common and

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[25] Sullivan, supra note 3.
[26] *Id.*
[27] *Id.*
[28] *Id.*
[29] Providers and patient groups have raised concerns about rebate walls. See A Call to Action for Patients and Providers, Let My Doctors Decide (urging CMS, employers, insurers, and other decision-makers to adopt patient-centered principles: "Prohibit contracts that use rebates and other volume discounts to ban inclusion of other treatment options from formularies.") available at b11210_767d46893ae14185a2e1b5e4b03df338.pdf; see

pernicious rebate wall tactics is to require that patients "fail first" on a blockbuster drug before insurers will cover an alternative medicine.[30] A doctor cannot prescribe a medication to a patient unless the drug is on the formulary. Thus, patients are forced to try a drug preferred by the payor before being approved to use a drug that a doctor would have liked to prescribe at the outset. For certain drugs in the immunology space such as Humira, a patient may have to be on the drug for at least six months before being able to switch to a more effective drug. Delaying appropriate treatment like this can create long-term problems for patients, especially people struggling with degenerative or progressive diseases.[31] In the end, rebate walls raise the costs for patients and health plans because patients need to try older drugs and fail before gaining access to more effective and affordable treatments from the beginning.

IV. Conclusion

Consumers are currently paying higher prices resulting from the misuse of rebates in the prescription drug supply chain that incentivizes higher list prices and more expensive drugs over less expensive alternatives. Patients and providers must be empowered to no longer be at the mercy of drug manufacturers and PBMs. By requiring the pharmaceutical industry to provide specific information about their pricing practices, the legislation and proposed rules should encourage manufacturers to reconsider their standard practice of setting high prices when a drug first hits the market and then increasing those prices year after year. In this sense, the legislation and proposed rules are a step forward to meaningful reform.

We remain concerned that drug manufacturers with blockbuster drugs could still use rebate walls to disadvantage its rivals from obtaining access to PBMs and payors' drug formularies. Accordingly, we hope that the Insurance Commission consider the market realities that rebate walls exist and how rebate walls create barriers to more cost-effective therapies by foreclosing their access to drug formularies. The problem is that the most cost-effective products are unlikely to be available to patients if they cannot get on a drug formulary because of a rebate wall. We urge you to consider what steps you can take to monitor how rebate walls may be used to harm competition and patients.

Thank you for considering our comments. If you have any questions regarding these comments, please contact David Balto at david.balto@dcantitrustlaw.com.

Respectfully submitted,

Consumer Action

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also Global Health Living Foundation's comments at the FTC/FDA Joint Biosimilars Workshop available at https://beta.regulations.gov/comment/FDA-2019-N-6050-0012.

[30] Balto and Winegarden, *supra* note 2.

[31] Balto and Winegarden, *supra* note 2.

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

July 1, 2021

Victor Mullins
West Virginia Insurance Commission
900 Pennsylvania Ave
Charleston, WV 25302

Submitted via email: victor.a.mullins@wv.gov

Re: Proposed Rules Affecting Pharmacy Auditing Entities and Pharmacy Benefit Managers

Dear Mr. Mullins:

I. **Introduction**

On behalf of the National Association of Chain Drug Stores (NACDS) and our member pharmacies operating in West Virginia, we are pleased to have the opportunity to comment on the Insurance Commission's ("Commission") proposed rules to implement the provisions of recently passed legislation, House Bill 2263 ("HB 2263"), and to address issues that have arisen through the Insurance Commissioner's complaint process.

NACDS represents traditional drug stores, supermarkets, and mass merchants with pharmacies. Chains operate nearly 40,000 pharmacies, and NACDS' 80 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 155,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 21 countries. Please visit nacds.org.

Following in the wake of the Supreme Court of the United State's critical decision in *Rutledge vs. Pharmaceutical Care Management Association,*[1] the passage of HB 2263 is a significant step in the right direction to regulate the relationship between PBMs and the pharmacies that serve West Virginians every day.[2] In alignment with that decision, we offer the following

[1] No. 18-540, 2020 WL 7250098 (U.S. Dec. 10, 2020)

[2] *Rutledge v. PCMA* upheld a 2015 Arkansas' state law that sought to regulate the relationship between PBMs and pharmacies. Specifically, the 2015 Arkansas law: (1) required PBMs to promptly update their Maximum Allowable Cost ("MAC") pricing lists when a drug's prevailing wholesale cost increases by 10% or more; (2) required PBMs to grant appeals and increase reimbursements if a pharmacy was reimbursed below its acquisition cost, and the pharmacy shows it could not have purchased the drug for less from its primary

comments to aid the state in its implementation and enforcement of HB 2263 against PBMs operating in the state of West Virginia.

II. NACDS Urges Clarification Among Policies

First, we urge the Commission to clarify a number of related sections of the Code of West Virginia as you work to finalize the proposed rules. The following Code section existed prior to the enactment of HB 2263 and remains in the Code of West Virginia:

> **§33-51-9. Regulation of pharmacy benefit managers**
>
> (c) A pharmacy benefit manager may only directly or indirectly charge or hold a pharmacy, a pharmacist, or a pharmacy technician responsible for a fee related to the adjudication of a claim if:
>
> (1) The total amount of the fee is identified, reported, and specifically explained for each line item on the remittance advice of the adjudicated claim; or
>
> (2) The total amount of the fee is apparent at the point of sale and not adjusted between the point of sale and the issuance of the remittance advice.

Then, the following Code sections have been added by the enactment of HB 2263:

> **§33-51-9. Regulation of pharmacy benefit managers**
> ***
> (i)(2)(j) A pharmacy benefits manager may not:
> ***
> (2) Engage in any practice that:
> ***
> (B) Includes imposing a point-of-sale fee or retroactive fee;
> (*emphasis added*)
>
> **§33-51-3. Definitions.**
> ***
> "Point-of-sale fee" means all or a portion of a drug reimbursement to a pharmacy or other dispenser withheld at the time of adjudication of a claim for any reason. (*emphasis added*)

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wholesaler; and (3) allowed pharmacies to decline to dispense a drug if a PBM's MAC is less than what the pharmacy paid to purchase it. The Court ruled that the Arkansas law was "merely a form of cost regulation" and as such, that action is not preempted by federal law.

> ***
> "Retroactive fee" means all or a portion of a drug reimbursement to a pharmacy or other dispenser recouped or reduced following adjudication of a claim for any reason, except as otherwise permissible as described in this article. (*emphasis added*)

Read in concert, §33-51-9(i)(j)(2)(B) and §33-51-3 prohibit a pharmacy benefit manager (PBM) from engaging in any practice that includes imposing a "point-of-sale fee," which is "all or a portion of a drug reimbursement to a pharmacy or other dispenser withheld at the time of adjudication . . . for any reason," a PBM may no longer impose fees on pharmacies or dispensers for any reason that would have been withheld at the time of claim adjudication.

However, a "retroactive fee," that is a reduction or recoupment of a drug reimbursement following claim adjudication, would be subject to the limitations of "as otherwise permissible as described in [Article 33]."Consequently, we request that the Commission clarify what fees would be permitted under §33-51-9(c)(1). We request clarification as to how certain contracting mechanisms, such as effective rates, are to be assessed under this section of the West Virginia Code.[3]

Broadly, we also suggest that a third subcategory under §33-51-9 could be added to limit any other further fees, which could read as follows:

> **§33-51-9. Regulation of pharmacy benefit managers**
>
> (c) A pharmacy benefit manager may only directly or indirectly charge or hold a pharmacy, a pharmacist, or a pharmacy technician responsible for a fee related to the adjudication of a claim if:
> ***
> (3) The fee to adjudicate the same claims are not charged to any other entity (health plan payor, plan sponsor, employer).

III. NACDS Urges Adoption of Proposed Rule Provisions

Turning to the specific language of the Commission's proposed rules, we would like to highlight a number of provisions that NACDS supports and urges the Commission to adopt as proposed:

[3] That is, "The total amount of the fee is identified, reported, and specifically explained for each line item on the remittance advice of the adjudicated claim."

- §2.24 – We appreciate the Commission's recognition that the term "rebate" does not include any discount or payment made through the 340B program.

- §§4.2.10 and 6.1.4 – We appreciate the Commission's recognition that specific oversight may be needed when a PBM uses a network from another PBM or covered entity.

- §5.7 – We appreciate the Commission's proposed oversight of "other adjustments" that PBMs may attempt to impose on 340B covered entities; we support the Commission's proposal to ensure that PBMs do not place additional requirements, restrictions, or unnecessary burdens on 340B entities and their contract pharmacies; and we further support the Commission's opinion that having to include a modifier on a claim for a 340B drug or having to reprocess or resubmit a claim for a 340B drug would be a discriminatory practice that should be prohibited by the Commission.

- §5.15.6 - We appreciate and support the Commission's opinion that a pharmacy or pharmacist should not be charged or deducted a fee, recoupment, charge-back, or any other monetary penalty, amount or adjustment due to a PBM's or third-party's miscalculations, and that the PBM or third party should be responsible for accurate calculations.

- §6.1.3 – Due to the impacts of PBM practices on pharmacies that are contributing to increasing numbers of pharmacies to cease operations, we support the Commission's proposal to require that covered entities report to the Commissioner the number of pharmacies that have terminated their network participation — such terminations are not only indicative of pharmacies' going out of business but also can provide compelling information about patients' access to the pharmacies of their choice;

- §8.1.5 – Due to the undue burdens that PBMs often impose on their business partners, we appreciate and strongly support the Commissioner's proposed complaint process for PBM violations of West Virginia law or rules. We urge the Commission to adopt the complaint process provisions as proposed, especially with respect to the calculation of interest to the aggrieved party in the event that an award is made. Including interest in the award should encourage PBMs to comply with the award payment obligation in a timely manner.

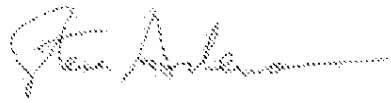
- §9.3.3 – With respect to the plan notification requirements, we support the Commission's proposals to define and clarify "reasonable means" and "regular intervals" to help ensure that beneficiaries receive convenient and timely information about their prescription medication benefits and local pharmacy access.

- §9.4 -We appreciate the Commission's proposing in its rules the necessary details of how an injured party or pharmacy may seek injunctive relief when they have suffered harm because of the actions or inactions of PBMs and health plans.

IV. Conclusion

NACDS thanks the Commission for your attention to these timely matters, and again, for the opportunity to provide our perspectives on rules to implement the provisions of HB 2263. In sum, we urge the Commission to adopt the rules as proposed and also to clarify in the final rule the application of §33-51-9(c)(1) as described above. If we can provide further assistance, please do not hesitate to contact Sandra Guckian at sguckian@nacds.org.

Sincerely,



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

7/1/21

Mr. Victor Mullins
West Virginia Office of the Insurance Commissioner

RE: 114CSR99 Pharmacy Auditing Entities and Pharmacy Benefit Managers

Dear Mr. Mullins,

The Coalition of State Rheumatology Organizations (CSRO) is comprised of a group of state and regional professional rheumatology societies throughout the country, including our member society in West Virginia, formed to advocate for excellence in rheumatologic disease care and to ensure access to the highest quality care for the management of rheumatologic and musculoskeletal diseases. Our nationwide coalition serves practicing rheumatologists in charge of patient care for these illnesses.

CSRO was encouraged by the passage of HB 2263, and the ensuing draft rulemaking published by your office. We offer the following comments on the draft rule for your consideration.

§114-99-1.6 – Applicability

CSRO has long believed that the states play an important role in health policy, and this role extends to the important work of regulating the practices of pharmacy benefit managers who play a central but under scrutinized role in pricing and access for prescription drugs. It is imperative that this important work has the maximum possible effect using the full scope of states' regulatory authority. The recent United States Supreme Court decision upholding Arkansas Act 900 in Rutledge v. Pharmaceutical Care Management Association (PCMA) affirmed that state laws which affect costs, pricing, or alter incentives are not pre-empted by the Employee Retirement Income Security Act of 1974 (ERISA).[1] Such regulatory schemes are neither impermissibly connected to ERISA plans nor do they interfere with uniform plan administration by virtue of their regulation of pharmacy benefit managers administering prescription drug benefits in conjunction with such a plan. CSRO was encouraged that the draft rule recognized this principle in considering the scope of the rule's application, particularly as it relates to §114-99-5 (Responsibilities and Prohibited Acts). **As such, CSRO encourages the insurance commissioner's office to implement and enforce section §114-99-1.6 as written.**

[1] 592 U.S. No. 18-540 (2020) (https://www.supremecourt.gov/opinions/20pdf/18-540_m64o.pdf)

§114-99-2.24 – Definitions: "Rebate"

The draft rule defines a rebate to include any payments "that accrue to a PBM or its health plan client, directly or ***indirectly***, from a pharmaceutical manufacturer…associated directly or ***indirectly in any way*** with claims administered on behalf of a health plan client."[2] PBMs are infamous for their lack of transparency and ability to obfuscate the sources of their revenue generation. It is no coincidence that PBMs have been able to leverage a seemingly innocuous position in the middle of the pharmaceutical supply chain to become perhaps the most profitable entities involved in it. As scrutiny of PBMs anti-competitive and harmful contracting practices has increased, PBMs have endeavored to find new means to evade scrutiny and circumvent regulation.

One of the ways that PBMs have sought to accomplish this is through the use of rebate aggregators. These subsidiary organizations have allowed PBMs to obscure the true amount of rebate dollars they receive from their plan sponsor clients.[3][4][5] They do so by improperly passing rebate dollars through the aggregator, which many plan clients are unable to independently audit.

Use of these pass-through entities could seriously compromise West Virginia's ability to confirm that patient cost-sharing reductions commensurate with rebates received in connection with the patient's prescription under §114-99-5.15 accurately reflect the total rebate received by a PBM.

Luckily, the draft rule provides that rebates include amounts that accrue ***indirectly to a PBM in any way***. Capturing information on these amounts that PBMs are increasingly accruing indirectly via rebate aggregators will be important for verifying compliance, and the definition of rebate in the draft rule accomplishes this purpose. **As such, CSRO encourages the office of the insurance commissioner to finalize the definition of rebate as written, and use the authority provided by the legislature to effectuate the provisions of §114-99-5.15 by policy to proactively monitor the indirect collection of rebates by PBM subsidiaries.**

§114-99-5.15 - Responsibilities and Prohibited Acts

[2] Emphasis added.
[3] https://www.frierlevitt.com/articles/cautionary-tale-plan-sponsors-losing-manufacturer-rebate-dollars-to-pbms-through-rebate-aggregators/#_ftn1
[4] https://www.frierlevitt.com/articles/service/pharmacylaw/recent-successes/frier-levitt-successfully-obtains-a-6-25-million-settlement-on-behalf-of-its-plan-sponsor-client-against-a-pharmacy-benefits-manager/
[5] https://www.lehighcounty.org/Portals/0/PDF/controller/General_Reports/Highmark%20Audit%20Final%20Issue%20Public%20Release.pdf?ver=8I-keiHO6hwG0v9G811WZw%3D%3D

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Patients across the country face untenable out-of-pocket costs for prescription drugs. The use of coinsurance based on the list price and not the negotiated price of a drug is a large contributing factor in this problem. Under this cost-sharing design, patients pay a percentage of a drugs list price, which can amount to thousands of dollars per dose. However, the true cost of the drug to a health plan is almost always substantially reduced by rebates. In many cases this can be over 50% of the drug's list price. In effect, PBMs and health plans use patients' utilization of prescription drugs to pocket rebate dollars while also extracting cost-sharing amounts from these same patients that are not commensurate with the true cost of the drug to the plan.

