



August 9, 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 Stakeholder Draft

Dear Director:

I am writing to provide the Pharmaceutical Care Management Association (PCMA) comments on the Maryland Insurance Administration (MIA) draft rule dealing with pharmacy benefit manager (PBM) contract filings and reimbursement appeals. PCMA was involved in the legislative process as these bills were being debated and has participated in multiple stakeholder discussions led by the MIA. 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. 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 throughout the regulation, there is a disconnect between the statutes and the regulatory sections. The regulations should link directly to the statutes they are clarifying, and to those only. There are multiple sections in the regulation that have been duplicated, but the language contained in those sections isn't necessarily applicable given the unique statutory language in the section being clarified. There should not be any mixing of the issues. 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)(5) defines a fee or performance-based reimbursement as “**any adjustment** of an adjudicated claim....” This definition appears to make restrictions on fees or performance-based reimbursement apply to adjustments that have either up or downside risk. This effectively precludes any type of performance-based contract term, based on how the term is used later in the rule. In addition, this term should not be used in the MAC section of law. It relates only to performance-based contracts sections in the law (§1628.3), so does not need to be defined here. It should be defined under the rule provisions addressing performance-based contracts.



- Subsection (B)(5) 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)(8) establishes a definition for “MAC Complaint Form.” This definition is unnecessary and adding terms that are unnecessary will confuse regulated entities. PCMA suggests striking.
- Subsection (B)(10) defines “multisource generic drug” as “interchangeable biological product as defined in Health Occupations Article § 12-101, Annotated Code of Maryland and does not include a brand name drug as that term is defined in Health Occupations, § 12-504, Annotated Code of Maryland.” This definition appears only to mean biologics. PCMA suggests using a definition that includes small molecule generics.
- Subsection (B)(17) defines “pricing information” to mean modifiers or factors applied in the mathematical calculation to determine the payment to a contracted pharmacy. It is not clear what is intended by “factors” in pricing information.

.03 Disclosures to Pharmacy in Contract

- Subsections (B)(1)-(3) establish substantive requirements unrelated to *contractual disclosures* and should be removed or moved to the regulatory sections that address substantive requirements on PBMs related to MAC pricing updates and appeals.
- Subsection (B)(2) of the proposed rule adds the words “**and pricing**” after the term “MAC lists” – the lists for which PBMs must establish a process for pharmacies to access. The reason for these additional words is unclear. Without a reason for additional words, PCMA suggests consistency with the statute and thus, the deletion of “and pricing.”
- Subsections (C), (D), & (E) relate to fees and performance-based reimbursements and appears 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.

With regard to the language itself, the subsection indicates that a PBM must disclose the *specific dollar amount* or the *specific percentage of potential adjustment* relating to reimbursement of a claim on the initial remittance advice. The terms “specific dollar amount” and “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.

- At the very least, PCMA requests the following amendment, which does not cure the issue but clarifies the language:

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 disclosing:

(1) The specific dollar amount of a fee that ~~may apply~~ applies to the claim during claim processing; or

(2) The ~~specific percentage value~~ value of the potential adjustment ~~relating to the pharmacy's reimbursement based on contractually agreed to performance-based reimbursement metrics of a claim~~ on the initial remittance advice.

- Subsection (D) provides that "except for in subsection (E)," a pharmacy is not responsible for fee or performance-based reimbursement. Subsection (D) establishes the situations where a PBM is allowed to charge a fee or implement a performance-based contract term. Thus, (D) appears unnecessary if (E) is effective and enforced. PCMA believes that unnecessary language in rule will confuse both regulators and regulated entities and suggests striking the unnecessary language in (D).
- Subsection (E) establishes the situations where a PBM may charge a fee or performance-based reimbursement.

