



October 14, 2019

Director of Regulatory Affairs
Maryland Insurance Administration
200 St. Paul Place, Ste. 2700
Baltimore MD 21202

Via email: InsuranceRegReview.mia@maryland.gov

Re: Pharmacy Benefit Manager Rulemaking – Comments on 2nd Stakeholder Draft

Dear Director:

I am writing to provide the Pharmaceutical Care Management Association (PCMA) comments on the Maryland Insurance Administration's (MIA) second draft rule dealing with pharmacy benefit manager (PBM) contract filings and reimbursement appeals. PCMA is the national trade association for the PBMs, which manage prescription drug benefits on behalf of health plans, large and small employers, labor trusts and government programs. PCMA was involved in the legislative process as these bills were being debated and has participated in multiple stakeholder discussions led by the MIA. We appreciate the willingness of MIA to take feedback from stakeholders and continue an open dialogue. Our goal is to ensure that the final rule is clear, understandable, and it provides fair notice to PBMs on how to comply.

At the outset, we note that in some areas of the regulation, there is a disconnect between the statutory sections and the regulatory sections. The regulations should correspond directly to the statutes they are clarifying, and to those only. Areas of concern are noted below. In addition, please see our detailed comments on the proposed rule below. We are happy to have further discussions on any of these issues.

Chapter 46 – MAC

.02 Definitions

- Subsection (B)(6)(c) defines “fee or performance-based reimbursement related to an adjudicated claim or incentive program” and includes using the application of “combined aggregate overall percentage discounts applied to all adjudicated claims.” Additional clarification is needed on this definition and its applicability to either adjudication fees and performance network fees or just performance networks.
- Subsection (B)(18) defines “pricing information” to mean anything used in the mathematical calculation to determine the payment to a contracted pharmacy. We appreciate MIA revising this term from the prior version of the rule, but we remain concerned about this language. There is no need to define this term. The statute is clear that “pricing information” is part of the compensation program (§15-1601(c-2)), and the

compensation program is subject to review by the Commissioner under certain circumstances (§15-1628.1(i)(1)(i), §15-1628.2(a)(4)). In addition, MAC “pricing information” must be updated every 7 days and the updated information must be used in calculating payments (§15-1628.1(c)). The statute also calls for sources for MAC to be disclosed (§15-1628.1(b)) and mathematical calculations to be provided (§15-1628.1(f)(4)). In all of these cases, the statute is clear and very prescriptive. Thus, there is no need for additional definition.

.03 Disclosures to Pharmacy in Contract

- Subsections (B)(1)-(3) establish substantive requirements unrelated to *contractual disclosures* and should be removed or moved to a section of the rule that addresses substantive requirements on PBMs related to MAC pricing updates and appeals.
- Subsection (B)(2) of the proposed rule adds the words “**and price list**” after the term “MAC lists” (i.e., the lists for which PBMs must establish a process for pharmacies to access). PCMA commented on the earlier version of the rule which referred to “MAC lists and pricing” and we appreciate MIA for re-examining the language. However, we still believe the reason for the additional words “and price list” is unclear and thus the words are unnecessary. MAC lists and price lists are one and the same, and without a reason for the additional words, PCMA suggests consistency with the statute and thus, the deletion of “and price list.”
- Subsections (C), (D), & (E) relate to fees and performance-based reimbursements and appear to be improperly included in this section of the draft rule. The requirement in the law is found not under §15-1628.1 (the MAC section of the law) but under §15-1628.3 and therefore, from a drafting perspective, should not be included in this section of the rule. As we noted above, this issue should be addressed in its own chapter to avoid confusion and provide clarity.

First, subsection (C) provides that “except as provided in §§D and E,” a contracted pharmacy shall not be charged a fee or held responsible by a purchaser or PBM for specified items. Subsection (D) establishes the situations where a PBM is allowed to charge a fee or implement a performance-based contract term, and (E) provides the parameters for disclosures. Thus, (C) appears unnecessary if (D) and (E) are effective and enforced. PCMA believes that unnecessary language in rule will confuse both regulators and regulated entities and suggests striking the unnecessary language in (C).