§114-99-5.15 requires that PBMs and health plans reduce patient coinsurance amounts commensurate with 100% of rebates received by a PBM in conjunction with the administration of that patient's claim. This provision directly addresses the aforementioned problem and provides direct and immediate benefit to patients. **CSRO strongly supports its implementation.**

CSRO also strongly supports policy that establishes guidelines for the creation of mechanisms to calculate patient coinsurance amounts consistent with the provisions of §114-99-5.15. CSRO is aware that in some circumstances the total rebate amount owed to a PBM or health plan may not be received at or around the time of claim administration, which may create an additional opportunity for PBMs and health plans to circumvent their obligations to reduce patient coinsurance amounts under §114-99-5.15. PBMs may be incentivized to delay receipt of rebate amounts in order to obscure their connection to the dispensing of a particular prescription for a particular patient. **To that end, CSRO strongly supports the Office's proposal to require the patient's coinsurance reduction must fully reflect the amount of** "rebate received, ***or to be received***[6]." The requirement to account for future amounts to be received when calculating a patient's coinsurance amount should be finalized in some form.

CSRO is sympathetic to the possibility that there may be an inability to predict the total amount of a rebate with pinpoint accuracy at the time of claim administration due to contractual incentives that may be based on broader utilization beyond a single claim. As a result, there may be some discrepancy between cost-sharing reduction at the time of claim administration and total rebate received. **In order to ensure that coinsurance amounts are being calculated in good faith, the Office should consider implementing additional reporting requirements that allow the department to appropriately monitor compliance with this section.**

[6] Emphasis added.

Thank you for your consideration of these comments. If you require additional information, please do not hesitate to contact us.

Sincerely,

Sincerely,

Madelaine Feldman, MD, FACR
President – Coalition of State Rheumatology Organizations
MFeldmanCSRO@gmail.com

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July 1, 2021

VIA ELECTRONIC MAIL – victor.a.mullins@wv.gov

Victor Mullins
West Virginia Offices of the Insurance Commissioner
900 Pennsylvania Avenue
Charleston, WV 25302

Re: Proposed Rule "Pharmacy Auditing Entities and Pharmacy Benefit Managers"

Dear Mr. Mullins:

The Pharmaceutical Research and Manufacturers of America ("PhRMA") appreciates the opportunity to comment on the proposed regulations published by the West Virginia Offices of the Insurance Commissioner (the "Commissioner") on June 1, 2021 titled "Pharmacy Auditing Entities and Pharmacy Benefit Managers" (the "Proposed Rule"), implementing the requirements of HB 2263, which was enacted in the 2021 legislative session (the "Act"). PhRMA is a voluntary nonprofit organization representing the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives.

We provide below our comments, concerns, and recommendations with respect to the Proposed Rule.

PhRMA is supportive of the Act and applauds the Commissioner for its prompt action in promulgating proposed regulations to implement the important patient protections afforded under this law. PhRMA supports improving the status quo for Americans who rely on medicines. Medicines have revolutionized the treatment of numerous serious health conditions, saving lives, improving quality of life, and reducing the need for hospitalization. Continued advances in medicines are indispensable to addressing some of our society's biggest health and economic challenges. Likewise, better use of medicines, such as improved adherence to needed treatments, offers the opportunity for improved results for patients and an estimated $213 billion per year in health care savings.[1] We are in a new era of medicine in which breakthrough science is transforming patient care and enabling us to more effectively treat chronic disease, the biggest cost

[1] IMS Institute for Healthcare Informatics, *Avoidable Costs in US Healthcare: the $200 Billion Opportunity from Using Medicines More Responsibly* (Jun. 2013), available at: https://www.quotidianosanita.it/allegati/allegato4982969.pdf.

driver in our health care system. Diseases that once were regarded as deadly are now manageable and even curable.

As discussed in greater detail below, PhRMA has long been concerned that health plans and pharmacy benefit managers ("PBMs") are not making directly available to patients the substantial rebates and discounts that manufacturers provide through negotiations with plans and PBMs, leaving patients paying deductibles and coinsurance that do not reflect the net cost of these therapies to their plan. For the reasons discussed below, we believe that implementation of the Act is an important step to redress this fundamental inequity. In particular, Section 33-51-9(l) of the Act, as implemented by § 114-99-5.15 of the Proposed Rule, requires PBMs to calculate a patient's cost sharing at the point of sale based on a price that is reduced by an amount equal to at least 100% of rebates[2] received, or to be received, in connection with the dispensing or administration of the prescription drug. In effect, this will require PBMs to base cost sharing on net price (or a good faith estimate thereof), rather than list price. This change will help enhance patient access to the medicines that they need to live healthy and productive lives.

Ensuring that Patients Benefit from Rebates at the Point of Sale

a. *PBMs and Payers Generally Calculate Cost Sharing Based on List Price, Which Negatively Affects Patients*

PhRMA commends the state of West Virginia, and the Commissioner, for being the first in the nation to enact and implement legislation ensuring that patients will benefit from rebates at the point of sale. PhRMA has long advocated for sharing directly with patients at the pharmacy counter the $187 billion in rebates and discounts given by biopharmaceutical companies to the government, issuers, plans, and PBMs.[3] Sharing negotiated rebates with patients is an important step toward improving medicine affordability and ensuring patients can access the medicines they need.

Currently, plans and PBMs typically determine patient cost sharing at the point of sale based on a medicine's list price without regard to manufacturer rebates, rather than the lower, discounted price paid by the plan net of such rebates.[4] In reality, plans and PBMs negotiate discounts, in the form of rebates, on brand medicines on behalf of health plans, employers, and other payers that substantially reduce the net price paid by the plan. On average, manufacturers rebate more than 40% of a medicine's list price back to health plans, PBMs, the government, and other entities in the pharmaceutical supply chain.[5] Yet too often, the benefits of these manufacturer rebates are not directly shared with patients by plans, PBM, or other recipients.

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[2] We note that the definition of "rebate" under Section 33-51-3 of the Act and Section 114-99-2.24 of the Proposed Rule is broad and includes any and all payments that accrue to a PBM or its health plan client directly or indirectly. We assume that bona fide service fees as defined at 42 C.F.R. § 414.802 would not be considered "rebates" for purposes of the Act.

[3] PhRMA Press Release, "*West Virginia Becomes the First State to Lower Patient Costs by Sharing the Savings*" (Apr. 20, 2021), available at: https://catalyst.phrma.org/west-virginia-becomes-the-first-state-to-lower-patient-costs-by-sharing-the-savings.

[4] More than half of commercially insured patients' out-of-pocket spending for brand medicines is based on list price. PhRMA Report, "*Commercially-Insured Patients Pay Undiscounted List Prices for One in Five Brand Prescriptions, Accounting for Half of Out-of-Pocket Spending on Brand Medicines,*" available at: http://www.phrma.org/report/commercially-insured-patients-pay-undiscounted-list-prices-for-one-in-five-brand-prescriptions-accounting-for-half-of-out-of-pocket-spending-brand-medicines.

[5] IQVIA, "*Use of Medicines in the U.S.: Spending and Usage Trends and Outlook to 2025*" (May 2021), available at: https://www.iqvia.com/insights/the-iqvia-institute/reports/global-medicine-spending-and-usage-trends-outlook-to-2025.

Compounding these issues are the growth of plans that incorporate high out-of-pocket cost sharing and deductible obligations on enrollees. Enrollment in high-deductible health plans and use of coinsurance for medicines has grown sharply in recent years, increasingly exposing patients to high out-of-pocket costs based on undiscounted list prices.[6] Further, use of deductibles and coinsurance has increased particularly acutely for new medicines that represent the most innovative therapies and often treat the sickest patients.

High cost-sharing is a cause for concern, as a substantial body of research clearly demonstrates that increases in out-of-pocket costs are associated with both lower medication adherence and increased abandonment rates, putting patients' ability to stay on needed therapies at risk.[7] Research consistently shows that patients facing high cost sharing are less likely to initiate or adhere to their prescribed medication regimens. For beneficiaries with a serious illness or multiple chronic conditions, out-of-pocket expenses for prescription medicines can easily add up to many thousands of dollars annually, resulting in patients with chronic or life-threatening illnesses such as diabetes, schizophrenia, multiple sclerosis, and cancer *walking away from the pharmacy counter without filling vital prescriptions*.

For example, one published study found that where beneficiary cost sharing exceeds $250, 71% of new specialty prescriptions were abandoned.[8] Even among patients with debilitating or life-threatening illnesses, abandonment rates were alarmingly high. For example, more than 6 out of 10 new oncology prescriptions and more than 7 out of 10 new antipsychotic and multiple sclerosis prescriptions were abandoned at the pharmacy counter when their cost sharing exceeded $250. These rates of medication nonadherence raise fundamental concerns about patient health and safety, as well as costs for the broader health care system. It is well established that medication nonadherence is associated with poor clinical outcomes and higher overall health care costs.[9]

A significant contributing factor to enhanced patient out-of-pocket costs is the practice of payers calculating patient cost sharing and deductibles based on list price rather than discounted or net price. This practice can result in a plan or PBM realizing a net gain when a prescription is filled. For example, imagine a patient enrolled in a high-deductible health plan who takes a medication

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[6] The share of patient out-of-pocket drug spending represented by coinsurance more than doubled over the past 10 years in the commercial market, while the share accounted for by deductibles tripled. Claxton G., Levitt L., Damico, A., Cox, C., Kaiser Family Foundation, "*Examining High Prescription Drug Spending for People with Employer-Sponsored Health Insurance*" (Oct. 27, 2016) available at: http://www.healthystemtracker.org/insight/examining-high-prescription-drug-spending-for-people-with-employer-sponsored-health-insurance/.

[7] IMS Institute for Healthcare Informatics, "*Emergency and Impact of Pharmacy Deductibles. Implications for Patients in Commercial Health Plans*" (Sept. 2015); Doshi JA, Li P, Huo H, et al. "*High Cost Sharing and Specialty Drug Initiation Under Medicare Part D: A Case Study in Patients with Newly Diagnosed Chronic Myeloid Leukemia*" American Journal of Managed Care. 2016;22(4 Suppl):S78-S86; Brot-Goldberg ZC, Chandra A, Handel BR, et al. "*What Does A Deductible Do? The Impact of Cost Sharing on Health Care Prices, Quantities, and Spending Dynamics*," NBER Working Paper 21632, October 2015; Eaddy MT, Cook CL, O'Day K, et al. "*How Patient Cost Sharing Trends Affect Adherence and Outcomes*," Pharmacy & Therapeutics. 2012;37(1):45-55.

[8] Amundsen Consulting, "*Medicare Part D Abandonment: Deep Dive into Branded Product Abandonment*," (Nov. 2017); see also Doshi, JA., Li, P, Huo, H, et al. "*Medicare Part D Cost sharing And Specialty Drug Initiation In Newly Diagnosed Chronic Myeloid Leukemia Patients*" Value in Health, 2016;19(3):78-86; Doshi, JA, Hu, T, Li, P, et al. "*Specialty Tier-Level Cost sharing and Biologic Use in the Medicare Part D Initial Coverage Period among Beneficiaries with Rheumatoid Arthritis*" Arthritis Care & Research, 2016.

[9] Boswell KA, Cook CL, Burch SP, et al. *Associating Medication Adherence with Improved Outcomes: A Systematic Literature Review*. American Journal of Managed Care. 2012;4(4):e97-e108.

with a list price of $400. The patient's health plan has negotiated a 55% rebate, which substantially reduces the cost to the plan. However, because the patient has not yet met his deductible, his plan does not provide any coverage for the prescription, and the patient's bill reflects the medication's full list price of $400. Despite paying nothing for this patient's medicine, the plan still collects the rebate, earning over $220.[10] In essence, plans and PBMs have historically "double dipped." Not only do they receive manufacturer rebates, but rather than allowing them to be carried forward to patients, they also calculate cost sharing and deducible obligations based on a list price that does not reflect the actual cost that has been incurred by the plan or PBM for the drug.

Instead of sharing the full benefit of discounts on the price of medications with the patient at the pharmacy counter, plans sometimes apply negotiated rebates to reduce premiums for all enrollees. Putting aside that the fraction of retained rebates that plans use toward reducing patient premiums is not always significant or adequate,[11] this also creates fundamental mis-incentives with respect to plan design: It means that the sick are subsidizing the healthy. As the actuarial firm Milliman has pointed out, the practice results in a system of "reverse insurance" where payers require sicker patients using brand medicines with rebates to pay more out-of-pocket, while rebate savings are spread out among all plan enrollees in the form of lower premiums.[12] Asking sicker patients with high medicine costs to subsidize premiums for healthier enrollees is the opposite of how health insurance is intended to work. This means that patients taking medicines with large rebates are subsidizing coverage for other beneficiaries—which is effectively a tax on the sick.[13]

b. Calculating Cost Sharing Based on Net Price is Good Policy

As noted, PhRMA applauds West Virginia for adopting and implementing the Act, which will provide West Virginians with immediate and visible relief from high costs at the pharmacy counter and help them better afford the medicines they desperately need. Implementation of the Act will ensure that West Virginians directly benefit from negotiated prices. Actuarial research shows the tangible impact of calculating patient cost sharing based on net price rather than list price: patients enrolled in plans with high deductibles and coinsurance could save between $145 and $800 annually.[14] With the implementation of the Act, West Virginians will access reduced cost sharing, which – as discussed above – has been shown to increase medication adherence. And, as numerous studies have shown, patient outcomes are significantly improved when adherence to therapies is increased.[15]

Indeed, even plans and PBMs have begun to acknowledge the clear problems created by calculating cost sharing based on list price: Statements from the two largest PBMs note that high

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[10] For illustrative examples of the flow of payment for prescription medicines across the supply chain, see PhRMA Press Release, "*Follow the Dollar*" (Nov. 2017), available at: http://phrma-docs.phrma.org/files/dmfile/Follow-the-Dollar-Report.pdf.

[11] Fein, A. "*Employers Are Getting More Rebates Than Ever– But Sharing Little With Their Employees*," (Jan. 18, 2018), available at: https://www.drugchannels.net/2018/01/employers-are-getting-more-rebates-than.html ("[M]ore than two-thirds of employers use rebate payments to offset overall spending on drug costs. Only 11% use rebates to offset member premiums, an option that spreads the benefit to all employees.").

[12] Girod CS et al. "*2017 Milliman Medical Index*," (May 2017), available at: http://www.milliman.com/uploadedFiles/insight/Periodicals/mmi/2017-milliman-medical-index.pdf.

[13] Id.

[14] Bunger A, Gomberg J, Petroske J. "*Sharing Rebates May Lower Patient Costs and Likely Has Minimal Impact on Premiums*" (Oct. 12, 2017), available at: http://www.phrma.org/report/point-of-sale-rebate-analysis-in-the-commercial-market.

[15] MC Roebuck, "*Medical Cost Offsets from Prescription Drug Utilization among Medicare Beneficiaries*," J Manag Care Pharm. 2014;20(10):994-95.

deductibles for medicines put patients in a "very difficult position" and indicate that sharing rebate savings directly with patients is a "best practice."[16]

The following chart provides an example of how the Act will decrease patient out-of-pocket expenses at the point of sale:

Table: Current Process versus Post-Implementation of the Act[17]

Consider an illustrative patient who takes a drug with a list price of $400. The PBM has negotiated a 55% rebate ($220) with the manufacturer, making the net price of the medicine to the PBM $180. The PBM is contracted to reimburse the pharmacy the full $400 list price of the medicine.