- (1) requires itemization during claims processing by specifically identifying the **actual alternative reimbursement** amount that will be reimbursed. “Actual alternative reimbursement” is language not in the statute and these new terms will cause confusion among regulators and regulated entities. In addition, given the current proposed definition of “fee or performance-based contract,” it appears to prohibit any up or downside risk of a performance-based contract. The legislature did not intend to outlaw performance-based contracts, but the operation of this language would necessarily prevent any retrospective, performance-based contract terms if final reimbursement amounts could not be determined at the time of claims processing (or on the remittance advice, as described below).
- (2) requires the “**amount provided at claims processing and the actual reimbursement amount of adjudicated claim.**” PCMA is concerned that there is no way for a post-performance adjusted payment ever to work. The final payment may be unknowable at the time of claims processing and would depend on whether the pharmacy met the agreed-upon performance metric. The legislature did not intend on eliminating the possibility for performance-based contract provisions that require a look-back period to evaluate performance.

.04 Internal Appeals

- Subsection (A), requiring written procedures on appeals, appears to be re-stated in subsection (B). For clarity, PCMA suggests striking (A) because it is unnecessary and duplicative of (B), which will cause confusion for regulators and regulated entities.
- Subsection (B)(2) requires appeal procedures to contain administrative safeguards that the **contract provisions have been applied consistently with respect to similarly situated pharmacies**. This appears to be a new substantive standard that does not exist in statute and goes beyond the intent of the law. PCMA notes that during the stakeholder workgroup on July 9, 2019, the MIA indicated its intent is to ensure that (1) the PBM has an appeals process in place, and (2) is complying with its appeals process.
 - PCMA suggests the following language to clarify this intent: (B)(2) Contain administrative processes and safeguards designed to ensure and verify that the MAC pricing was determined in accordance with the participating pharmacy contract and Maryland law, and that the contract provisions have been applied consistently with respect to similarly situated pharmacies with the written appeal procedures.

.05 MAC Complaint Process

- Subsection (D) requires that a PBM accept an appeal from a contracted pharmacy **or its designee**. The term “designee” is not used in the statute. Instead of creating a new term which may cause confusion for regulators and regulated entities, PCMA suggests that



the term "Contracted agent" (used in §1628.1(5)(ii)(2)(B), relevant to MAC appeals) be used.

- Subsection (F)(2) requires PBMs to respond to the MIA with specified information within **three business days**. The statute is silent on time period. PCMA understands that the information should be provided in a timely manner but believes three working days is too short of a timeframe to comply and believes seven working days is a more reasonable timeframe. In addition, the proposed rule uses both "working days" and "business days." For consistency, PCMA suggests the use of "working days."
 - PCMA suggests the following amendment: "(2) Within ~~three~~ seven ~~business~~ working days of receiving the Commissioner's notice, the PBM shall provide the Commissioner..."
- Subsection (F)(2)(a) requires PBMs to provide a complete, unredacted copy of contract 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 (F)(2)(a) because (F)(2)(b)-(e) provide the information that MIA needs for an appropriate review.
- Both the statute and subsection (F)(2)(b) refer to "pricing information," but PBMs are unclear what this term means, when used with "mathematical calculation."
- Subsection (F)(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 (F)(2)(f)(iii).



Chapter 47 – “Cost pricing and reimbursement other than MAC”

.03 Disclosures to Contracted Pharmacy

- Subsection (A)(1) requires that PBMs disclose the “applicable terms conditions and reimbursement rates, including (a) the sources; and (b) **the program, policy, or process.**” The language in (b) is not supported by the statute, and PCMA is unclear to what it is referring. §15-1628(a) requires the disclosure within specified timeframes of “applicable terms, conditions and reimbursement rates” but does not refer to a “program, policy, or process.” Neither does §15-1628.1, which requires in (b) that “sources used to determine maximum allowable cost pricing” and in (f), “a process to appeal, investigate and resolve disputes” be disclosed in the participating pharmacy contract.
 - PCMA suggests striking (A)(1)(b) or providing clarification that the “program, policy or process” in (b) is referring to a “process to appeal, investigate, and resolve disputes” as is required by statute.
- Subsections (B)(1) through (3) require updated pricing info every 7 days, a reasonable process for access to pricing, and for the PBM to use the updated pricing. This language is not in §15-1628.2 and is instead in the maximum allowable cost law. Updated pricing every 7 days is needed in MAC reimbursement methodologies because of frequently fluctuating pricing in the multisource generic drug market. It does not make sense for “other” reimbursements or drugs not on a MAC list that are contemplated by §15-1628.2. This is an expansion of the statute and should be stricken.
- Subsections (C), (D), & (E) relate to fees and performance-based reimbursements and appears 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 draft rule. As we noted above, this issue should be addressed in its own chapter to avoid confusion and provide clarity