With regard to the language in subsections (D)(1)-(2), these indicate that a PBM must disclose the *specific dollar amount or alternative reimbursement*, or the *specific percentage of potential adjustment*... relating to reimbursement of a claim, either during claims processing or described in detail on the initial remittance advice (subsection (E)). We appreciate MIA re-examining the language proposed in the first stakeholder draft of the rule. However, we remain concerned. The terms “specific dollar amount” and “specific percentage of potential adjustment” are not in the statute. The statute indicates that the fee must be “specifically enumerated,” not necessarily the exact amount.

Because performance-based contracts necessarily have a look-back period, providing the exact dollar amount of a final payment that is contingent upon a pharmacy's performance may be impossible on the remittance advice. It would appear that any performance-based payments or recoupments that rely on assessment of a pharmacy's performance *after performing* necessarily would be prohibited. **The Maryland Legislature could have prohibited performance-based contracting between PBMs, PSAOs and pharmacies, but it declined to do so.** Instead, the legislature opted to ensure pharmacies have been notified of the contingent nature of payments under performance-based contracts. PCMA suggests clarification here.

Additionally, these requirements are inconsistent with current electronic claims (NCPDP) technical standards for adjudication and it would be difficult, if not impossible, to implement at the time of claims processing. PBMs do not have control over NCPDP fields or standardized claims processes and changes can require action by the NCPDP and federal Centers for Medicare and Medicaid. These proposed requirements do not take into account that pharmacies also opt to get electronic remittance advices called 835 files and those are accessed and populated in a completely different manner than paper remittance advices. Due to these technical issues, which are outside of the direct and exclusive control of PBMs, compliance with this requirement will be problematic if not impossible.

PCMA requests the following amendment, which ensures that pharmacies have agreed to performance metrics beforehand and are aware of the range of the potential adjustment:

C. Except as provided in §§D and E of this regulation, a contracted pharmacy shall not be charged a fee or held responsible by a purchaser or PBM for:

(1) A fee or performance-based reimbursement related to an adjudicated claim; or

(2) An incentive program.

D. A PBM, whether its contract is directly with a pharmacy or indirectly with a pharmacy through a PSAO or group purchasing organization, shall disclose any fee or performance-based reimbursement that relates to the adjudication of a claim or incentive program by stating:

(1) The specific dollar amount of a fee or alternative reimbursement; or

(2) The specific percentage range of the potential adjustment relating to reimbursement of a claim based on contractually agreed to performance-based metrics.

E. The disclosure described in §D shall be provided:

(1) During claims processing; or

(2) Described in detail on the initial remittance advice.

.04 Internal Appeals

- Subsection (A), requiring written procedures on appeals, appears to be re-stated in subsection (B)(1). For clarity, PCMA suggests striking (A) because it is unnecessary and



duplicative of (B). Any time there are additional, unnecessary words, we are concerned that duplicative, unnecessary words will be given different meanings, which will cause confusion for both regulators and regulated entities.

.05 MAC Complaint Process

- Throughout this section of the proposed rule, reference is made to the pharmacy's **designee** having the ability to file a reimbursement appeal. The term "designee" should be more specific and refer to an entity that has contracted with the pharmacy to act on its behalf. PCMA suggests that the term "Contracted agent" (used in §1628.1(f)(5)(ii)(2), relevant to MAC appeals) be used.
- Subsection (E)(2)(a) requires PBMs to provide a complete, unredacted copy of the applicable portion of the contract relating to the compensation program, the complaint, and "**any other contract** under which the pricing information is determined." The statute requires PBMs to file with the MIA contracts with pharmacies, PSAOs, or GPOs and to submit the compensation program upon MIA request, but does not specify "any other contract." This requirement is an expansion of the statute and should be removed.

