July 11, 2018

Commissioner Allen Kerr
Arkansas Department of Insurance
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Re: Comment Letter on Proposed Rule 118 – PHARMACY BENEFITS MANAGERS REGULATION

Commissioner Kerr:

Thank you on behalf of the Pharmaceutical Care Management Association (PCMA) for the opportunity to offer comments on the proposed Rule 118, Pharmacy Benefits Managers Regulation.

PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 266 million Americans with health coverage provided through Fortune 500 employers, health insurance plans, labor unions, state and federal employee-benefit plans, and Medicare.

Per the Department's request, whenever possible we have attempted to provide alternative language or suggestions to the current draft language. While we have made some broad comments for your consideration on Section 9 of Rule 118 concerning the recent 8th Circuit opinion in *Rutledge v. PCMA*, in other areas we have identified the specific section and made brief comments and language suggestions.

Section 4(8) defines "Pass-through pricing" however it is not used in the rule and thus the definition should be deleted.

Section 4(20) defines "spread-pricing" however the definition should not include administrative fees. Administrative fees are a separate and distinct issue. We suggest that the definition for "spread-pricing" be removed and the language in Section (9)(C)(1) be amended so that it mirrors the applicable law in § 4-88-803. We offer the following change: "~~(2) engaged in Spread pricing for pharmacy benefits of a Healthcare insurer~~" and replace with language from the law: (2) "paying the amounts it receives for pharmacist services provided in connection with a pharmacy benefits plan or program to the pharmacies or pharmacists that provided the pharmacist service."

Section 5(A)(7) references sections of the Arkansas code that includes MAC law and clawback law among others. These items may not necessarily be incorporated into the contract itself, rather they may be included in the provider manual. We suggest that you modify the language to read "A copy of the PBMs standard, generic contract template, provider manual or other appropriate items incorporated by reference which it uses for contracts entered into by the PBM…"

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Section 5(A)(10) requires the PBM to submit the policies and procedure for pharmacies to appeal MAC which are normally outlined in provider manual and should be submitted as part of the requirements in Section 5(A)7. The language in Section 5(A)10 should be amended to add the following sentence at the end of the Section **"If compliance with this Section can be demonstrated by the items required for submission under Section 5(A)7 please note in your submission."**

Section 5(A)(13) seeks an explanation of risk **if** the PBM uses "spread pricing". It is unclear here if the Department is referencing "operational business risk" which every business assumes as part of its daily activity or the more specific "insurance risk" which is reserved for companies that collect premiums with a promise of providing future benefits. PBMs do not collect premiums and the obligation to deliver any future benefit always remains with the health benefit plan. Pharmacy claims are adjudicated at the point of sale and actual reimbursement follows in accordance with the contractual terms negotiated between the two entities. The process for reimbursement to the pharmacy remains constant whether the contract between the PBM and the health benefit plan contains reimbursement terms that include "spread-pricing" or not. The operational business risk for the pharmacy is the same under a "spread-pricing" PBM/health benefit plan contract or traditional PBM/health benefit plan contract. This section is unnecessary and should be deleted.

Section 5(A)(15) requires the PBM to disclose any business relationships with an insurance company that was terminated for "any alleged fraudulent, illegal or dishonest activities." The term dishonest seems broad and is undefined. We suggest that the word "dishonest" be stricken.

Section 5(B)3(B) is concerned with when the Department shall deny an initial application or renewal of a license. We suggest amending the language so that the PBM will not be denied an initial license or the renewal of the license under this section if the PBM has an appropriate remedy or corrective action plan in place that will satisfy the Commissioner. The amended language should read "the PBM has been determined by the Commissioner to be in violation or non-compliance with the requirements in the Rule or Arkansas state law and has not taken appropriate steps to remedy the deficiency or submitted an approved corrective action plan to the Commissioner;

Section 5(D), the Confidentiality Section uses an inconsistent citation pursuant to how it is cited throughout the law. This section should be amended with the following Arkansas Code Ann., § 23-61-107(a)(4) ~~23-61-103~~ and § 23-61-207; Additionally, the statute cites the entire FOIA law whereas the proposed rule is limited by only citing a specific section of said law. We suggest changing the FOIA site as follows: § 25-19-105 ~~(b)(9).~~ In addition, we think it is unusual to require a redacted copy of the information to be submitted to the Department before any information has been requested under FOIA. We believe it is appropriate to deal with such requests on a case by case basis. If the Department receives a FOIA request the Department should notify the company and request a redacted copy. The last sentence of this section should be deleted.