Patient Cost Sharing Scenario	Process Today	After Implementation of the Act
Co-Pay ($10)[18]	Patient pays the pharmacy a $10 co-pay for a drug. PBM pays the pharmacy the remaining $390, and receives $220 in rebates, incurring a net cost of $170 on its portion of the claim.	***No change.***
Coinsurance (20%)	Patient pays the pharmacy $80 coinsurance (20% of $400). PBM pays the pharmacy the remaining $320 but receives a rebate of $220, incurring a net cost of $100 on its portion of the claim.	Patient pays the pharmacy $36 (20% of $180, which is the total price on the claim reduced by manufacturer rebates pursuant to the Act). ***Savings of $44 for the patient.*** PBM pays the pharmacy the remaining $364 and receives a rebate of $220, incurring a net cost of $144 on its portion of the claim.
Deductible ($1,000)	Patient has $1,000 deductible and has paid $0 towards the deductible. Patient pays the pharmacy the full $400. The PBM pays the pharmacy zero, and receives the entire $220 rebate from the manufacturer.	Patient has $1,000 deductible and has paid $0 towards the deductible. Patient pays the pharmacy $180, which is the total price on the claim reduced by manufacturer rebates pursuant to the Act. ***Savings of $220 for the patient.*** The PBM pays the pharmacy the remaining $220, but receives a $220 rebate from the manufacturer.
	In these scenarios, the patient receives zero direct benefit from rebates. The PBM receives the	***In the coinsurance and deductible scenario, the patient benefits from rebates commensurate with the patient's cost-***

[16] Seeking Alpha. Express Scripts Holding (ESRX) Q4 2016 Results -- Earnings Call Transcript. February 15, 2017; Seeking Alpha. CVS Health (CVS) Q4 2016 Results -- Earnings Call Transcript. February 9, 2017.

[17] This table is intended to present a simplified, illustrative example demonstrating implementation of the Act. Note that the actual amount that a pharmacy receives for a drug may vary depending on the specific reimbursement formula negotiated between the pharmacy and the PBM. Pharmacies are typically paid at Average Wholesale Price (AWP) minus a certain negotiated percentage. That said, for purposes of simplicity, we have assumed a scenario where the pharmacy is paid at the drug's list price.

[18] The definition of the term "defined cost sharing" under Section 33-51-3 of the Act and Section 114-99-2.6 of the Proposed Rule includes deductibles and coinsurance, but does not include copays. However, for purposes of illustrating the full spectrum of patient out-of-pocket obligations before and after the implementation of the Act, we have included a copay example here.

Patient Cost Sharing Scenario	Process Today	After Implementation of the Act
	entire manufacturer rebate, in some cases realizing a gain.	***sharing burden relative to the PBM, which is required to share the benefit of its rebates with the patient.***

c. Calculating Patient Cost Sharing Based on Net Price will Have Minimal and Manageable Effect on Premiums

Research demonstrates that requiring PBMs to calculate cost sharing based on net price will have minimal and manageable impact on premiums. Actuarial research conducted by Milliman estimates that premiums may increase by one percent or less.[19]

In fact, OptumRx recently implemented a policy requiring all new employer plans, beginning in 2020, to provide discounts directly to patients at the pharmacy.[20] According to OptumRx, in just two months, the program lowered patient costs by an average of $130 per eligible prescription, and patients' medication adherence improved by four to six percent. Further, the policy implementation led to only very "modest increases" in premiums, in the low-single digits.

The average savings patients would likely see at the pharmacy counter would more than offset potential increases in premiums, and the benefit of rebates would directly accrue to the very patients utilizing the medicines on which the rebates are provided by manufacturers. Furthermore, in the event that the amount of negotiated rebates exceeds the amount of the patient's cost sharing for total cost of the drug, any excess must be used by the plan to reduce premiums.

d. Calculating Patient Cost Sharing Based on Net Price is Known to be Currently Operational

Plans and PBMs already have ample experience in implementing the calculation of patient cost sharing based on a price that takes into account rebates at the point of sale. Insurers and PBMs *currently* offer point-of-sale rebate sharing to commercial clients, covering millions of lives across the country.[21] The technical capacity to calculate cost sharing at the point of sale based on net price

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[19] Bunger A, Gomberg I, Petroske J., "*Sharing Rebates May Lower Patient Costs and Likely Has Minimal Impact on Premiums*" (Oct. 12, 2017), available at: http://www.phrma.org/report/point-of-sale-rebate-analysis-in-the-commercial-market.

[20] UnitedHealth Group Press Release, "*Successful Prescription Drug Discount Program Expands to Benefit More Consumers at Point-of-Sale*" (Mar. 12, 2019), available at: https://www.unitedhealthgroup.com/newsroom/2019/2019-03-12-prescription-drug-program-expands-to-benefit-consumers-point-of-sale.html.

[21] CVSHealth White Paper, "*A Prescription for Better Diabetes Management.*" available at: https://payorsolutions.cvshealth.com/sites/default/files/cvs-health-payor-solutions-a-prescription-for-better-diabetes-management-white-paper-january-2020.pdf (More than 80 clients covering 10.3 million members have adopted the option of adopting point-of-sale rebates, which allows them to pass all or a portion of rebates to members at the point of sale to help lower out of pocket costs.); UnitedHealth Group Press Release, "*Successful Prescription Drug Discount Program Expands to Benefit More Consumers at Point-of-Sale*" (Mar. 12, 2019), available at: https://www.unitedhealthgroup.com/newsroom/2019/2019-03-12-prescription-drug-program-expands-to-benefit-consumers-point-of-sale.html. (existing point-of-sale discount programs serve more than 9 million consumers in 2019).

is well established.[22] Most PBMs can administer rebates at the point of sale, and have expressed a willingness to do so.[23] Indeed, one PBM testified to Congress that PBMs currently "administer point-of-sale discounts . . . through proven, stable, secure, and highly efficient systems that have evolved through three decades of investment, innovation, and partnership with key stakeholders."[24] Implementing the Act will be a matter of expanding already-operationalized policies to additional plans and contracts, but will not require sweeping new infrastructure given industry familiarity with and expertise in implementing point-of-sale rebates.

e. Good Faith Estimate of Net Price is Sufficient

PhRMA also notes that, while the precise amount of rebates may not always be known at the point of sale, PBMs have sufficient information to calculate cost sharing based upon a good faith estimate of rebates. PhRMA believes that a good faith estimate is sufficient and will allow for immediate implementation of the Act and corresponding patient benefit. Indeed, the Commissioner can exercise its broad discretion in implementation of the Act to expressly require that rebates be based on good faith estimates.[25]

In addition to requiring PBMs to calculate cost sharing based upon a price that takes into account a good faith estimate of rebates, the Commissioner could consider requiring the PBM to conduct an end-of-year true up calculation once the PBM has enough information to calculate actual rebates received. In the event that the end of year true-up identifies any errors that exceed a material threshold, the Commissioner could decide how best to require the PBM to correct the error.

Calculating patient cost sharing based on a price that takes into account a good faith estimate of rebates also helps to protect the confidentiality of commercially sensitive drug pricing data. This would effectuate the intent of the West Virginia legislature, which incorporated significant confidentiality protections to safeguard such commercially sensitive information.

It also is sound public policy for more fundamental reasons: Maintaining the confidentiality of such data preserves incentives for market-based competition. As the Federal Trade Commission has recognized, keeping proprietary pricing information confidential is important to the effective

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[22] See PCMA and AHIP comment letters submitted in response to CMS-4182-P: Medicare Program: Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program (Jan. 16, 2018).

[23] CVS Health Press Release "Aetna to provide pharmacy rebates at time of sale, encourages transparency from drug manufacturers" (Mar. 27, 2018), available at: https://cvshealth.com/news-and-insights/press-releases/aetna-to-provide-pharmacy-rebates-at-time-of-sale-encourages; Drug Channels "*Employers Slowly Warm to Point-of-Sale Rebates—But Must Move Faster for Insulin*" (Sept. 19, 2019), available at: https://www.drugchannels.net/2019/09/employers-slowly-warm-to-point-of-sale.html; Roberts, J. "*Consumer Transparency: Helping Members With High-Cost Drugs at the Point of Sale*" (Jun. 7, 2017), available at https://payorsolutions.cvshealth.com/insights/consumer-transparency.

[24] Testimony of Sumit Dutta, MD, Chief Medical Officer, OptumRx Before the U.S. House of Representatives Energy & Commerce Subcommittee on Oversight and Investigations (Apr. 16, 2019), available at: https://congress.gov/116/meeting/house/109299/witnesses/HHRG-116-IF02-Wstate-DuttaS-20190410.pdf; Testimony of John M. Prince, Chief Executive Officer, OptumRx Before the U.S. Senate Committee on Finance (Apr. 9, 2019). Available at: https://www.finance.senate.gov/imo/media/doc/John%20Prince%20OptumRx%20Testimony%20Senate%20Finance%20Committee_04.09.19.pdf.

[25] To the extent PBMs express any concern about how rebates should be calculated, the Commissioner could also issue a policy statement announcing that it will exercise enforcement discretion and not seek to penalize PBMs that make good faith estimates of rebates at the point-of-sale.

functioning of competitive markets.[26] Similarly, the empirical literature has amply demonstrated that confidentiality of pricing arrangements is a fundamental requirement for vigorous negotiations, which is vital in helping to hold net prices for medicines steady.[27]

f. PBMs Should be Required to Certify Compliance with the Act[28]

PhRMA also suggests that the Commissioner require PBMs to submit an annual certification, in a form to be determined by the Commissioner, that they have complied with the requirements of the Act relating to calculation of patient cost sharing. The Commissioner could consider incorporating this certification requirement into the reporting required under Section 114-99-6.2 of the Proposed Rule. This would be an important step towards ensuring compliance that would be minimally burdensome both for the Commissioner and PBMs.

The Commissioner has the authority to audit PBMs to monitor compliance with the "pass through" requirement.[29] PhRMA encourages the Commissioner to exercise its audit authority to ensure that PBMs are complying with the requirement to calculate patients' defined cost sharing net of rebates. And, if based upon the audit the Commissioner determines that the PBM is not in compliance, PhRMA encourages the Commissioner to exercise its disciplinary authority and impose penalties as appropriate.

We also note that PBMs may try to evade the intent of the Act by shifting patient out-of-pocket obligations to copay structures, and away from coinsurance and deductibles.[30] As discussed above, the definition of "defined cost sharing" under Section 33-51-3 of the Act and Section 114-99-2.6 of the Proposed Rule includes deductible payments and coinsurance amounts, but does not expressly address copays. Patient out-of-pocket obligations are more predictable and often lower when cost sharing shifts from coinsurance to a fixed copay, but the Commissioner should exercise its audit authority to monitor whether PBMs are improperly shifting patient out-of-pocket obligations to unduly high copays in order to circumvent the requirements and the purpose of the Act.

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[26] Koslov T., Jex E., "*Price Transparency or TMI?*" Federal Trade Commission (Jul. 2, 2015), available at: https://www.ftc.gov/news-events/blogs/competition-matters/2015/07/price-transparency-or-tmi ("Too much transparency can harm competition in any market, including in health care markets. . . We are especially concerned when information disclosures allow competitors to figure out what their rivals are charging, which dampens each competitor's incentive to offer a low price.").

[27] IQVIA, "*Medicine Use and Spending in the U.S.*" (Apr. 2018), available at: https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-use-and-spending-in-the-us-review-of-2017-outlook-to-2022.

[28] We note that some PBMs have moved toward using the term Group Purchasing Organization ("GPO") to describe their role and their provision of services relating to rebates. Regardless of whether an entity characterizes itself as a PBM or GPO, where the entity provides "pharmacy benefits management" services as defined under Section 33-51-3 of the Act and Section 114-99-2.19 of the Proposed Rule, the entity is considered a PBM for purposes of the Act and Proposed Rule and is subject to all applicable requirements.

[29] West Virginia's proposed auditing regulations refer to the rebate reduction provisions of the Act as "pass-through" requirements. This nomenclature does not appear in the Act, and PhRMA notes that the Act does not operate as a literal pass-through and instead is contemplated as a discount on the price used to determine the amount paid by the patient at the point-of-sale for deductibles or co-insurance. In order to avoid the potential for confusion, the Commissioner may wish to consider revising its regulations to avoid the potentially misleading pass-through nomenclature.

[30] PBMs are adept at making changes to patient cost sharing in response to market changes, as evidenced by the shift from copays to deductibles and coinsurance, and changes could be made in the opposite direction in response to this new law. *See* Peterson Center on Healthcare-KFF, "*Tracking the rise in premium contributions and cost-sharing for families with large employer coverage*" (August 2019), available at: https://www.healthsystemtracker.org/brief/tracking-the-rise-in-premium-contributions-and-cost-sharing-for-families-with-large-employer-coverage/.

The Statute Does Not Provide Authority for Prohibitions Relating to the Use of 340B Claims Modifiers

PhRMA and our member companies have long supported the 340B program and the critical safety-net role it was intended to play in our nation's health care system. Congress established the 340B drug discount program nearly three decades ago to help make prescription medicines more accessible to uninsured or vulnerable patients treated at safety net facilities by requiring manufacturers provide substantial discounts on covered outpatient drugs.

The 340B law creates an absolute prohibition on duplicate discounts, which prohibits covered entities from purchasing a drug at a 340B discount that also generates a Medicaid rebate.[31] Despite this straightforward statutory imperative, current prevention methods are insufficient to address the duplicate discounts that persist throughout the 340B program.[32] The complications with duplicate discounts were magnified by the expansion of Medicaid rebates to Medicaid Managed Care Organization (MCO) enrollees' utilization.[33] The lack of transparency and appropriate claims identification mechanisms or standards prevent states and manufacturers from properly applying payment policies. Claims modifiers also give manufactures data that can help identify cases of diversion, which occurs when a covered entity requests a 340B discount for someone who is not an eligible patient under the federal statute. The sharing of information via a modifier can help ensure 340B discounts are being properly applied and stakeholders operate in a compliant manner. However, covered entities and contract pharmacies have refused to consistently utilize this voluntary standard.[34]

We do not read the statute as enabling West Virginia to adopt regulations that govern the use of 340B claims modifiers. Section 33-51-9 titled "Regulation of Pharmacy Benefit Managers" prohibits certain PBM financial practices such as PBM fees, certain pharmacy reimbursement rates, and anti-340B discriminatory practices, and Section (d) prohibits PBMs from "reimburs[ing] the 340B entity for pharmacy-dispensed drugs at a rate lower than that paid for the same drugs to pharmacies similar in prescription volume that are not 340B entities," and *"assess[ing] any fee, charge-back, or other adjustment upon the 340B entity on the basis that the 340B entity participates in the program set forth in 42 USC 256b."* (emphasis added).