Additionally, PCMA is unclear as to why an *unredacted* copy is necessary to file when the appealing pharmacy has already "provided a copy of the relevant contract or the provisions that are related to the MAC appeal" and the PBM is already required to provide a template contract to the department initially.

- PCMA suggests striking (E)(2)(a) because (E)(2)(b)-(f) provide the information that MIA needs for an appropriate review. In the alternative, PCMA suggests the following amendment:
 - (a) A ~~complete, unredacted~~ copy of the applicable portion of the participating pharmacy contract relating to the compensation program and the complaint filed with the Commissioner, including any other ~~contract under which the pricing information is determined~~ relevant price schedule.
- Both the statute and subsection (E)(2)(b) refer to "pricing information," but PBMs are concerned about how "pricing information" is different than what is included in the compensation program ("pricing information" is part of the compensation program in §15-1601(c-2)), or the "mathematical calculation." The rule should refer to the compensation program, mathematical calculation, or sources, and this is an unnecessary term.
 - PCMA suggests the following amendment:
 - (b) A copy of the applicable source and ~~pricing information~~ used to calculate the MAC.

- Subsection (E)(2)(f)(iii) of the proposed rule provides the commissioner authority to ask for any other information necessary to determine the PBM's compliance with its *compensation program*. We are unclear what the distinction is between determining *compliance with the compensation program* and *determining compliance with the contract or law*. MIA evaluating a PBM's compliance based on the applicable terms of the pharmacy contract and the law is enough, as these already encompass the information needed to make a determination based on the complaint filed. PCMA believes this language is unnecessary, will cause confusion, and suggests striking (E)(2)(f)(iii).

Chapter 47 – Cost pricing and reimbursement other than MAC

.01 Scope

- The proposed rule indicates that this section of the rule applies to all cost pricing and reimbursement disputes *or* a request to review the failure to pay the contracted reimbursement amount. PCMA questions why this language was added and believes it is unnecessary. There is no “request to review the failure to pay the contracted rate” that is not a “cost pricing and reimbursement dispute.”

.02 Definitions

- Subsection (B)(8) defines “direct or indirect remuneration fee.” Although we understand that this term is used in the statute, we note for the MIA that “direct or indirect remuneration fee” is a term of art used in the federal Medicare Part D program, referring to a pay-for-performance program for pharmacies. The statute this rule is implementing does not affect this Medicare program. In addition, the apparent applicability of this term to generic effective rate contracts goes beyond the statute. PCMA suggests deleting this definition.
- Subsection (B)(18) defines “review decision.” It is unclear why this definition is used, as it is not used in the statute and does not seem to be necessary to provide the protections established in the statute. PCMA suggests deleting this definition.

.03 Disclosures to Contracted Pharmacy

- Subsections (B), (C), & (D) relate to fees and performance-based reimbursements and appear to be improperly included in this section of the draft rule. The requirement in the law is found not under §15-1628.2 (the “cost pricing” disputes section of the law) but under §15-1628.3 and therefore, from a drafting perspective, should not be included in this section of the rule. As we noted above, this issue should be addressed in its own chapter to avoid confusion and provide clarity.

First, subsection (B) provides that “except as provided in §§C and D...” a contracted pharmacy shall not be charged a fee or held responsible by a purchaser or PBM for



specified items. Subsection (C) establishes the situations where a PBM is allowed to charge a fee or implement a performance-based contract term. Thus, (B) appears unnecessary if (C) and (D) are effective and enforced. PCMA believes that unnecessary language in rule will confuse both regulators and regulated entities and suggests striking the unnecessary language in (B).