Section 6(A)3 the fees section, we recall the reference at the interested parties' meeting to the AWP statute (Ark. Code Ann. 23-99-204(b)). That code section does include a standard of

maintaining quality and controlling costs, but does not include any reference to the standard of "objective evidence," which we believe to be extreme and unnecessary. The fees at issue here have been part of contractual relations between PBMs and pharmacies (and between contracting parties in any number of other contractual relationships) for many years, as a cost of doing business. We suggest that a standard such as "specific" or "detailed" would be more appropriate.

Section 7(B) 1 references reimbursement, it should be clear that pharmacies reimbursement is measured in the aggregate, as with all retail businesses, a pharmacy may lose money on a single transaction, but their aggregate reimbursement is profitable. The Commissioner's review and any determinations of the adequacy of a reimbursement "program" of compensation must be on an aggregate basis, not on the basis of individual prescriptions, consistent with the approach stated in B.2. The suggested amendment clarifies what we believe to be the intent. Therefore the first sentence of Section 7(B)1 needs to be amended as follows:
"Pursuant to Ark. Code Ann. 23-92-506(a)(1), the Commissioner may, in his or her discretion, review a PBM's *aggregate* reimbursement program or compensation, for a Pharmacy benefit plan of a Healthcare insurer, to determine if the *aggregate* reimbursement is fair and reasonable to provide an adequate Pharmacy benefits network for a Health benefit plan."

In Section 7(B) 1, the second sentence is impermissibly vague, giving Healthcare insurers" literally no guidance on what they must do to "**reasonably ensure**" that the PBM's reimbursement program does not adversely impact the pharmacy network. The sentence should be either deleted or provide sufficient guidance to Healthcare insurers and PBMs regarding the standards that they would be compelled to adhere to.

In Section 7(B)1, in the same second sentence referenced above, the proposed rule improperly refers to "Pharmacists" participation in plan networks. PBMs contract with ***Pharmacies,*** not individual ***"Pharmacists"*** (see definitions in Section 4) to participate in their networks. This error should be corrected throughout this Section and the entire proposed rule.

Section 7(B)2(b) should be amended in order to make it clear that the standard of review is consistent. It should be amended as follows: "the extent to which the compensation or reimbursement program has an impact on pharmacy participation in Health benefit plans *either* on a state-wide basis, or *in a* significant geographical area of the State."

Section 7(B)2(b) Sub. (1) of the definition of "adverse impact" refers to a 10% reduction in pharmacy participation in the network but does not provide a timeframe for measurement of that reduction. Three months? A year? We respectfully request that the department define the timeframe so that Healthcare insurers and PBMs know the standard that they will be required to comply with. Sub. (2) is impermissibly vague, subjective and overly simplistic, basing regulatory action on the standard of whether the reduction in participation is "solely" due to a reduction in compensation or reimbursement. Independent of reimbursement, pharmacies have any number of variable costs and revenue streams. Rent could increase, as could insurance, taxes, labor costs, cost of goods sold in in the front of the store or behind the pharmacy counter. A new competitor could open in a free-standing store or in a supermarket, drawing patients away, which would reduce revenues. Amid these and other variables that are inherent in any

business, not just pharmacies, at what point and how does the Department determine that the pharmacy's decision not to continue participating in a network is due "solely" to a reduction in compensation or reimbursement? Consistent with our comment above on B.1, Sub. (2) should also be amended to refer to aggregate reimbursement, to clarify that the decision is not made on an individual prescription, and to correct the reference to a pharmacist, not a pharmacy: "(2) the reduction in participation is solely due to a reduction in the ***aggregate*** compensation or reimbursement to ***a pharmacy***." In addition, this section appears to be broad and should be limited to generic drugs on the MAC list in order to avoid raising costs for health benefit plans and their beneficiaries.

Section 7(B)2 contains a paragraph on a pharmacist's decision not to dispense a generic drug because the pharmacy will be reimbursed below the pharmacy's invoice price. This presents some issues. First, that same pharmacy might fill 100 other prescriptions for the same Healthcare insurer through the same PBM without any issue, yet a decision not to dispense a single prescription represents a "circumstance negatively impacting participation"? The same patient may have brought three prescriptions to the pharmacy to fill at the same time, and the pharmacist has refused to dispense only one. Clearly, the patient had access to a network pharmacy, and it is not clear how that circumstance could be viewed as a negative impact on pharmacy participation.

In addition, subsection (1) of that same paragraph would require Healthcare insurers and PBMs to track or monitor such declinations, an impossible standard, and a requirement that goes beyond the authorizing statutes for this proposed rule. PBMs have no way of knowing when a pharmacy has declined to dispense, because no claim has been submitted. If the Department wants to track these events, it should require the pharmacies that have declined to dispense to report their actions to the Department directly, with copies to the PBM and the Healthcare insurer.