The proposed regulation at Section 5.7 broadly defines the term "other adjustment" to include "any additional requirements" that result in increased costs or fees to a 340B entity, including a 340B claims modifier. This interpretation of "other adjustment" goes beyond the statutory language at Section 33-51-9, which refers to adjustments to PBM reimbursement "rates" of pharmacy-dispensed drugs to a 340B entity, not the identification of a 340B claim. Nor does it make sense for a PBM to "assess" a claims modifier requirement on a pharmacy— the statutory ban on "assess[ing] any fee, charge-back, or other adjustment" on a 340B pharmacy plainly bans a PBM from imposing financial penalties on 340B pharmacies, not from requiring that 340B covered entities or pharmacies use claims modifiers. In fact, the word "modifier" (340B-specific or not)

[31] Sec. 340B PHSA(a)(5)(i).
[32] HHS Office of the Inspector General, *"State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates,"* June 2016.
[33] CMCS Informational Bulletin, *"Best Practices for Avoiding 340B Duplicate Discounts in Medicaid,"* (Jan. 2020), available at: https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib010820.pdf
[34] https://www.ncpdp.org/NCPDP/media/pdf/340B_Information_Exchange_Reference_Guide.pdf

does not appear anywhere in the entire statute governing PBMs ("Article 51"). Accordingly, the statute does not support the state's overly broad interpretation of "other adjustment" to include claims modifiers, so this proposed regulatory prohibition on requiring 340B claims modifiers is an unreasonable interpretation of the statute that should be removed from the proposed regulation.

Nor does the statute at Section 33-55-11 or elsewhere support the state's interpretation in Section 5.8 of the proposed regulation banning the required use of a 340B claims modifier as a "discriminatory practice that prevents or interferes with a patient's choice to receive drugs at a 340B entity." Section 33-51-11 prohibits certain PBM or health benefit plans practices that limit, place conditions on, or impose higher costs on an individual's decision to choose their pharmacy under a health plan. Proposed Section 5.8 refers to a 340B claims "modifier" as such a "discriminatory practice" but fails to explain how a modifier would impact an individual's choice of pharmacy. In almost all cases, an individual has no way of knowing whether a particular pharmacy participates in the 340B program. A PBM requirement for a claim to be identified by the pharmacy via a 340B claims modifier – an electronic standard used in a digital communications transaction between PBM and pharmacy[35] would not be visible to the individual and therefore, could not impact or limit their choice of pharmacy. This proposed regulatory prohibition on requiring 340B claims modifiers does not protect individuals from any "discriminatory practice" and is not supported by the statute, so the modifier prohibition should be removed from the proposed regulation.

Finally, PhRMA is concerned that this prohibition is being added in a piecemeal fashion that has broader implications on a federal drug discount program woefully in need of modernization to ensure it works for 340B patients. If enacted as drafted, these proposed changes have the potential to undermine program integrity by further increasing the risk of duplicate discounts and diversion within the 340B program, interfere with contractual terms between trading partners, and introduce additional opaqueness into prescription claims information critical to determining appropriate patient cost sharing and covered entity reimbursement. Transparency should be paramount in ensuring proper governance in the 340B program. We respectfully request that these additions not be adopted as proposed.

We look forward to working with stakeholders at the local and federal levels on holistic and meaningful improvements to ensure the 340B program is overseen and operated in a way that sustains the program for the long-term so that patients may benefit from the discounts provided by biopharmaceutical manufacturers. We are committed to the 340B program and want to ensure that uninsured and vulnerable patients of West Virginia benefit from manufacturer 340B discounts on covered outpatient drugs.

PhRMA Supports the Proposed Spread Pricing Provision

PhRMA supports the Act's spread pricing provision, as implemented in the Proposed Rule, which requires PBMs to offer plans the option to purchase a prescription drug at the same price the PBM pays the pharmacy for the drug and prohibits the use of spread pricing outright when contracting with plans administered on behalf of the state or a political subdivision of the state. PBMs use spread pricing to profit off the difference between the amount they charge their plan clients and

[35] https://www.ncpdp.org/NCPDP/media/pdf/340B_Information_Exchange_Reference_Guide.pdf.

the amount they reimburse pharmacies. This can create perverse incentives that could directly harm patients.

Spread pricing practices have come under increased scrutiny in recent years due to growing evidence suggesting the abuse of such practices. One Ohio investigation determined that use of spread pricing resulted in more than $200 million per year in excess profit from the state to PBMs, relative to what PBMs actually reimbursed to pharmacies.[36] The investigation led Ohio to prohibit spread pricing contracts in Medicaid managed care plans.[37] Similarly, other states and the Centers for Medicare & Medicaid Services ("CMS") have also taken action to limit the use of spread pricing by PBMs.[38] In 2019, CMS issued new guidance addressing spread pricing in Medicaid to ensure PBMs are not up-charging taxpayers.[39] CMS noted that states were "increasingly reporting instances of spread pricing in Medicaid" and expressed "concern[] that spread pricing is inflating prescription drug costs that are borne by beneficiaries and taxpayers."[40] PhRMA supports West Virginia's efforts to combat spread pricing and welcomes this change.

PhRMA Supports PBM Reporting Requirements

PhRMA also supports the imposition of new reporting requirements for PBMs under the Act and Section 114-99-6 of the Proposed Rule. The Act and the Proposed Rule require PBMs to submit an annual report to the Commissioner that includes, among other things, information on the aggregate amount of rebates received by the PBM, distributed to health plans and covered entities that contract with the PBM, and used to decrease enrollee cost sharing at the point of sale. The Act and the Proposed Rule also require PBMs to submit an annual report to the Commissioner and plans on the difference between the amount the PBM reimbursed a pharmacy and the amount the PBM charged a plan (i.e., spread pricing information). PhRMA appreciates West Virginia's recognition that transparency efforts should look beyond manufacturers and consider the role that PBMs and other entities play in shaping drug spending. PhRMA believes this is a reasonable policy solution that will provide meaningful transparency.

The complex set of rebates and fees involved in PBM pricing practices make it difficult for plans to assess whether they are fully benefiting from all price concessions that PBMs negotiate. Lack of transparency over PBM-retained fees in contracts between issuers and PBMs has led many issuers to question the share of rebate savings being passed through, how much the PBM is retaining for administrative fees, and whether the PBM is disclosing and passing on other price concessions, such as savings from price protection rebates.[41] The Act's PBM reporting provisions,

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[36] Ohio Auditor of State, "*Ohio's Medicaid Managed Care Pharmacy Services*," (Aug. 2018), available at: https://audits.ohioauditor.gov/Reports/AuditReports/2018/Medicaid_Pharmacy_Services_2018_Franklin.pdf.

[37] Ohio Auditor of State, "*Auditor's Report: Pharmacy Benefit Managers Take Fees of 31% on Generic Drugs Worth $208M in One-Year Period*," (Aug. 16, 2018), available at: https://ohioauditor.gov/news/pressreleases/Details/5042.

[38] Kaiser Family Foundation, "*Prohibition of Spread Pricing in Medicaid MCO Contracts*," (July 1, 2019), available at: https://www.kff.org/other/state-indicator/prohibition-of-spread-pricing-in-medicaid-mco-contracts/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.

[39] CMS Press Release, "*CMS Issues New Guidance Addressing Spread Pricing in Medicaid, Ensures Pharmacy Benefit Managers are not Up-Charging Taxpayers*," (May 15, 2019), available at: https://www.cms.gov/newsroom/press-releases/cms-issues-new-guidance-addressing-spread-pricing-medicaid-ensures-pharmacy-benefit-managers-are-not.

[40] *Id.*

[41] *See, e.g.*, Midwestern Business Group on Health, "*Drawing a Line in the Sand: Employers Must Rethink Pharmacy Benefit Strategies*," (Sept. 2017) (discussing this phenomena in the context of employer sponsored health plans), available at:

as implemented in the Proposed Rule, will promote greater transparency and accountability around PBM pricing practices. PhRMA applauds West Virginia for joining the list of states that have enacted similar PBM transparency and reporting measures.

PhRMA proposes that the Commissioner should define "aggregate" such that it does not permit disclosure of individual drug information. Specifically, PhRMA urges the Commissioner to clarify that the "aggregate" information reported pursuant to the Act and the Proposed Rule shall be expressed in a manner that does not disclose the price(s) charged for a specific drug or class of drugs, the amount of any rebates provided for a specific drug or class of drugs, the manufacturer, or that would otherwise have the potential to compromise the financial, competitive, or proprietary nature of that information.

PhRMA also urges the Commissioner to revise the reporting requirement under Section 114-99-6.2.1.c of the Proposed Rule to align with the requirement of Section 33-51-9(l) of the Act, and Section 114-99-5.15 of the Proposed Rule.

Section 33-51-9(l) of the Act and Section 114-99-5.15 of the Proposed Rule require:

> "A covered individual's defined cost sharing for each prescription drug shall be calculated at the point of sale based on a price that is reduced by an amount equal to at least 100% of all rebates received, or to be received, in connection with the dispensing or administration of the prescription drug."

By contrast, Section 114-99-6.2.1.c of the Proposed Rule requires PBMs to report:

> "The aggregate amount of rebates passed on to the enrollees of each covered entity or health plan at the point of sale that reduced the enrollees [sic] applicable deductible, copayment, coinsurance, or other cost sharing amount."

We believe that Section 114-99-6.2.1.c of the Proposed Rule is intended to require PBMs to report the amount of rebates that were used to decrease patient cost sharing in accordance with Section 33-51-9(i) of the Act and Section 114-99-5.15 of the Proposed Rule, and Section 33-51-9(l) of the Act. But as proposed, the language in Section 114-99-6.2.1.c of the Proposed Rule does not precisely align with the language of Section 33-51-9(l) of the Act and Section 114-99-5.15 of the Proposed Rule. This could lead to confusion and, more importantly, inaccurate reporting—because the proposed regulations currently say that rebates "passed on to enrollees" should be reported instead of the amount of rebates used to reduce cost sharing at the point of sale (and importantly, not via premium reductions). We urge the Commissioner to correct this irregularity by revising Section 114-00-6.2.1.c as follows, to conform to Section 33-51-9(l) of the Act and Section 114-99-5.15 of the Proposed Rule:

> "The aggregate amount of rebates ~~passed on to the enrollees of each covered entity or health plan~~ used at the point of sale to ~~that~~ reduced ~~the enrollees applicable deductible,~~

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https://highergroupdownload.s3.amazonaws.com/MBGH/4f7f512a-e946-4060-9575-b27e65545cb8/UploadedImages/Specialty%20Pharmacy/DM3_MBGH_Line_in_the_Sand_RV12_9617.pdf

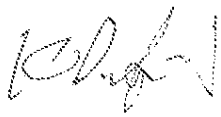
~~copayment, coinsurance, or other~~ a covered individual's defined cost sharing ~~amount~~ in accordance with subsection 114-99-5.15 of this rule."

Finally, for the reasons stated above, PhRMA urges the Commissioner to ensure that commercially sensitive information such as drug price information be kept confidential to the extent practicable, because confidentiality preserves incentives for market-based competition. PhRMA therefore strongly supports the Commissioner's proposal under Section 114-99-6.5 of the Proposed Rule to make information submitted by a PBM in its annual report proprietary and confidential, privileged, "not open to public inspection, not subject to subpoena, not subject to discovery or admission in evidence in any criminal, private civil, or administrative action, and not subject to production pursuant to court order."

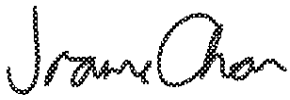
* * *

Thank you again for the opportunity to provide comments and feedback on the Proposed Rule. PhRMA stands ready to be a constructive partner in this dialogue related to providing affordable access to medicines and improved health care for patients. If there is additional information or technical assistance that we can provide as these regulations are further developed, please contact Shauna Gardner at sgardner@phrma.org or (847) 651-5096.

Sincerely,



Kipp Snider
Vice President, State Advocacy



Joanne Chan
Assistant General Counsel / Head of State Legal Affairs, Law

Transmitted by email: victor.a.mullins@wv.gov

July 1, 2021

Mr. Victor Mullins, Associate Council
West Virginia Insurance Commission
900 Pennsylvania Avenue
Charleston, WV 25302

RE: Legislative Rule Related to Pharmacy Auditing Entities & Pharmacy Benefit Managers

Dear Mr. Mullins:

On behalf of the groups below, we want to commend the Commissioner for moving quickly to implement HB 2263, *"Pharmacy Auditing Entities & Pharmacy Benefit Mangers,"* which will help to ensure West Virginians benefit as soon as possible from the important new consumer protections under this law. Specifically, the undersigned are uniquely interested in, and highly supportive of, provisions within the rule that require Pharmacy Benefit Managers (PBMs) to share pharmaceutical manufacturer rebates with West Virginia patients at the pharmacy counter.

It was recently announced that pharmaceutical companies provided $187 billion in rebates to insurance companies and PBMs in 2020. On average, one-third of gross spending for medicines is rebated back to plans, PBMs and other entities in the pharmaceutical supply chain.[1] Yet too often the benefits of these manufacturer rebates are not carried forward to actual patients.

A recent Milliman study showed that if rebates could be shared with the patient, it would result in savings of $145-$800/per person per year and only increase the plan premium for the patient by just 1%. This addresses the misconception that if rebates are shared with the patient, it would significantly increase their plan premium.

In 2018, UnitedHealth and its PBM, OptumRx, implemented a similar rebate plan to the one passed in HB 2263. It was so successful that the companies expanded the program to include nine (9) million customers. According to OptumRx, sharing rebates with patients has lowered patient costs by an average of $130 per eligible prescription among employers currently participating in their program, helping to improve patient medication adherence.

Imagine the enormous savings this bill will provide for many West Virginia patients.

In comments to *Politico*, OptumRx also said: "The shift to point-of-sale rebates has led to only very "modest increases" in premiums in the low single digits, according to Daniel Schumacher, UnitedHealthcare president and CEO, while having a "very material impact to consumers," especially those with chronic diseases.

[1] Nephron Research. Presentation at the Operationalizing a World Without Rebates Forum; March 21, 2019; Washington, DC.

West Virginia, as the first state in the country to reduce prescription drug costs for state residents with commercial insurance in this manner, is a national leader. Lower drug costs will lead to better medication adherence, less sick days, and a more engaged West Virginia workforce and general population.

We want to thank you again for the opportunity to share our support for HB 2263 and urge you to maintain the intent and purpose of the legislation in the Final Legislative Rule specifically as it relates to PBMs sharing the rebates they receive from drug manufacturers directly with West Virginia patients and consumers at the pharmacy counter.

Sincerely,

Charleston Parkinson's Support Group
222 Capitol Street, Suite 500
Charleston, WV 25301
Contact: George Manahan

Bioscience Association of West Virginia
P.O. Box 20065
Charleston, WV 25362
Contact: Bryan Brown

Mountain Mission
1620 Seventh Avenue
Charleston, WV 25387
Contact: John Roberts

West Virginia State Rheumatology Society
505 Summers Street
Charleston, WV 25301
Contact: Doshia Petry

WV Podiatric Medical Association
200 Hampton Center, Suite B
Morgantown, WV 26505
Contact: Diane Slaughter

West Virginia Health Right
1520 Washington Street, East
Charleston, WV 25311
Contact: Angie Settle

WV Orthopaedic Society
P.O. Box 13604
Charleston, WV 25360
Contact: Diane Slaughter

West Virginia Association of Orthopaedic Executives
P.O. Box 13604
Charleston, WV 25339
Contact: Diane Slaughter

WV Academy of Otolaryngology
P.O. Box 13604
Charleston, WV 25360
Contact: Diane Slaughter

PCMA

July 1, 2021

Victor Mullins
Associate Counsel
West Virginia Offices of the Insurance Commissioner
900 Pennsylvania Ave.
Charleston, WV 25302

Delivered via email

RE: PCMA Comments on 114CSR99 – Pharmacy Auditing Entities and Pharmacy Benefit Managers

Dear Mr. Mullins:

On behalf of the Pharmaceutical Care Management Association (PCMA) we respectfully submit the following comments for consideration. PCMA is the national trade association for PBMs, which administer prescription drug plans for more than 266 million Americans with health coverage provided by large and small employers, health insurers, labor unions, and federal and state-sponsored health programs. PBMs exist to make drug coverage more affordable for plan sponsors.