With regard to the language in (C) and (D), these subsections indicate that a PBM must disclose the *specific dollar amount or alternative reimbursement, or the specific percentage of potential adjustment...* relating to reimbursement of a claim, either during claims processing or described in detail on the initial remittance advice. We appreciate MIA re-examining the language proposed in the first stakeholder draft of the rule. However, we remain concerned. The terms “specific dollar amount” and “specific percentage of potential adjustment” are not in the statute and PCMA is unclear as to their meaning. The statute indicates that the fee must be “specifically enumerated,” not necessarily the exact amount. Because performance-based contracts necessarily have a look-back period, providing the exact dollar amount of a final payment that is contingent upon a pharmacy’s performance may be impossible on the remittance advice. It would appear that any performance-based payments or recoupments that rely on assessment of a pharmacy’s performance *after performing* necessarily would be prohibited. **The Maryland Legislature could have prohibited performance-based contracting between PBMs, PSAOs and pharmacies, but it declined to do so.** Instead, the legislature opted to ensure pharmacies have been notified of the contingent nature of payments under performance-based contracts. PCMA suggests clarification here.

Additionally, these requirements are inconsistent with current electronic claims (NCPDP) technical standards for adjudication and it would be difficult, if not impossible, to implement at the time of claims processing. PBMs do not have control over NCPDP fields or standardized claims processes and changes can require action by the NCPDP and federal Centers for Medicare and Medicaid. These proposed requirements do not take into account that pharmacies also opt to get electronic remittance advices called 835 files and those are accessed and populated in a completely different manner than paper remittance advices. Due to these technical issues, which are outside of the direct and exclusive control of PBMs, compliance with this requirement will be problematic if not impossible.

PCMA requests the following amendment, which ensures that pharmacies have agreed to performance metrics beforehand and are aware of the range of the potential adjustment:

- B. Except as provided in §§C and D of this regulation, a contracted pharmacy shall not be charged a fee or held responsible by a purchaser or PBM for:
 - (1) A fee or performance-based reimbursement related to an adjudicated claim; or
 - (2) An incentive program.
- C. A PBM, whether its contract is directly with a pharmacy or indirectly with a pharmacy through a PSAO or group purchasing organization, shall disclose any

fee or performance-based reimbursement that relates to the adjudication of a claim or incentive program by stating:

- (1) The specific dollar amount of a fee or alternative reimbursement; or
- (2) The specific percentage range of the potential adjustment relating to reimbursement of a claim based on contractually agreed to performance-based metrics.

D. The disclosure described in §C shall be provided:

- (1) During claims processing; or
- (2) Described in detail on the initial remittance advice.

.04 Internal Appeals Procedures

- Subsection (E) refers to substantive requirements relating to internal appeals. This section creates ambiguity around the existing appeals processes and timelines. The pharmacy has 21 days to appeal a reimbursement, and the PBM has 90 days to respond and 30 days to pay if a payment is due. It is unclear why there is a reference to 180 days and how it relates to the existing timeframes for appeals, processing, and payments. PCMA suggests deleting this section, as it is unnecessary.

.05 Complaint Process

- Subsection (B)(1) indicates that a contracted pharmacy may file a complaint with the Commissioner when the PBM's pricing does not comply with Title 15, Subtitle 16. However, unlike §15-1628.1, §15-1628.2 does not lay out any substantive requirements for contract provisions or standards for MIA review. PCMA notes that MIA indicated at the stakeholder meeting that it does not have authority to evaluate reimbursement amounts, but rather it can evaluate compliance with the contract terms and appeals procedures established.
- Subsection (B) and (C) requires a PBM to accept an appeal from a contracted pharmacy **or its designee**. The term "designee" should be more specific and refer to an entity that has contracted with the pharmacy to act on its behalf. PCMA suggests that the term "Contracted agent" (used in §15-1628.1(f)(5)(ii)(2)), relevant to MAC appeals) be used.
- Subsection (E)(2)(a) requires PBMs to provide a complete, unredacted copy of the applicable portion of the contract relating to the compensation program and "**any other contract** under which MAC pricing is determined." The statute requires PBMs to file contracts with pharmacies, PSAOs, or GPOs but does not specify "any other contract." This requirement is an expansion of the statute and should be removed.