With regard to the language itself, the subsection indicates that a PBM must disclose the *specific dollar amount* or the *specific percentage of potential adjustment* relating to reimbursement of a claim on the initial remittance advice. The terms “specific dollar amount” and “percentage of potential adjustment” are not in the statute and PCMA is unclear what these mean. 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. 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, PSAsOs 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 requirements do not take into account that pharmacies also chose 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.

- At the very least, PCMA requests the following amendment, which does not cure the issue but clarifies the language:

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 disclosing:

(1) The specific dollar amount of a fee that ~~may apply~~ applies to the claim during claim processing; or

(2) The ~~specific percentage value~~ value of the potential adjustment ~~relating to the pharmacy's reimbursement based on contractually agreed to performance-based reimbursement metrics of a claim~~ on the initial remittance advice.

- Subsection (D) provides that “except for in subsection (E),” a pharmacy is not responsible for a fee or performance-based reimbursement. Subsection (D) establishes the situations where a PBM is allowed to charge a fee or implement a performance-based contract term. Thus, (D) appears unnecessary if (E) is effective and enforced. PCMA believes that unnecessary language in the rule will confuse both regulators and regulated entities and suggests striking the unnecessary language in (D).
- Subsection (E) establishes the situations where a PBM may charge a fee or performance-based reimbursement.
 - (1) requires itemization during claims processing by specifically identifying the **actual alternative reimbursement** amount that will be reimbursed. “Actual alternative reimbursement” is language not in the statute and these new terms will cause confusion among regulators and regulated entities. In addition, given the current proposed definition of “fee or performance-based contract,” it appears to prohibit any up or downside risk of a performance-based contract. The legislature did not intend to outlaw performance-based contracts, but the operation of this language would necessarily prevent any retrospective, performance-based contract terms if final reimbursement amounts could not be



determined at the time of claims processing (or on the remittance advice, as described below).

- (2) requires the “**amount provided at claims processing and the actual reimbursement amount of adjudicated claim.**” PCMA is concerned that there is no way for a post-performance adjusted payment ever to work. The final payment may be unknowable at the time of claims processing and would depend on whether the pharmacy met the agreed-upon performance metric. PCMA believes the legislature did not intend on eliminating the possibility for performance-based contract provisions that require a look-back period to determine performance.

.04 Investigation of Appeals

- Section .04 is named “Investigation of Appeals.” For consistency and clarity that there are not two separate internal processes required (see “.04 Internal Appeals Procedures” referred to in MAC portion of rule), PCMA suggests that the term “Internal Appeals Procedure,” as used in the prior section of the proposed rule, be used.
- Subsection (A), requiring written procedures on appeals, appears to be re-stated in subsection (B). For clarity, PCMA suggests striking (A) because it is unnecessary and duplicative of (B), which will cause confusion for regulators and regulated entities.
- Subsection (B)(2) requires appeal procedures to contain administrative safeguards that the **contract provisions have been applied consistently with respect to similarly situated pharmacies**. This appears to be a new substantive standard that does not exist in current statute and goes beyond the intent of the law. PCMA notes that during the stakeholder workgroup on July 9, 2019, the MIA indicated its intent is to ensure that (1) the PBM has an appeals process in place, and (2) is complying with its appeals process.
 - PCMA suggests the following language to clarify this intent: (B) Contain administrative processes and safeguards designed to ensure and verify that the MAC pricing was determined in accordance with the participating pharmacy contract and Maryland law, and that the contract provisions have been applied consistently with respect to similarly situated pharmacies with the written appeal procedures.