During the legislative process we shared many of the concerns outlined in our comments and we wanted to ensure that we made them clear to your office during the rule making process. Below I have outlined four key themes that we want to highlight with our comments and our detail comments are included in the attached proposed rule.

1. As a preliminary matter, except for the freedom of consumer choice provision, the application of this law beyond fully insured plans cannot be fixed by a rule promulgated by the Insurance Commissioner. If the legislature intended the law, or discrete parts of the law, to apply to self-funded plans (aside from the freedom of consumer choice provision), the legislature would have amended the controlling definitions of "covered entity", "health benefit plan", and "health insurance policy" in W. Va. Code § 33-51-3. The legislature failed to do this. Removing express ERISA exemptions from certain provisions does not correct this issue. We do applaud the Insurance Commissioner for acknowledging that certain provisions do not apply to health plans that are subject to ERISA. For example, our position is that the freedom of consumer choice provisions are preempted by ERISA for self-funded ERISA plans. Due to how "health benefit plan" and "health plan" are defined in HB 2263, many provisions of the law do not apply to self-funded plans. Neither term as defined in HB 2263 includes self-funded plans. Outlined below and in our attached comments we have highlighted areas that are still preempted by ERISA.
    a. 5.9 – Based on the definition of PBM and the underlying definitions of terms used in that definition, this provision does not apply to self-funded plans.
    b. 5.14 – 5.15.6 – Does not included self-funded plans bases on the definition of health plan/health benefit plan/covered individual/covered entity.
    c. 6.1.1 – 6.1.4 – Does not apply to self-funded plans.
    d. 6.2.1 – 6.2.3 – Does not apply to self-funded plans.
    e. 6.3.2.e – Does not apply to self-funded government plans.

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

PCMA

2. The definition section includes inconsistencies from the definitions provided in HB 2263 and we request that any inconsistencies be rectified. There are a few instances where the terms defined in the rule are not consistent with how they are defined in HB 2263, the rule includes terms that are not defined in HB 2263, and some definitions are circular and unclear, for example:
    a. The proposed rule's use of "third-party" in 5.15.1 – 5.15.6 exceeds the statutory scope. This term is not use for this section in the underlying law.
    b. The term "other adjustment" is not defined in HB 2263 but is found in 5.7.
3. There are several areas in the proposed rule that are outside the statutory authority granted by HB 2263 and need to be removed from the rule, for example:
    a. The use of "other adjustment" in section 5.7,
    b. The removal of 340B eligibility language in section 5.8, and
    c. Section 5.15.5 is not in HB 2263.
4. Lastly, we have major concerns with the point-of-sale (POS) rebate language and the reimbursement mandate in HB 2263 and the proposed rule. We understand this is out of the agency's control but believe this is important to note.
    a. Rebates are used by the plan sponsor to either reduce monthly premiums for all beneficiaries of the plan or pass them through to the beneficiaries. Removing this option will be costly to the plan sponsor and the beneficiaries. Additionally, rebates are not calculated in real time and are adjusted based on actual utilization. It will be nearly impossible to accurately calculate all rebates at POS.
    b. Reimbursing at NADAC or WAC plus a professional dispensing fee of $10.49 will be costly to the citizens and businesses in West Virginia. The reimbursement portion of HB 2263 is estimated to cost employers and citizens $111 million annually.

We appreciate your time and consideration and hope to be a resource to the department. The attached document contains more detailed comments that includes a few changes for consideration. If you should have any questions, please feel free to contact me at 202-756-5736.

Sincerely,

Michael Power
Senior Director, State Affairs
Pharmaceutical Care Management Association

WEST VIRGINIA SECRETARY OF STATE
MAC WARNER
ADMINISTRATIVE LAW DIVISION

eFILED
6/1/2021 2:47:11 PM
Office of West Virginia
Secretary Of State

NOTICE OF PUBLIC COMMENT PERIOD

AGENCY: Insurance Commission TITLE-SERIES: 114-99

RULE TYPE: Legislative Amendment to Existing Rule: Yes Repeal of existing rule: No

RULE NAME: PHARMACY AUDITING ENTITIES AND PHARMACY BENEFIT MANAGERS

CITE STATUTORY AUTHORITY: W. Va. Code §§33-51-8, 33-51-10 and 33-2-10.

COMMENTS LIMITED TO:

Written

DATE OF PUBLIC HEARING:

LOCATION OF PUBLIC HEARING:

DATE WRITTEN COMMENT PERIOD ENDS: 07/01/2021 5:00 PM

COMMENTS MAY BE MAILED OR EMAILED TO:

NAME: Victor Mullins

ADDRESS: 900 Pennsylvania Ave

Charleston, WV 25302

EMAIL: victor.a.mullins@wv.gov

PLEASE INDICATE IF THIS FILING INCLUDES:

RELEVANT FEDERAL STATUTES OR REGULATIONS: No

(IF YES, PLEASE UPLOAD IN THE SUPPORTING DOCUMENTS FIELD)

INCORPORATED BY REFERENCE: No

(IF YES, PLEASE UPLOAD IN THE SUPPORTING DOCUMENTS FIELD)

PROVIDE A BRIEF SUMMARY OF THE CONTENT OF THE RULE:

This rule generally provides a process for licensing and regulating pharmacy auditing entities and pharmacy benefit managers. It provides for defined terms that are used throughout the rule, provides for the registration of auditing entities and licensing of pharmacy benefit managers, sets forth responsibilities and prohibited acts, sets forth network adequacy requirements and reporting requirements of pharmacy benefit managers to the Insurance Commissioner, provides for penalties, as well as a formal process for an entity to seek restitution and reimbursement, provides for examinations of pharmacy benefit managers by the Insurance Commissioner, and sets for provisions regarding consumer choice for pharmacy benefits.

SUMMARIZE IN A CLEAR AND CONCISE MANNER CONTENTS OF CHANGES IN THE RULE AND A STATEMENT OF CIRCUMSTANCES REQUIRING THE RULE:

The Legislature passed House Bill 2263 (2021), which updated various regulatory requirements in regard to pharmacy benefit managers. This rule requires amendment to reflect the changes made in House Bill 2263, as well as to clarify concerns and questions that have arisen up since this rule was promulgated in 2020 and address issues that have arisen through the Insurance Commissioner's consumer complaint process. Specifically, the rule expands upon the applicability section in regard to Medicare plans, ERISA plans, and workers' compensation plans, adds additional defined terms from House Bill 2263, finalizes the effective date of licensure, which occurred since this rule was promulgated, provides guidance on leased networks, provides additional filing requirements for methodologies, as required by House Bill 2263, provides guidance on "other adjustments" being assessed against 340B entities, sets forth pharmacy reimbursement requirements, as required by House Bill 2263, sets forth additional prohibited practices, as required by House Bill 2263, provides for point-of-sale rebates, as required by House Bill 2263, sets forth additional reporting requirements, as required by House Bill 2263, sets forth a formal process for restitution and reimbursements, and provides for consumer choice for pharmacy benefits and services, as required by House Bill 2263. The amendments also makes various stylistic and technical changes, and updates the rule's numbering to conform with the Secretary of State's requirements regarding the same.

SUMMARIZE IN A CLEAR AND CONCISE MANNER THE OVERALL ECONOMIC IMPACT OF THE PROPOSED RULE:

A. ECONOMIC IMPACT ON REVENUES OF STATE GOVERNMENT:

None anticipated since this rule was last amended in 2020.

B. ECONOMIC IMPACT ON SPECIAL REVENUE ACCOUNTS:

None anticipated since this rule was last amended in 2020.

C. ECONOMIC IMPACT OF THE RULE ON THE STATE OR ITS RESIDENTS:

Unknown. Various stakeholder groups have opined that that provisions of House Bill 2263 (2021), which are reflected in this rule, will lower the out-of-pocket costs of prescription medication to consumers in this state, especially due to the point-of-sale rebate requirements. However, pharmacy benefit managers have opined that certain provisions of House Bill 2263, which are reflected in the rule amendments, will increase the costs of prescription drug coverage, generally.

D. FISCAL NOTE DETAIL:

Effect of Proposal	Fiscal Year		
	2021 Increase/Decrease (use "-")	2022 Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost			
Personal Services			
Current Expenses			
Repairs and Alterations			
Assets			
Other			
2. Estimated Total Revenues			

E. EXPLANATION OF ABOVE ESTIMATES (INCLUDING LONG-RANGE EFFECT):

N/A.

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENT IS TRUE AND CORRECT.

Yes
Allen R Prunty -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.

114CSR99

TITLE 114
LEGISLATIVE RULE
INSURANCE COMMISSIONER

SERIES 99
PHARMACY AUDITING ENTITIES AND
PHARMACY BENEFIT MANAGERS

§114-99-1. General.

1.1. Scope. -- The purpose of this rule is to ~~implement the Pharmacy Audit Integrity Act~~ provide for the regulation of pharmacy auditing entities and pharmacy benefit managers and to provide licensing, reporting and activity standards for pharmacy benefit managers ~~which~~ that provide claims processing services or other prescription drug or device services, or both, for health benefit plans. The rule also provides registration requirements for pharmacy auditing entities.

1.2. Authority. -- W. Va. Code §§33-51-8, 33-51-10 and 33-2-10.

1.3. Filing Date. -- ~~February 27, 2020.~~

1.4. Effective Date. -- ~~April 1, 2020.~~

1.5. Sunset provision. -- This rule shall terminate and have no further force or effect upon ~~April 1, 2025~~ the expiration of five years from its effective date.

1.6. Applicability. -- This rule applies to pharmacy benefit managers (PBMs) that perform pharmacy benefit management for covered entities, which may include health benefit plans, and persons or companies that perform pharmacy audits, as provided ~~by the Pharmacy Audit Integrity Act~~ in Article 51, Chapter 33, of the West Virginia Code. Certain sections of this rule may not apply to Medicare Part D plans or Medicare Advantage plans that offer prescription drug coverage as 42 U.S.C. §1395w-26(b)(3) and 42 U.S.C. §1395w-112(a) provide that standards established under 42 U.S.C. §1395w-101 *et seq.* and 42 U.S.C. §1395w-21 *et seq.* shall supersede any state law or regulation, other than state licensing laws or state laws relating to plan solvency. PBMs that perform pharmacy benefits management for Medicare Part D plans and Medicare Advantage plans in this state must be appropriately licensed. Additionally, certain sections of this rule may not be applicable to health benefit plans or health plans that are subject to the Employee Retirement Income Security Act of 1974 (ERISA) if the subject provision of the rule regulates a key facet or essential part of plan administration or design and is preempted by ERISA. However, certain sections of this rule that only affect costs, pricing or alter incentives for ERISA plans are not preempted by ERISA and may be applicable. PBMs that perform pharmacy benefits management for ERISA plans in this state must be appropriately licensed. A PBM that performs pharmacy benefit management for workers' compensation insurers or self-insured employers must be licensed to operate in this state if it manages prescription drug coverage for "covered entities," as that term is defined in W. Va. Code §33-51-3 and this rule.

§114-99-2. Definitions.

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 or pharmacies, contracted with the participating entity to dispense drugs purchased through such program.

2.2. "Affiliate" means a pharmacy, pharmacist or pharmacy technician which, either directly or indirectly through one or more intermediaries:

2.2.1. Has an investment or ownership interest in a PBM;

Summary of Comments on 106-17436-54221-2021-06-01-14-47-59-442

Page: 4

Number: 1 Author: mpower Subject: Sticky Note Date: 7/1/2021 12:42:50 PM
The law has conflicting information with respect to the effective date. Providing clarification through the rule would be helpful.

Suggestion:

January 1, 2022. The revisions to existing law enacted through WV HB 2263 are effective for policies, contracts, plans or agreements that are delivered, executed, amended, adjusted, or renewed on or after January 1, 2022.

Number: 2 Author: mpower Subject: Sticky Note Date: 7/1/2021 12:58:42 PM
Many provisions of the law do not apply to self-funded plans based on the definitions of health benefit plan/health plan in the law because the definition of these terms do not include self-funded plans; thus ERISA preemption is not an issue with respect to those provisions.

Number: 3 Author: mpower Subject: Sticky Note Date: 7/1/2021 12:58:21 PM
This sentence, " However... may be applicable." seems in conflict with the sentence prior.

Incentives for ERISA plans are part of plan design and are preempted by ERISA. Having this language in a rule does not change that fact (until litigated). It would be cleaner to have this language removed to avoid confusion

Number: 4 Author: mpower Subject: Sticky Note Date: 7/1/2021 1:01:11 PM
We need to be certain that the terms as defined in the regulation are consistent with how the terms are defined in the statute.

2.2.2. Shares common ownership with a PBM; or

2.2.3. Has an investor or ownership interest holder which is a PBM.

~~2.2.~~ 2.3. "Auditing entity" means a person or company that performs a pharmacy audit, including a covered entity, pharmacy benefits manager, managed care organization, or third-party administrator.

~~2.3.~~ 2.4. "Covered entity" means a contract holder or policyholder providing pharmacy benefits to a covered individual under a health insurance policy pursuant to a contract administered by a pharmacy benefits manager and may include a health benefit plan.

~~2.4.~~ 2.5. "Covered individual" means a member, participant, enrollee, or beneficiary of a covered entity who is provided health coverage by a covered entity, including a dependent or other person provided health coverage through the policy or contract of a covered individual.

2.6. "Defined cost sharing" means a deductible payment or coinsurance amount imposed on an enrollee for a covered prescription drug under the enrollee's health plan.

2.7. "Health benefit plan" or "health plan" means a policy, contract, certificate or agreement entered into, offered or issued by a health carrier to provide, deliver, arrange for, pay for or reimburse any of the costs of health care services.

2.8. "Health carrier" means any insurer who issues a "health insurance policy" as that term is defined in W.Va. Code §33-51-3 and section 2.9 of this rule.

~~2.5.~~ 2.9. "Health insurance policy" means a policy, subscriber contract, certificate, or plan that provides prescription drug coverage. The term includes both comprehensive and limited benefit health insurance policies.

~~2.6.~~ 2.10. "Insurance Commissioner" or "Commissioner" means the Insurance Commissioner of West Virginia.

2.11. "Maximum allowable cost" means the per unit amount that a PBM reimburses a pharmacist for a prescription drug, excluding dispensing fees and copayments, coinsurance or other cost sharing charges, if any.

2.12. "National average drug acquisition cost" means the monthly survey of retail pharmacies conducted by the federal Centers for Medicare and Medicaid Services (CMS) to determine average acquisition cost for Medicaid covered outpatient drugs.

~~2.7.~~ 2.13. "Network" means a pharmacy or group of pharmacies that agree to provide prescription services to covered individuals on behalf of a covered entity or group of covered entities in exchange for payment for its services by a pharmacy benefits manager or pharmacy services administration organization. The term includes a pharmacy that generally dispenses outpatient prescriptions to covered individuals or dispenses particular types of prescriptions, provides pharmacy services to particular types of covered individuals or dispenses prescriptions in particular health care settings, including networks of specialty, institutional or long-term care facilities.

~~2.8.~~ 2.14. "Nonproprietary drug" means a drug containing any quantity of any controlled substance or any drug which is required by any applicable federal or state law to be dispensed only by prescription.

2.15. "Pass-through pricing" means the model of prescription drug pricing wherein a PBM charges the health benefit plan or covered entity the same price for a prescription drug that it pays the pharmacy for the same prescription drug.