Additionally, PCMA is unclear as to why an unredacted copy is necessary to file when the appealing pharmacy has already "provided a copy of the relevant contract or the provisions that are related to the MAC appeal" and the PBM is already required to provide a template contract to the department initially.

- PCMA suggests striking (E)(2)(a) because (E)(2)(b)-(e) provide the information that MIA needs for an appropriate review. In the alternative, PCMA suggests the following amendment:
 - (a) A ~~complete, unredacted~~ copy of the applicable portion of the participating pharmacy contract relating to the compensation program and the complaint filed with the Commissioner, including any other ~~contract under which the pricing information is determined~~ relevant price schedule.
- Both the statute and subsection (E)(2)(b) refer to “pricing information,” but PBMs are concerned about how “pricing information” is different than what is included in the compensation program (“pricing information” is part of the compensation program in §15-1601(c-2)), or the “mathematical calculation.” The rule should refer to the compensation program, mathematical calculation, or sources.
 - PCMA suggests the following amendment:
 - (b) A copy of the applicable source ~~and pricing information~~ used to calculate the pharmacy reimbursement amount.
- Subsection (E)(2)(f)(iii) of the proposed rule provides the commissioner authority to ask for any other information necessary to determine the PBM’s compliance with its **compensation program**. We are unclear what the distinction is between determining *compliance with the compensation program* and *determining compliance with the contract or law*. MIA evaluating a PBM’s compliance based on the applicable terms of the pharmacy contract and the law is sufficient, as these already encompass the information required to make a determination based on the complaint filed. PCMA believes this language is unnecessary, will cause confusion, and suggests striking (F)(2)(f)(iii).

Chapter 48 – Filing of contracts and amendments

.03 Submission requirements

- PCMA appreciates the filing deadline extensions provided through recent bulletins, but notes the most updated deadline is August 9, 2019, and this regulation has not yet been finalized. Section 15-1628 requires the Commissioner to “adopt rules to establish the circumstances under which the Commissioner may disapprove a contract.” PCMA does not see how the MIA may go forward with implementation without the rules being finalized and circumstances for disapproval established.
- Subsection (A) requires all contracts and amendments to be filed with the Commissioner. PCMA notes that at the stakeholder meeting on July 9, 2019, the MIA indicated that filing templates of contracts and Maryland regulatory compliance addenda will be sufficient. For ease of administration and streamlining the process, PCMA appreciates and supports this decision.

- Subsection (B) outlines the deadlines and procedural filing requirements. PCMA believes it is important to be clear on timelines and substantive filing requirements. PCMA notes that the MIA indicated during the July 9, 2019 stakeholder meeting that the timelines for gaining MIA approval of contracts and pharmacy notice timelines may run concurrently; however, if the MIA disapproves a contract, the timeline for pharmacy notice would stop and the 30 days will start again once the reason for disapproval is cured and the contract is approved.
- PCMA notes that this proposed rule does not establish a standard for the MIA to formally acknowledge the receipt of a PBM filing, to start the running of the clock for the review and approval. PBMs seek a streamlined approach to regulatory review and wants to achieve approval as soon as possible so as not to disrupt care for patients or any part of the pharmacy network. During the stakeholder meeting on August 13, 2019, the MIA indicated that a process would be established whereby notification of receipt may not be automatic, but the 30-day clock would start on the date the MIA receives the filing. PCMA appreciates this accommodation and supports an expeditious review.