.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 (D) requires that a PBM accept an appeal from a contracted pharmacy **or its designee**. The term “designee” is not used in the statute. Instead of creating a new term which may cause confusion for regulators and regulated entities, PCMA suggests that the term “Contracted agent” (used in §15-1628.1(5)(ii)(2)(B), relevant to MAC appeals) be used.
- Subsection (F)(2) requires PBMs to respond to the MIA within **three business days**, and provide the MIA with specified information. The statute is silent on time period. PCMA understands that the information should be provided in a timely manner but believes three working days is too short of a timeframe to comply and seven working days would be a more reasonable timeframe. In addition, the proposed rule uses both “working days” and “business days.” For consistency, PCMA suggests the use of “working days.”
 - PCMA suggests the following amendment: “(2) Within three seven business working days of receiving the Commissioner’s notice, the PBM shall provide the Commissioner...”
- Subsection (F)(2)(a) requires PBMs to provide a complete, unredacted copy of contract 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 is an expansion of the statute and should be removed.

Additionally, we are 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 this subsection because (F)(2)(b)-(e) provide the information that the MIA needs for an appropriate review.
- Both the statute and subsection (F)(2)(b) refer to “pricing information,” but PBMs are unclear what this term means, when used with “mathematical calculation.”
- Subsection (F)(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

.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 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 or 30 days have passed without a disapproval.
- 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 want 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 July 9, 2019, the MIA indicated that a process would be established that there would be a formal acknowledgement of receipt automatically generated upon receipt. PCMA appreciates this automatic acknowledgement and supports an expeditious review process.

.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)(3) requires a definition of multisource generic drug consistent with Chapter 46, but that definition appears to limit the definition to biologics. PCMA suggests providing a definition that includes multisource generic drugs that are small-molecule drugs.
- Subsection (A)(4) prohibits PBMs from requiring accreditation or credentialing of pharmacies except for the Medicare and Medicaid programs. This provision is not supported by statutory language and deviates from the intent of the legislation enacted by this legislature. This legislature acted on pricing transparency, providing contract information to MIA, registration, and an appeals process for pharmacies. Credentialing and accreditation programs are for verifying that a pharmacy is a legitimate business and is qualified to provide the services that it is required to provide under the contract. Accreditation is used to determine whether a pharmacy is capable of providing a higher level of service related to serving patients with complex conditions or taking certain high-cost drugs or drugs that require special handling that cannot be stocked in every pharmacy. Accreditation and credentialing are programs that help ensure a high level of quality for patients and the legislature did not adopt this policy. Please see the enclosed materials on the importance of accrediting pharmacies to ensure patient safety and streamlined access to specialty drugs.

At the July 9, 2019 stakeholder meeting, MIA provided §15-112 as justification for establishing this regulatory provision. Based on a plain reading of §15-112, which is about the establishment of carrier provider panels, this section was not drafted with an understanding or intent to impact pharmacy accreditation as it is not included anywhere in the statute and the credentialing requirements are not applicable here – this section was clearly drafted to focus on requirements of provider panels of medical professionals such as primary care providers. Pharmacy accreditation and credentialing requirements are different than medical professionals and are both critical components to ensuring



patient safety and quality of care. If the legislature had intended this section of the law to apply to pharmacy credentialing, the language of the statute would have clearly indicated this and differentiated it from medical provider panel requirements.

In all other states where this issue has been considered from a pharmacy perspective, it has been discussed at the legislative level as a unique policy issue. In Maryland, the General Assembly has considered the issue on many different occasions and chosen not to restrict PBMs from requiring pharmacies to be accredited. Even the MIA discussed in the 2017 stakeholder meetings that it did not have enough information on the matter of specialty accreditation to decide whether a restriction on requiring accreditation from multiple accrediting bodies was appropriate. It is unclear how the MIA moved from not having enough information on the matter to attempting to restrict *any* accreditation.

Finally, state licensure evaluations by the Board of Pharmacy do not include measures to validate a pharmacy's ability to comply with contractual provisions and regulatory requirements, such as inventory control for claim payment audits, quality management, liability, patient compliance and adherence, safety, clinical programs, etc. These are all components to an accreditation program. Therefore, such a new requirement as included in this draft rule would restrict the ability of health plans and employers to ensure that pharmacies are meeting such critical requirements through their network contracts. Based on all the above reasons, PCMA suggests striking this subsection.