~~2.9.~~ 2.16. "Pharmacist" means an individual licensed by the West Virginia Board of Pharmacy to engage in the practice of pharmacy.

~~2.10.~~ 2.17. "Pharmacy" means any place within this state where drugs are dispensed and pharmacist care is provided.

~~2.11.~~ 2.18. "Pharmacy audit" means an audit, conducted on-site by or on behalf of an auditing entity of any records of a pharmacy for prescription or nonproprietary drugs dispensed by a pharmacy to a covered individual.

~~2.12. "Pharmacy Audit Integrity Act" means those provisions set forth in W. Va. Code §33-51-1 et seq.~~

~~2.13.~~ 2.19. "Pharmacy benefits management" means the performance of any of the following:

~~2.13.a.~~ 2.19.1. The procurement of prescription drugs at a negotiated contracted rate for dispensation within the State of West Virginia to covered individuals;

~~2.13.b.~~ 2.19.2. The administration or management of prescription drug benefits provided by a covered entity for the benefit of covered individuals; or

~~2.13.c.~~ 2.19.3. The administration of pharmacy benefits, including:

~~2.13.c.1.~~ 2.19.3.a. Operating a mail-service pharmacy;

~~2.13.c.2.~~ 2.19.3.b. Claims processing;

~~2.13.c.3.~~ 2.19.3.c. Managing a retail pharmacy network;

~~2.13.c.4.~~ 2.19.3.d. Paying claims to a pharmacy for prescription drugs dispensed to covered individuals via retail or mail-order pharmacy;

~~2.13.c.5.~~ 2.19.3.e. Developing and managing a clinical formulary including utilization management and quality assurance programs;

~~2.13.c.6.~~ 2.19.3.f. Rebate contracting administration; and

~~2.13.c.7.~~ 2.19.3.g. Managing a patient compliance, therapeutic intervention, and generic substitution program.

~~2.14.~~ 2.20. "Pharmacy benefits manager" or "PBM" means a person, business, or other entity that performs pharmacy benefits management for covered entities.

~~2.15.~~ 2.21. "Pharmacy record" means any record stored electronically or as a hard copy by a pharmacy that relates to the provision of prescription or nonproprietary drugs or pharmacy services or other component of pharmacist care that is included in the practice of pharmacy.

~~2.16.~~ 2.22. "Pharmacy services administration organization" means any entity that contracts with a pharmacy to assist with third-party payer interactions and that may provide a variety of other administrative

services, including contracting with pharmacy benefits managers on behalf of pharmacies and managing pharmacies' claims payments from third-party payers.

2.23. "Point-of-sale fee" means all or a portion of a drug reimbursement to a pharmacy or other dispenser withheld at the time of adjudication of a claim for any reason.

2.24. "Rebate" means any and all payments that accrue to a PBM or its health plan client, directly or indirectly, from a pharmaceutical manufacturer, including, but not limited to, discounts, administration fees, credits, incentives, or penalties associated directly or indirectly in any way with claims administered on behalf of a health plan client. The term "rebate" does not include any discount or payment that may be provided to or made to any 340B entity through such program.

2.25. "Retroactive fee" means all or a portion of a drug reimbursement to a pharmacy or other dispenser recouped or reduced following adjudication of a claim for any reason, except as otherwise permissible as described in Article 51, Chapter 33 of the West Virginia Code or this rule.

~~2.17.~~ 2.26. "Spread pricing" means the model of prescription drug pricing in which the pharmacy benefits manager charges a covered entity or health benefit plan a contracted price for prescription drugs although the contracted price may differ with the amount the pharmacy benefits manager pays the pharmacist or pharmacy.

~~2.18.~~ 2.27. "Third party" means any insurer, health benefit plan for employees which provides a pharmacy benefits plan, a participating public agency which provides a system of health insurance for public employees, their dependents and retirees, or any other insurer or organization that provides health coverage, benefits, or coverage of prescription drugs as part of workers' compensation insurance in accordance with state or federal law. The term does not include an insurer that provides coverage under a policy of casualty or property insurance.

§114-99-3. Registration of Auditing Entities.

3.1. Prior to conducting business in this state, an auditing entity shall make an application on a form and in a manner prescribed by the Commissioner.

3.2. An initial registration application shall include the following:

~~3.2.a.~~ 3.2.1. The identity, address and telephone number of the applicant;

~~3.2.b.~~ 3.2.2. The name, business address and telephone number of the contact person for the applicant;

~~3.2.c.~~ 3.2.3. When applicable, the federal employer identification number for the applicant; and

~~3.2.d.~~ 3.2.4. A nonrefundable filing fee sufficient to fund the Commissioner's regulatory duties in relation to ~~the Pharmacy Audit Integrity Act~~ Article 51, Chapter 33 of the West Virginia Code and this rule, not to exceed $1,000, which shall be set annually by the Commissioner via Bulletin or Notice on or before July 1.

3.3. A licensed insurer or other entity licensed by the Commissioner who conducts pharmacy audits shall comply with the standards and procedures of ~~the Pharmacy Audit Integrity Act~~ Article 51, Chapter 33 of the West Virginia Code and this rule, but is not required to separately register as an auditing entity.

3.4. The term of registration shall be two years. However, the Commissioner may, in his or her discretion, fix the date of expiration regarding the initial registration of an auditing entity 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 registration of an auditing entity for a period less than or more than two years.

3.5. An auditing entity's registration shall be renewed every two years on October 1 upon the submission of a renewal application and the payment of a renewal filing fee sufficient to fund the Commissioner's regulatory duties in relation to ~~the Pharmacy Audit Integrity Act~~ Article 51, Chapter 33 of the West Virginia Code and this rule, not to exceed $1,000, which shall be set annually by the Commissioner via Bulletin or Notice on or before July 1. The renewal application fee will be returned to the auditing entity if the renewal of the registration is not granted.

3.6. An auditing entity's renewal application shall be on the same form as the initial application and shall include the same information as required under ~~subsection~~ section 3.2 of this ~~section~~ rule.

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

4.1. ~~On or after the effective date of this rule, a~~ A PBM shall apply for a license on a form and in a manner prescribed by the Commissioner.

~~4.1.a.~~ 4.1.1. A PBM ~~registered pursuant to W. Va. Code §33-5-7 at the time of the effective date of this rule and~~ that desires to ~~continue to~~ lawfully do business ~~as a PBM~~ in this state shall submit an application for licensure ~~within six months of said effective date~~ effective October 1, 2020.

~~4.1.b.~~ 4.1.2. 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.

4.2. An initial licensure application shall be verified by an officer or authorized representative of the applicant and shall include the following:

~~4.2.a.~~ 4.2.1. The identity, address, and telephone number of the applicant;

~~4.2.b.~~ 4.2.2. The name, business address, and telephone number of the contact person for the applicant;

~~4.2.c.~~ 4.2.3. When applicable, the federal employer identification number for the applicant;

~~4.2.d.~~ 4.2.4. A nonrefundable filing fee sufficient to fund the Commissioner's regulatory duties in relation to ~~the Pharmacy Audit Integrity Act~~ Article 51, Chapter 33 of the West Virginia Code and this rule, not to exceed $10,000, which shall be set annually by the Commissioner via Bulletin or Notice on or before July 1;

~~4.2.e.~~ 4.2.5. Financial responsibility in an amount of $1 million evidenced by one of the following:

~~4.2.e.1.~~ 4.2.5.a. A cash or surety bond issued by a corporate surety authorized to issue surety bonds in the State of West Virginia;

~~4.2.e.2.~~ 4.2.5.b. An irrevocable letter of credit;

~~4.2.e.3.~~ 4.2.5.c. Securities with a minimum value of $1 million;

~~4.2.e.4.~~ 4.2.5.d. A written parental guarantee; or

~~4.2.e.5.~~ 4.2.5.e. One million dollars in working capital and/or surplus as reflected in audited financial statements submitted to the Commissioner;

~~4.2.f.~~ 4.2.6. Proof of registration with the West Virginia Secretary of State;

~~4.2.g.~~ 4.2.7. A list of the names, addresses and official positions of the persons who are to be responsible for the conduct of the affairs of the PBM applicant, including all members of the board of the directors, board of trustees, executive committee, or other governing board or committee, the principal officers in the case of a corporation, and the partners or members in the case of a partnership or association;

~~4.2.h.~~ 4.2.8. A copy of the basic organizational document of the PBM, such as the articles of incorporation, articles of association, partnership agreement, trust agreement or other applicable documents, and all amendments thereto;

~~4.2.i.~~ 4.2.9. A copy of the bylaws, rules and regulations or similar document, if any, regulating the conduct of the internal affairs of the applicant;

~~4.2.j.~~ 4.2.10. 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, for the purpose of ensuring that such contracts comply with W. Va. Code §33-51-9. If a PBM leases or otherwise uses, or anticipates using, a network from another PBM or covered entity, the PBM seeking licensure must submit a copy of the contract that it has, or anticipates having, with the other licensed PBM or covered entity;

~~4.2.k.~~ 4.2.11. A copy of the most recent year-end audited financial statement of the PBM, which may be a consolidated audited financial statement if applicable;

~~4.2.l.~~ 4.2.12. A description of the projected population or numbers of covered individuals to be administered by the PBM in this state on an annual basis for all covered entities with whom the PBM has contracted, and, if applicable, the population or numbers of covered individuals administered by the PBM in the previous year for each covered entity;

~~4.2.m.~~ 4.2.13. A network report describing the PBM's network service areas by county in this state for a covered entity and the PBM's pharmacy provider directory list for a covered entity;

~~4.2.n.~~ 4.2.14. 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;

~~4.2.o.~~ 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 for any reason by any state or federal entity;

~~4.2.p.~~ 4.2.16. A description of whether the applicant had a business relationship with an insurance company terminated for any legal finding or judgment of fraudulent or illegal activities in connection with the administration of a pharmacy benefits plan; ~~and~~

~~.~~ 2.17. Any and all methodologies utilized by a PBM in connection with reimbursement shall be filed at initial licensure and all reimbursement methodologies must comply with the requirements set forth

Number: 1 Author: mpower Subject: Sticky Note Date: 7/1/2021 1:02:50 PM
The statute clearly sets reimbursement at NADAC plus a $10.49 professional dispensing fee or WAC when NADAC is not available. The law essentially mandates the methodology. We are concerned that this could be read to require reporting of additional methodologies not mandated by law.

in Article 51, Chapter 33 of the West Virginia Code. If a PBM was initially licensed prior to the time methodologies were required to be filed, a PBM shall file any and all methodologies utilized by a PBM in connection with reimbursement at its first renewal after January 1, 2022. A PBM shall refile any and all methodologies utilized in connection with reimbursement at any time thereafter that a methodology is changed by the PBM for use in determining maximum allowable cost appeals. The methodologies are confidential and exempt from disclosure under the *West Virginia Freedom of Information Act*, W. Va. Code §29B-1-4(a)(1); and

~~4.2.q.~~ 4.2.18. Any other information which is deemed necessary by the Commissioner in evaluating the application to comply with ~~the Pharmacy Audit Integrity Act~~ Article 51, Chapter 33 of the West Virginia Code or requirements of this rule or deemed necessary or appropriate by the Commissioner to establish the qualifications of the PBM to hold a license.

4.3. Review and Approval Process. -- For initial licensure applications, upon receipt of a complete application for items required under ~~subsection~~ section 4.2 of this ~~section~~ rule, the Commissioner shall review the application and within 90 days:

~~4.3.a.~~ 4.3.1. Approve the application and issue the applicant a PBM license;

~~4.3.b.~~ 4.3.2. Notify the applicant in writing that the application is incomplete and that additional information is needed to complete the review of the application. If the missing or necessary information is not received within 30 days from the date of the notification, the Commissioner shall deny the application unless good cause is shown; or

~~4.3.c.~~ 4.3.3. Deny the application. -- If the Commissioner determines that the PBM applicant does not meet the requirements for licensure, the Commissioner shall:

~~4.3.c.1.~~ 4.3.3.a. Provide written notice to the PBM applicant that the application has been denied stating or explaining the basis of the denial; and

~~4.3.c.2.~~ 4.3.3.b. Advise the PBM applicant that a request for a hearing may be filed with the Commissioner in accordance with W. Va. Code §33-2-13.

4.4. Renewal. -- A PBM license shall be renewed every two years on October 1. A renewal application shall be deemed approved by the Commissioner after 45 days from the date of the receipt of the renewal application by the Commissioner, unless approved or denied by the Commissioner during that time period.

~~4.4.a.~~ 4.4.1. A renewal application shall be accompanied by the following:

~~4.4.a.1.~~ 4.4.1.a. A renewal filing fee sufficient to fund the Commissioner's regulatory duties in relation to ~~the Pharmacy Audit Integrity Act~~ Article 51, Chapter 33 of the West Virginia Code and this rule, not to exceed $10,000, which shall be set annually by the Commissioner via Bulletin or Notice on or before July 1;

~~4.4.a.2.~~ 4.4.1.b. A copy of the most recent year-end audited financial statement of the PBM, which may be a consolidated financial statement, if applicable;

~~4.4.a.3.~~ 4.4.1.c. Evidence of financial responsibility in the amount of $1 million as stated in ~~subdivision 4.2.e~~ subsection 4.2.5 of this ~~section~~ rule;

~~4.4.a.4.~~ 4.4.1.d. Any changes made to the items in ~~subsection~~ section 4.2 of this ~~section~~ rule from the date of its most recent licensure; and

~~4.4.a.5.~~ 4.4.1.c. Any other 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.

~~4.4.b.~~ 4.4.2. The Commissioner may require additional information or submissions from an applicant and may obtain any documents or information reasonably necessary to verify the information in the renewal application.

~~4.4.c.~~ 4.4.3. For disapprovals or denials of a renewal licensure by the Commissioner, the Commissioner shall:

~~4.4.c.1.~~ 4.4.3.a. Provide written notice to the renewal applicant that the licensure renewal was denied stating or explaining the basis of the denial; and

~~4.4.c.2.~~ 4.4.3.b. Advise the renewal applicant that a request for a hearing may be filed with the Commissioner in accordance with W. Va. Code §33-2-13.

4.5. Denial of Initial or Renewal Application.

~~4.5.a.~~ 4.5.1. The Commissioner shall deny an initial application for licensure or deny license renewal of a PBM for the following reasons:

~~4.5.a.1.~~ 4.5.1.a. The 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~~ subsection 4.2.5 of this ~~section~~ rule;

~~4.5.a.2.~~ 4.5.1.b. The PBM has been determined by the Commissioner to be in violation or noncompliance with the requirements of this rule or West Virginia law;

~~4.5.a.3.~~ 4.5.1.c. The PBM has failed to timely submit information under ~~subsection~~ section 4.2 of this ~~section~~ rule to complete a review of the initial application or has failed to submit a renewal application and information under ~~subsection~~ section 4.4 of this ~~section~~ rule; or

~~4.5.a.4.~~ 4.5.1.d. The PBM fails to provide the Commissioner with its network report as required by W. Va. Code §33-51-8(d)(2) and (3).

~~4.5.b.~~ 4.5.2. In lieu of a denial of an initial licensure or renewal application, the Commissioner may permit the PBM to submit to the Commissioner an acceptable corrective action plan to cure or correct deficiencies.