.04 Noncompliant terms

- §15-1628(b)(2) provides for regulations to be adopted that establish the circumstances under which the Commissioner may disapprove a contract. There are multiple provisions in this section that set restrictions on PBMs and contracts, and thus are new policy proposals not contemplated by the legislature and that greatly expand the scope of the current statutes. Such mandates would substantially change the face of contracting, impact patient safety, and create government mandated reimbursement levels. None of these issues were included in the authorizing legislation and some of these subsections of the draft rule go well beyond the authority of the MIA to promulgate and therefore should be stricken.
- Subsection (A)(1) lists a host of statutory sections that the MIA is attempting to extend to PBMs through this rule. However, most of these statutory sections apply only to carriers or HMOs, and are not applicable to PBMs. Specifically, Insurance Article Title 15, sections 112, 112.2(a)-(e), 123(d), 1004, 1005, 1008(c), 1009, and Health General Article Title 19, sections 710(s) and 710(t). These sections do not apply to PBMs and to extend their reach to PBM contracts via rule exceeds the scope of those statutes and the statute this proposed rule is intended to clarify.
- Subsection (A) (2) sets forth the situations where a contract can be disapproved, including if the contract “does not disclose the **components of** the compensation program through which a reimbursement is set.” “Components of...” is new language that expands the reach of the statute. §15-1628, the statute on contract provisions that must be shared, requires “applicable terms, conditions, and reimbursement rates....” Not components of a compensation program. Though the mathematical calculation can go to MIA upon request, it is unclear what “components of compensation program” are as



compared to mathematical calculation, factors, sources, pricing, pricing information, etc. PCMA suggests consistency and clarity in the use of these terms.

- Subsection (A)(4) prohibits a PBM from reimbursing a drug “in an amount that differs...based on the identity of the wholesaler used by a contracting pharmacy for acquisition of the drug.” This appears to say that a PBM can’t reimburse a pharmacy based on a price offered by a wholesaler **that is different than the pharmacy used to acquire the drug**. This is a completely new substantive requirement for reimbursement levels (the price at which the pharmacy acquired the drug from the wholesaler), which the legislature did not adopt. The legislature adopted transparency provisions and requirements for appeals/complaints, but did not establish mandatory minimum reimbursement levels or mandate mathematical formulas. This provision establishes guaranteed profit for pharmacies and is cost-inflationary. It is both bad policy and not intended by legislature. PCMA suggests striking this subsection.
- Subsection (A)(5) indicates that a PBM may not “reclassify, etc.” adjudicated claims. This new substantive requirement is not in the statute and PCMA is unclear as to what this is referring. There is already a statute on what types of recoupments are allowed (§15-1631). PCMA suggests striking this subsection.
- Subsection (A)(6) indicates that a PBM may not require fees for inclusion in a provider panel. The legislature in 2019 enacted detailed legislation dealing with PBM fees assessed on pharmacies, which requires only enumeration and notice of fees related to adjudication of a claim. It did not choose to prohibit pharmacy network panel fees. Establishing this new substantive requirement is an expansion of the statute and should be stricken.

Other Concerns

At the July 9, 2019 stakeholder meeting, PCMA provided feedback on a broader issue that may arise when there is a pharmacy services administrative organizations (PSAO) acting as a contracting intermediary between a PBM and pharmacy. In these cases, the PSAO is contracted with both the PBM and the pharmacy, and the PBM has no insight into the terms of the PSAO-pharmacy contract. MIA indicates that it has no authority over PSAOs and cannot require PSAOs to file their contracts with pharmacies. PCMA is concerned that when the direct relationship is between the PSAO and the pharmacy (and not the PBM and the pharmacy), the PSAO itself may have contract terms, including compensation terms, that impact the pharmacy’s final reimbursement amounts. In these cases, the PBM does not have knowledge nor control over these terms. Those terms may be not be in the pharmacy’s best financial interests or may result in recoupments from contracted pharmacies in violation of the spirit of this statute. MIA acknowledged that PBMs will not be held accountable for contract terms between PSAOs and pharmacies that depart from the substantive provisions of this proposed rule. PCMA encourages the MIA to keep this in mind if there are concerns brought up by pharmacies that stem from these PSAO-pharmacy contracts.



Thank you for the opportunity to provide feedback on the proposal. Please contact me at 202-756-5743, or our Maryland-based counsel, Michael Johansen, if you have any questions about our comments.

Sincerely,

A handwritten signature in black ink that reads "April C. Alexander". The signature is written in a cursive style with a prominent initial "A" and a long, sweeping underline.

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