We also suggest deleting Sub. (2) of that paragraph, which would require Healthcare insurers and PBMs to develop a system to track when pharmacies terminate their network participation because of a reduction in compensation. As noted above, a pharmacy's financial stability is subject to a number of variables, and how can a Healthcare insurer or PBM verify that a reduction in compensation is the causative factor in a pharmacy's decision?

In Section 7(B)5, for consistency in throughout this section of the proposed rule, we suggest amending the third sentence as follows:" If after review or examination, the Commissioner determines a network adequacy violation exists due to ~~non-participation from compensation or reimbursement reductions,~~ ***adverse impact on pharmacy participation***, it shall be the responsibility of the Healthcare insurer, * * *[.]"

We also recommend that the rule expressly confirm that all of the financial information submitted by Healthcare insurers and PBMs to the Department under this proposed Section 7 (Compensation) is being collected as part of the Department's review pursuant to Ark. Code Ann. 23-92-506(a)(1) and therefore subject to the confidentiality provisions of Ark. Code Ann. 23-92-506(a)(2).

PCMA believes that Section 9 of the proposed rule is preempted by federal law. The Employee Retirement Income Security Act of 1974 (ERISA) preempts state record-keeping, reporting and disclosure requirements such as the ones included in the proposed rule. ERISA is the federal law that governs all employer-based health plans, including both insured and self-insured plans, and Arkansas residents who work for private sector employers are for the most part enrolled in ERISA plans. PBMs provide administrative services to those ERISA plans. ERISA provides a "comprehensive system for the federal regulation of employee benefit plans,"[1] and as the Supreme Court recently noted, there must be a "single uniform national scheme for the administration of ERISA plans without interference from the laws of several states."[2] No state mandate can directly or indirectly interfere with key matters of plan administration. As the Supreme Court noted in *Gobeille*, ERISA's "reporting, disclosure, and recording requirements for welfare benefit plans are extensive," and states cannot impose differing or parallel regulations on administrators.

As you know, the Eighth Circuit, in *PCMA v. Rutledge*, recently ruled that Act 900, the maximum allowable cost (MAC) law enacted in 2015, was preempted by ERISA. The *Rutledge* Court relied heavily on the *PCMA v. Gerhart* case which overturned an Iowa MAC law, and the *Gobeille* case that overturned a Vermont law that dealt with reporting requirements. Under this line of cases, the prior Arkansas MAC law—§17-92-507—is preempted, as well.

The *Rutledge* Court found that Act 900 made an implicit reference to ERISA plans, adopting from *Gerhart* that "the Iowa statute both explicitly and implicitly referred to ERISA by regulating the conduct of PBMs administering or managing pharmacy benefits."[3] The *Rutledge* Court held that it was "completely bound" by *Gerhart*'s reasoning that the "Iowa law also makes implicit reference to ERISA through regulation of PBMs who administer benefits for 'covered entities,' which, by definition, include health benefit plans and employers, labor unions, or other groups 'that provide[] health coverage.' These entities are necessarily subject to ERISA regulation." [4] By this logic, the entirety of Arkansas Statute § 17-92-507 would be preempted as implicitly referring to ERISA, as Act 900 did not change the MAC law's pre-existing definitions of "pharmacy benefits manager" or "pharmacy benefits plan or program."

In addition, the remainder of Arkansas § 17-92-507 would be preempted as having an impermissible connection with ERISA under *Gobeille* and *Gerhart*. By declaring what particular drugs must exist on a MAC list and requiring a PBM to render particular MAC disclosures and provide particular appeal procedures, the law regulates plan administration and disclosure.

Finally, the MAC reporting requirements outlined in Section 9(A) and (B) would be preempted by ERISA under *Gobeille* and the PCMA cases. Section 9 requires PBMs to develop a specific type of record keeping system relating to MAC appeals and to develop a system to accept pharmacy provider complaints related to MAC. Requiring record-keeping, reporting or disclosures to a state official or agency intrudes on what the federal courts have called "a matter central to plan administration," and further "interferes with nationally uniform plan administration."[5] Because

[1] District of Columbia v. Greater Was. Bd. Of Trade, 606 U.S. 125, 127 (1992).
[2] Gobeille v. Liberty Mutual Ins. Co., 136 S. Ct. 936 (2016).
[3] PCMA v. Gerhart, Slip op. at 5.
[4] Id. (quoting *PCMA v. Gerhart*, 852 F.3d 722 (8th Cir. 2017)).
[5] *Gobeille*, 136 S.Ct at 945.

PBMs are performing key administrative functions for ERISA plans, states cannot impose mandates—either directly or indirectly—that interfere with that administration, or that result in the imposition of a patchwork of differing regulatory requirements on PBMs.

Thank you for your consideration of these comments. If you have any questions please free to contact me with questions on my cell at 270-454-1773.

Sincerely,

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