4.6. Evidence of financial responsibility as noted under ~~subdivision 4.2.e~~ subsection 4.2.5 of this ~~section~~ rule shall be maintained at all times by the PBM during its licensure with the Commissioner, and the Commissioner shall have the right to confirm or verify the PBM's qualifications to hold a license and its financial responsibility at any time. The Commissioner may, however, reduce the amount of the financial responsibility requirement in ~~subdivision 4.2.e~~ subsection 4.2.5 of this ~~section~~ rule if the amount required is unreasonable relative to the size of the PBM's business operations in this state and would cause a significant financial hardship.

4.7. 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 a "trade secret", is not open to public inspection, is not subject to subpoena, is not subject to discovery or admissible in evidence in any criminal, private civil or administrative action and is not subject to production pursuant to court order. The Commissioner is authorized to use the documents, materials or other information in the furtherance of any regulatory or legal action brought as part of the

Commissioner's official duties.

§114-99-5. ~~Prohibited~~ Responsibilities and Prohibited Acts.

5.1. A PBM shall not cause or knowingly permit the use of any advertisement, promotion, solicitation, representation, proposal or offer that is untrue, deceptive or misleading.

5.2. An auditing entity conducting a pharmacy audit or person acting on behalf of the auditing entity may not seek any fee, charge-back, recoupment or other adjustment for a dispensed product, or any portion of a dispensed product, unless one of the following has occurred:

~~5.2.a.~~ 5.2.1. Fraud or other intentional and willful misrepresentation as evidenced by a review of the claims data, statements, physical review or other investigative methods;

~~5.2.b.~~ 5.2.2. Dispensing in excess of the benefit design, as established by the plan sponsor;

~~5.2.c.~~ 5.2.3. Prescriptions not filled in accordance with the prescriber's order; or

~~5.2.d.~~ 5.2.4. Actual overpayment to the pharmacy.

5.3. Any fee, charge-back, recoupment, or other adjustment is limited to the actual financial harm associated with the dispensed product, or portion of the dispensed product, or the actual underpayment or overpayment as set forth in the criteria in ~~subsection~~ section 5.2 of this ~~section~~ rule.

5.4. To assist healthcare 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 a pharmacy, pharmacist or pharmacy technician shall not be penalized by a PBM for discussing information in W. Va. Code §33-51-9 or the regulation of PBMs thereunder, or for selling a lower cost alternative, if one is available, without using a health insurance policy.

5.5. To prevent overcharges to consumers or insureds purchasing prescription drugs, so called "claw-back" provisions in contracts between pharmacies and PBMs are prohibited and a PBM shall not collect from a pharmacy, a pharmacist or a pharmacy technician a cost share or co-pay charged to a covered individual that exceeds the total submitted charges by the pharmacy or pharmacist to the PBM.

5.6. A PBM shall not directly or indirectly charge or hold a pharmacy, a pharmacist or a pharmacy technician responsible for a fee related to the adjudication of a claim unless:

~~5.6.a.~~ 5.6.1. The total amount of the fee is identified, reported and specifically explained for each line item on the remittance advice of the adjudicated claim; or

~~5.6.b.~~ 5.6.2. The total amount of the fee is apparent at the point of sale and not adjusted between the point of sale and the issuance of the remittance advice.

5.7. A PBM or any other third party that reimburses a 340B entity for drugs that are subject to an agreement under 42 U.S.C. §256b shall not reimburse the 340B entity for pharmacy-dispensed drugs at a rate lower than that paid for the same drug to pharmacies similar in prescription volume that are not 340B entities, and shall not assess any fee, charge-back, or other adjustment upon the 340B entity on the basis that the 340B entity participates in the program set forth in 42 U.S.C. §256b. For purposes of this section, the term "other adjustment" includes placing any additional requirements, restrictions or unnecessary burdens upon the 340B entity that results in administrative costs or fees to the 340B entity that are not placed upon other pharmacies that do not participate in the 340B program, including affiliate pharmacies

Number: 1 Author: mpower Subject: Sticky Note Date: 7/1/2021 1:04:25 PM
"other adjustment"

This term was not defined in HB 2263 and is outside the statutory authority granted to the department.

of the PBM, and further includes but is not limited to requiring a claim for a drug to include a modifier or be reprocessed or resubmitted to indicate that the drug is a 340B drug.

~~5.7.a.~~ 5.8. With respect to a patient eligible to receive drugs subject to an agreement under 42 U.S.C. §256b, a PBM or any other third party that makes payment for such drugs, shall not discriminate against a 340B entity in a manner that prevents or interferes with the patient's choice to receive such drugs from the 340B entity. For purposes of this ~~subsection~~ section, "third party" does not include the state Medicaid program when Medicaid is providing reimbursement for covered outpatient drugs, as that term is defined in 42 U.S.C. §1396r-8(k), on a fee-for-service basis; however, "third party" does include a Medicaid-managed care organization as described in 42 U.S.C. §1396b(m). For purposes of this section, it shall be considered a discriminatory practice that prevents or interferes with a patient's choice to receive drugs at a 340B entity if a PBM places additional requirements, restrictions or unnecessary burdens upon a 340B entity that results in administrative costs or fees to the 340B entity that are not placed upon other pharmacies that do not participate in the 340B program, including affiliate pharmacies of the PBM, and further includes but is not limited to requiring a claim for a drug to include a modifier or be reprocessed or resubmitted to indicate that the drug is a 340B drug.

5.9. A PBM may not reimburse a pharmacy or pharmacist for a prescription drug or pharmacy service in an amount less than the national average drug acquisition cost for the prescription drug or pharmacy service at the time the drug is administered or dispensed plus a dispensing fee of $10.49. If the national average drug acquisition cost is not available at the time a drug is administered or dispensed, a PBM may not reimburse in an amount that is less than the wholesale acquisition cost of the drug as defined in 42 U.S.C. §1395w-3a(c)(6)(B) plus a dispensing fee of $10.49.

5.10. Payment Parity. -- A PBM may not reimburse a pharmacy or pharmacist for a prescription drug or pharmacy service in an amount less than the amount the PBM reimburses itself or one of its affiliates for the same prescription drug or pharmacy service.

5.11. A PBM shall utilize the national average drug acquisition cost as a point of reference for the ingredient drug product component of a pharmacy's reimbursement for drugs appearing on the national average drug acquisition cost list.

5.12. A PBM shall not discriminate in reimbursement, assess any fees or adjustments, or exclude a pharmacy from the PBM's network on the basis that the pharmacy dispenses drugs subject to an agreement under 42 U.S.C. §256b.

5.13. A PBM shall not engage in any practice that:

5.13.1. Bases reimbursement for a drug on patient outcomes, scores, or metrics. This prohibition does not apply to reimbursement for pharmacy care, including dispensing fees, from being based on patient outcomes, scores or metrics so long as the terms are disclosed and agreed to by the pharmacy in advance;

5.13.2. Unless otherwise permitted pursuant to W. Va. Code §33-51-9(c), imposes a point-of-sale fee or retroactive fee; or

5.13.3. Derives any revenue from a pharmacy or insured in connection with performing pharmacy benefits management services. This prohibition shall not prohibit a PBM from receiving deductibles or co-payments.

5.14. A PBM shall offer a health plan the option of pass-through pricing. However, pass-through pricing is required in regard to a PBM that performs pharmacy benefit management on behalf of a health benefit plan administered by or on behalf of the state or a political subdivision of the state.

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Number: 1 Author: mpower Subject: Sticky Note Date: 7/1/2021 1:06:00 PM
The statute contains 3408 eligibility language:

"Patient is eligible to receive..."

We believe the elimination of this language is outside the statutory authority granted to the department.

Number: 2 Author: mpower Subject: Sticky Note Date: 7/1/2021 1:07:08 PM
Based on the definition of PBM and the underlying definitions of terms used in that definition, we believe this provision does not apply to self-funded plans.

Number: 3 Author: mpower Subject: Sticky Note Date: 7/1/2021 1:07:43 PM
A PBM does not actually receive the deductible or co-payment.

Number: 4 Author: mpower Subject: Sticky Note Date: 7/1/2021 4:16:24 PM
We believe that 5.14 to 5.15.6 does not include self-funded plans in scope based on the definition of health plan/health benefit plan/ covered individual/covered entity.

Number: 5 Author: mpower Subject: Sticky Note Date: 7/1/2021 4:16:41 PM
Delete: "performs pharmacy benefit management on behalf of" and insert "contracts with a..."

5.15. A covered individual's defined cost sharing for each prescription drug shall be calculated at the point-of-sale based on a price that is reduced by an amount equal to at least 100% of all applicable rebates received, or to be received, in connection with the dispensing or administration of the prescription drug up to the amount of a covered individual's defined cost sharing.

5.15.1. All rebates should be calculated by the PBM or third-party based upon the actual rebate amount negotiated between the PBM or health plan and the manufacturer and provided, or to be provided, by the manufacturer to the PBM or health plan.

5.15.2. Any price reduction based upon a rebate received, or to be received, must be completely reflected in the price of the prescription drug at the time the pharmacy dispenses it to the patient.

5.15.3. Any rebate that is calculated by the PBM or third-party to be over and above, or in excess of, a covered individual's defined cost sharing may not be retained by the PBM but must be passed on to the health benefit plan or covered entity and must be used by the health benefit plan or covered entity to reduce the cost of premiums.

5.15.4. The Commissioner may request information deemed necessary by the Commissioner from the pharmacy, PBM, third-party, health benefit plan or covered entity to determine compliance with these point-of-sale rebating requirements as needed to investigate complaints and as set forth in the annual reporting requirements in section 6 of this rule.

5.15.5. Nothing precludes an insurer or third-party from decreasing a covered individual's defined cost sharing by an amount greater than that set forth in section 5.15 of this rule.

5.15.6. A PBM or third-party shall be responsible for calculating a covered individual's defined cost sharing for each prescription drug. No PBM or third-party shall charge or deduct from a pharmacist or pharmacy any fee, recoupment, charge back, or other monetary penalty, amount or adjustment due to the PBM or third-party's miscalculation of a rebate or defined cost sharing amount.

~~5.8.~~ 5.16. A PBM's contract with a participating pharmacist or pharmacy shall not prohibit, restrict or limit disclosure of information to the Commissioner, law enforcement, or state and federal governmental officials investigating or examining a complaint or conducting a review of a PBM's compliance with the requirements under this rule or ~~the Pharmacy Audit Integrity Act~~ Article 51, Chapter 33 of the West Virginia Code.

~~5.9.~~ 5.17. 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.

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

6.1. Network adequacy.

6.1.1. A PBM shall maintain an a reasonably adequate and accessible network for the provision of prescription drugs for a health benefit plan. The network shall provide for convenient patient access to pharmacies within a reasonable distance from a patient's residence. A network shall not be comprised only of mail-order benefits but must have a mix of mail-order benefits and physical stores in this state.

~~6.2.~~ 6.1.2. A PBM shall, upon 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. Failure to provide a report may result in the suspension or revocation of a PBM's license by the Commissioner.

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Number: 1 Author: mpower Subject: Sticky Note Date: 7/1/2021 4:17:25 PM

This section may be difficult to implement. POS Rebates are a moving target - "rebates received, or to be received" as found in 5.15 can be difficult to accurately predict when many rebate agreements are reconciled retroactively. Trying to estimate the exact rebate amount to pass on to the member during Q1 without knowing what the rebate amounts we will be receiving until later is very challenging.

We believe the POS rebate language in HB 2263 impedes a plan design tool that is preempted by ERISA. Rutledge v. PCMA did not grant authority for states to regulate here.

Number: 2 Author: mpower Subject: Sticky Note Date: 7/1/2021 1:22:34 PM

We believe use of the term "third-party" exceeds the statutory scope. This terms is not used for this section of the underlying law.

Number: 3 Author: mpower Subject: Sticky Note Date: 7/1/2021 1:24:17 PM

We have two concerns here: this is not in the underlying law and this regulation is for PBMs, not "an insurer." Therefore, we believe this is outside the scope.

The law also makes it clear that any excess goes to the plan.

Number: 4 Author: mpower Subject: Sticky Note Date: 7/1/2021 1:25:25 PM

We believe that 6.1.1 to 6.1.14 are not applicable to self-funded plans based on the definition of health benefit plan.

6.1.3. 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.

6.1.4. A PBM using a leased network from another PBM or covered entity must ensure that the leased network is reasonably adequate and accessible as provided in subsection 6.1.1 of this rule and the PBM using the leased network must be able to provide the reports described in subsections 6.1.2 and 6.1.3 of this rule upon request by the Commissioner.

~~6.2.~~ 6.2. Annual Reports.

6.2.1. ~~Upon request, a~~ A PBM shall report to the Commissioner on or before March 1 of each year, or more often as the Commissioner deems necessary, for each covered entity or health plan the following information:

~~6.2.a.~~ 6.2.1.a. The aggregate amount of rebates received by the PBM;

~~6.2.b.~~ 6.2.1.b. The aggregate amount of rebates distributed to the appropriate covered entity or health plan;

~~6.2.c.~~ 6.2.1.c. The aggregate amount of rebates passed on to the enrollees of each covered entity or health plan at the point-of-sale that reduced the enrollees applicable deductible, copayment, coinsurance, or other cost sharing amount;

~~6.2.d.~~ 6.2.1.d. The individual and aggregate amount paid by the covered entity or health plan to the PBM for pharmacist services itemized by pharmacy, by product, and by goods and services; and

~~6.2.e.~~ 6.2.1.e. The individual and aggregate amount a PBM paid for pharmacist services itemized by pharmacy, by product, and by goods and services.

6.2.2. A PBM shall annually report in the aggregate to the Commissioner and to a health plan or covered entity the difference between the amount the PBM reimbursed a pharmacy and the amount the PBM charged a health plan or covered entity. The annual report required by this subsection shall be due on or before March 1 of each year.

6.2.3. A health plan or covered entity shall annually report to the Commissioner the aggregate amount of credits, rebates, discounts, or other such payments received by the health plan or covered entity from a PBM or drug manufacturer and disclose whether or not those credits, rebates, discounts or other such payments were passed on to reduce insurance premiums or rates. The Commissioner will use the information obtained in these reports when reviewing premium rates charged for individual and group accident and health insurance as set forth in W. Va. Code §§33-6-9(e), 33-24-6(e) and 33-25A-8. The annual report required by this subsection shall be due on or before March 1 of each year.

6.3. Quarterly Report.

6.3.1. A PBM shall produce a quarterly report to the Commissioner of:

6.3.1.a. All drugs appearing on the national average drug acquisition cost list reimbursed 10% and below the national average drug acquisition cost; and

6.3.1.b. All drugs appearing on the national average drug acquisition cost list reimbursed 10% and above the national average drug acquisition cost.

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Number: 1 Author: mpower Subject: Sticky Note Date: 7/1/2021 1:26:36 PM
6.1.3 is not in the law. Therefore, it is outside the statutory authority granted.

Number: 2 Author: mpower Subject: Sticky Note Date: 7/1/2021 1:27:25 PM
We believe that 6.2.1 to 6.2.3 are not applicable to self-funded plans based on the definition of health plan/covered entity.

Number: 3 Author: mpower Subject: Sticky Note Date: 7/1/2021 1:46:36 PM
We need clarification on this reporting requirement. 6.2.1.d and 6.2.1.c seems identical to the one set forth in 6.2.2? If not, can you clarify what is different?

6.3.2. For each drug listed in the quarterly report, a PBM shall include:

6.3.2.a. The month the drug was dispensed;

6.3.2.b. The quantity of the drug dispensed;

6.3.2.c. The amount the pharmacy was reimbursed;

6.3.2.d. Whether the dispensing pharmacy was an affiliate of the PBM;

6.3.2.e. Whether the drug was dispensed pursuant to a government health plan; and

6.3.2.f. The average national drug acquisition cost for the month the drug was dispensed.

6.3.3. The quarterly report shall exclude drugs dispensed pursuant to 42 U.S.C. §256b.

6.3.4. A copy of the quarterly report shall be published on the PBM's publicly available website for a period of at least 24 months.

6.3.5. The quarterly report is exempt from the confidentiality provisions of section 6.8 of this rule.

6.3.6. The quarterly report required by this section shall be filed on or before May 15, August 15, November 15 and March 1 of each year; the final quarterly report being submitted with the annual report(s) required in section 6.2 of this rule.

~~6.4. 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.~~

6.4. The reports required by this section shall be filed electronically by the PBM or health benefit plan via the portal made available on the Commissioner's website.

6.5. ~~The~~ With the exception of the quarterly report noted in section 6.3 of this rule, 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 a "trade secret", is not open to public inspection, is not subject to subpoena, is not subject to discovery or admissible in evidence in any criminal, private civil or administrative action and is not subject to production pursuant to court order. The Commissioner is authorized to use the documents, materials or other information in the furtherance of any regulatory or legal action brought as part of the Commissioner's official duties.

§114-99-7. Examinations.

7.1. The Commissioner may examine the affairs of a PBM for compliance with ~~the requirements of the Pharmacy Audit Integrity Act~~ Article 51, Chapter 33 of the West Virginia Code or the requirements of this rule.

7.2. Any examination permitted under this section shall follow the examination procedures and requirements applicable to covered entities under W. Va. Code §33-2-9, and the Commissioner may assess the costs of the examination or audit to the PBM.

7.3. A PBM shall not be regularly examined under the same time periods of insurers as required under W. Va. Code §33-2-9; however, the Commissioner may examine the PBM, pursuant to this section, at any

Number: 1 Author: mpower Subject: Sticky Note Date: 7/1/2021 1:29:47 PM
We believe that this does not apply to self-funded government health plans based on the definition of health plan.

time in which he or she believes it reasonably necessary to ensure compliance with ~~the Pharmacy Audit Integrity Act~~ Article 51, Chapter 33 of the West Virginia Code or the provisions of this rule.

7.4. The information and data obtained by the Commissioner from 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 a "trade secret", is not open to public inspection, is not subject to subpoena, is not subject to discovery or admissible in evidence in any criminal, private civil or administrative action and is not subject to production pursuant to court order. The Commissioner is authorized to use the documents, materials or other information in the furtherance of any regulatory or legal action brought as part of the Commissioner's official duties.

§114-99-8. Penalties and Reimbursement.

8.1. If the Commissioner finds that a licensed PBM has violated any provisions of this rule or ~~any provisions of the Pharmacy Audit Integrity Act~~ Article 51, Chapter 33 of the West Virginia Code that are applicable to the PBM, the Commissioner may, in addition to or in lieu of a licensure suspension or revocation, order the PBM to pay a penalty in a sum not to exceed $10,000 per violation. If the PBM fails to pay the penalty within 30 days after notice of the penalty, the Commissioner may revoke or suspend the license of the PBM. This section shall not affect the right of a PBM to make a written demand for a hearing before the Commissioner pursuant to the provisions of W. Va. Code §33-2-13.

8.2. If the Commissioner finds that a registered auditing entity has violated any provisions of this rule or any provisions of Article 51, Chapter 33 of the West Virginia Code, the Commissioner may, in addition to or in lieu of a registration suspension or revocation, order the auditing entity pay a penalty in a sum not to exceed $2,500 per violation. If the auditing entity fails to pay the penalty within 30 days after notice of the penalty, the Commissioner may revoke or suspend the registration of the auditing entity. This section shall not affect the right of an auditing entity to make a written demand for a hearing before the Commissioner pursuant to the provisions of W. Va. Code §33-2-13.

8.3. With respect to any person or entity operating in this state as a PBM without a license, the Commissioner may do one or both of the following:

~~8.3.a.~~ 8.3.1. File a complaint in the Circuit Court of Kanawha County, or in any county in which a PBM has operated without a license, to enjoin the PBM from operating; and

~~8.3.b.~~ 8.3.2. After notice and hearing in accordance with W. Va. Code §33-2-13, assess restitution in an amount sufficient to reimburse any person adversely affected by the operation of the unlicensed PBM and, in addition to or in lieu of restitution, impose a fine in a sum not to exceed $20,000 for each unauthorized act.

8.3.3. This section shall not affect the right of a PBM to make a written demand for a hearing before the Commissioner pursuant to the provisions of W. Va. Code §33-2-13.

8.4. With respect to any person or entity operating in this state as an auditing entity without being registered or exempted from registration, the Commissioner may do one or both of the following:

~~8.4.a.~~ 8.4.1. File a complaint in the Circuit Court of Kanawha County, or in any county in which an auditing entity has operated without a license, to enjoin the auditing entity from operating; and

~~8.4.b.~~ 8.4.2. After notice and hearing in accordance with W. Va. Code §33-2-13, assess restitution in an amount sufficient to reimburse any person adversely affected by the operation of the unregistered auditing entity and, in addition to or in lieu of restitution, impose a fine in a sum not to exceed $5,000 for each unauthorized act.

8.4.3. This section shall not affect the right of an auditing entity to make a written demand for a hearing before the Commissioner pursuant to the provisions of W. Va. Code §33-2-13.

8.5. The Commissioner may order reimbursement to an insured, pharmacy, or dispenser who has incurred a monetary loss as a result of a violation of Article 51, Chapter 33 of the West Virginia Code or the provisions of this rule by a PBM.

8.5.1. To seek reimbursement, an insured, pharmacy or dispenser should file a complaint with the Commissioner within one year following the actual or implied discovery of the violation.

8.5.2. The complaint should be filed on a form provided by the Commissioner and state with specificity the following:

8.5.2.a. The statutory provision, if known, which the person allegedly violated;

8.5.2.b. The facts and circumstances giving rise to the alleged violation;

8.5.2.c. The name of any individual or other entity involved in the alleged violation;

8.5.2.d. Reference to specific contract language that is relevant to the alleged violation, if known; and

8.5.2.e. Any other information the commissioner may require.

8.5.3. Upon receipt of a sufficiently complete complaint, the Commissioner shall provide a copy to the PBM.

8.5.4. Within 15 working days after receiving a complaint, the PBM must advise the Commissioner in writing of the status of negotiations with the insured, pharmacy or dispenser to resolve the complaint for reimbursement unless the complaint has already been resolved. If the PBM intends to take no action to resolve the complaint, the PBM shall advise the Commissioner accordingly, in writing, and provide the Commissioner with a substantive response to the allegations in the complaint.

8.5.5. After receiving a written response to the complaint from a PBM, the Commissioner shall determine whether to:

8.5.5.a. Close the complaint and take no further action;

8.5.5.b. Order reimbursement be made from the PBM to the insured, pharmacy or dispenser; or

8.5.5.c. Set the matter for administrative hearing and further determination as to whether the allegations in the complaint are meritorious and reimbursement should be ordered.

8.5.6. An insured, pharmacy or dispenser has the right to contest the Commissioner's decision to close a complaint, without hearing, and take no further action thereon to award reimbursement. A PBM has the right to contest the Commissioner's decision to award reimbursement from the PBM to the insured, pharmacy, or dispenser without hearing thereon. This subsection shall not affect the right of a PBM, insured, pharmacy or dispenser to make a written demand for a hearing pursuant to the provisions of W. Va. Code §33-2-13.

8.5.7. A hearing on a complaint shall be scheduled to be held within 90 days from the date of filing

the complaint by the insured, pharmacy or dispenser unless continued by agreement of all parties or by the Commissioner for good cause. Good cause includes but is not limited to a determination by the Commissioner that additional investigation is necessary.

8.5.8. The Commissioner shall assign a time and place for a hearing and shall mail written notice of the hearing to the parties at least 10 days in advance thereof.

8.5.9. To the extent such provisions are not in conflict with this rule, hearings shall be conducted in accordance with the procedures set forth in 114CSR13.

8.5.10. The Commissioner may add interest to an award of reimbursement to an insured, pharmacy or dispenser who has incurred a monetary loss as a result of a violation of Article 51, Chapter 33 of the West Virginia Code or the provisions of this rule by a PBM. If an award of interest is made, it shall be calculated from the date the payment to the insured, pharmacy or dispenser was initially due or should have been made and shall be calculated using the U.S. Prime Rate.

§114-99-9. Consumer Choice for Pharmacy Benefits.

9.1. Applicability.

9.1.1. Section 9 of this rule applies to all PBMs and health benefit plans providing pharmaceutical services or pharmacy benefits, including but not limited to prescription drugs, to any resident of West Virginia.

9.1.2. Section 9 of this rule applies to insurance companies and health maintenance organizations or "HMOs" that provide or administer coverages and benefits for prescription drugs.

9.1.3. Section 9 of this rule does not apply to any entity that has its own facility, employs or contracts with physicians, pharmacists, nurses and other health care personnel, and that dispenses prescription drugs from its own pharmacy to its employees and dependents enrolled in its health benefit plan.

9.1.4. Section 9 of this rule applies to an entity otherwise excluded under subsection 9.1.3. of this rule that contracts with an outside pharmacy or group of pharmacies to provide prescription drugs and services.

9.1.5. For purposes of section 9 of this rule, "health benefit plan" means any entity or program that provides reimbursement for pharmaceutical services or pharmacy benefits, including but not limited to prescription drugs, to any resident of West Virginia.

9.1.6. For purposes of section 9 of this rule, "beneficiary" means any person who receives benefits for pharmaceutical services or pharmacy benefits, including but not limited to prescription drugs, under a health benefit plan.

9.2. Prohibitions.

9.2.1. A PBM or health benefit plan may not:

9.2.1.a. Prohibit or limit any covered individual from selecting a pharmacy or pharmacist of his or her choice who has agreed to participate in the health benefit plan's network according to the terms offered by the health plan;

9.2.1.b. Deny a pharmacy or pharmacist the right to participate as a contract provider under

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Number: 1 Author: mpower Subject: Sticky Note Date: 7/1/2021 1:30:35 PM
8.5.10 is new language not found in HB 2263. We feel that this is outside Departments jurisdiction.

Number: 2 Author: mpower Subject: Sticky Note Date: 7/1/2021 1:31:21 PM
Generally this section contains extraterritorial issues.

Number: 3 Author: mpower Subject: Sticky Note Date: 7/1/2021 1:31:59 PM
9.1.6 is a specific example of an extraterritorial issue. It's critical to limit the scope of section 9.1.6 to WV.

Number: 4 Author: mpower Subject: Sticky Note Date: 7/1/2021 1:33:56 PM
As stated earlier when discussing rebates, many of the items under "prohibitions" are plan design tools that are requested/considered by the client who voluntarily sponsors the health benefit plan for their employees.

Many of these issues were not settled by Rutledge v. PCMA and are still preempted by ERISA.

the health insurance policy or health benefit plan's network if the pharmacy or pharmacist agrees to provide pharmacy services or benefits, including but not limited to prescription drugs, that meet the terms and requirements set forth by the insurer under the health insurance policy or health benefit plan's network and agrees to the terms of reimbursement set forth by the insurer;

9.2.1.c. Impose upon a beneficiary of pharmacy services under a health benefit plan any co-payment, fee or condition that is not equally imposed upon all beneficiaries in the same benefit category, class or co-payment level under the health benefit plan's network when receiving services from a contract provider;

9.2.1.d. Impose a monetary advantage or penalty under a health benefit plan that would affect a beneficiary's choice among those pharmacies or pharmacists who have agreed to participate in the health benefit plan's network according to the terms offered by the insurer. For purposes of this subdivision, "monetary advantage or penalty" includes higher co-payment, a reduction in reimbursement for services or the promotion of one participating pharmacy over another by these methods;

9.2.1.e. Reduce allowable reimbursement for pharmacy services to a beneficiary under a health benefit plan because the beneficiary selects a pharmacy of his or her choice, so long as that pharmacy has enrolled as a network provider with the health benefit plan under the terms offered to all pharmacies in the plan coverage area;

9.2.1.f. Require a beneficiary, as a condition of payment or reimbursement, to purchase pharmacy services, including but not limited to prescription drugs, exclusively through a mail-order pharmacy; or

9.2.1.g. Impose upon a beneficiary any co-payment, amount of reimbursement restriction upon the number of days of a drug supply for which reimbursement will be allowed, or any other payment or condition relating to purchasing pharmacy services from any pharmacy, including but not limited to prescription drugs, that is more costly or more restrictive to the beneficiary than that which would be imposed upon the beneficiary if such services were purchased from a mail-order pharmacy or any other pharmacy that is willing to provide the same services or products for the same cost and copayment as any mail-order service.

9.3. Notification.

9.3.1. If a health benefit plan restricts pharmacy participation through a network, the covered entity providing the health benefit plan shall notify, in writing, all pharmacies within the geographic coverage area of the health benefit plan and offer those pharmacies the opportunity to participate in the health benefit plan's network. Notification shall be provided at least 60 days prior to the effective date of the health benefit plan's network.

9.3.2. All pharmacies in the coverage area shall be eligible to participate in the network under identical reimbursement terms for providing pharmacy services, including prescription drugs.

9.3.3. A covered entity providing the health benefit plan shall inform the beneficiaries of the plan of the names and locations of pharmacies that are participating in the health benefit plan's network. Notification to beneficiaries should be provided through reasonable means, on a timely basis and at regular intervals. For purposes of this subsection, "reasonable means" may include written or electronic communications to beneficiaries by a health benefit plan, as well as publication on the health benefit plan's publicly available website. For purposes of this subsection, "regular intervals" should include notification to beneficiaries during a health benefit plan's open enrollment periods, as well as supplemental notification to beneficiaries at times during a plan year when a pharmacy enters or leaves a health benefit plan's network for pharmacy services.

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Number: 1 Author: mpower Subject: Sticky Note Date: 7/1/2021 4:17:58 PM

This is inconsistent with the above AWP/FOC law. We request clarification as to whether these provisions intend to allow for restricted networks despite what 9.2.1b says above?

9.3.4. Participating pharmacies shall be entitled to announce their participation in a health benefit plan's network to their customers through a means acceptable to the pharmacy and the covered entity providing the health benefit plan.

9.3.5. The notification provisions of this section shall not apply when an individual or group is enrolled in a health benefit plan, but when the health benefit plan enters a new county of the state.

9.4. Injunctive relief.

9.4.1. Any covered individual or pharmacy injured by a violation of section 9 of this rule may maintain a cause of action against a PBM or health benefit plan to enjoin the continuance of any such violation by filing a complaint in the Circuit Court of Kanawha County, or in any county in which the PBM or health benefit plan has committed the violation.

9.4.2. The Commissioner does not need to be made party to any complaint for injunctive relief filed against a PBM or health benefit plan, but may intervene in the lawsuit if he or she deems intervention necessary to enforce the provisions of this rule or of Article 51, Chapter 33 of the West Virginia Code.

9.4.3. The covered individual or pharmacy filing for injunctive relief shall provide a courtesy copy of the lawsuit to the Commissioner in order for the Commissioner to make a decision on intervention and to ensure administrative enforcement of this rule or of Article 51, Chapter 33 of the West Virginia Code.

9.4.4. The filing of an injunction against a health benefit plan for alleged violations of Article 51, Chapter 33 of the West Virginia Code or this rule does not alone affect any license or Certificate of Authority held by an insurer otherwise duly licensed in this state without separate regulatory action undertaken by the Commissioner.