- Subsection (A)(5) 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)(6) 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)(7) 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 about 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".

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

Enclosure

SPECIALTY PHARMACY: CREDENTIALING & ACCREDITATION



What Is a Specialty Pharmacy?

- Manages drug regimens — often for injectable or infusible drugs needing special handling — for those with complex, chronic diseases or rare medical conditions.
- Employs clinicians who educate patients on proper drug use (including injections) and manage side effects.
- Distribution of drugs for rare conditions to select pharmacies ensures their optimal use and is more efficient for manufacturers

Pharmacy Credentialing

- Credentialing is the process by which an organization obtains, verifies, and assesses a pharmacy's basic qualifications to provide patient care.
- PBMs and health plans typically require evidence of:
 - State licensure
 - Current federal DEA license
 - Current pharmacy malpractice insurance
 - Description of pharmacy services, hours and types of drugs regularly stocked
 - Photos with a GPS location to prove the pharmacy is legitimate
 - Electronic claim processing and e-prescribing capacity
- PBMs and health plans may have internal credentialing programs or may rely on third parties.

Specialty Pharmacy Accreditation

- **Accreditation** from a national body such as URAC or ACHC **demonstrates high standards of best practices**, including for patient care, proper drug handling and distribution, and home delivery of medications.
- **Accreditation assesses best practices** for:
 - Use of evidence-based practices and clinical decision support programs
 - Patient counseling and benefits coordination
 - Patient outcomes and quality of care
 - Many other clinical and patient care factors
- Accreditation is essential for demonstrating high expertise in caring for patients.
- Accreditation enables insurers to trust that accredited pharmacies are well qualified to care for these unique patients.



Pharmacy Accreditation: A Critical Tool for High Quality Patient Care

What is Pharmacy Accreditation?

- At its core, pharmacy accreditation focuses on the commitment of a pharmacy to meeting independently established standards that demonstrate a higher level of performance and patient care. An independent third party evaluates a pharmacy's quality of services and care against those standards and the pharmacy's ability to meet applicable regulatory requirements.
- Accreditation typically involves on-site surveys by qualified pharmacist surveyors and extensive document review, which assess best practices in multiple areas, including:
 - Comprehensive patient assessments;
 - Ongoing patient monitoring for drug interactions and other potential safety concerns;
 - Patient outcomes and quality of care;
 - Accuracy and turnaround time for dispensing prescriptions; and,
 - Protecting patient health information.

What Organizations Offer Pharmacy Accreditation Services, And What Other Health Care Entities Can Be Accredited?

- Several prominent national, independent organizations offer pharmacy accreditation services, such as:
 - The Joint Commission;
 - URAC;
 - The Accreditation Commission for Healthcare (ACHC); and,
 - The Center for Pharmacy Practice Accreditation (CPPA), which is a partnership established by the National Association of Boards of Pharmacy (NABP), the American Pharmacists Association (APA), and the American Society of Health-System Pharmacists (ASHP).
- Retail pharmacies are not being singled out for accreditation. Virtually every player in the health care delivery and reimbursement systems can be accredited (and some must be), from hospitals to health plans, laboratories, home care services, telehealth programs, PBMs, mail service pharmacies, and specialty pharmacies.



Why is Accreditation Particularly Important In Specialty Pharmacy?

- Specialty pharmacies manage drug regimens for patients with complex, chronic or rare conditions such as multiple sclerosis, hemophilia and cystic fibrosis, who often take multiple drugs for multiple conditions. They dispense drugs that often have unique storage or shipment requirements.
- Given this patient population, it is not only commonplace—but a best practice—for health plans and PBMs to require accreditation for specialty pharmacies to participate in their networks, where there is a greater need for robust infrastructure, such as nursing staff capacity and 24/7 access. These patient-centered services and coordinated benefit management strategies enhance adherence to prescribed drug therapies, improve the quality of care and reduce expenditures on unnecessary hospitalizations.
 - The number of accredited specialty pharmacies has been growing rapidly in recent years, with 550 specialty pharmacy locations being accredited by the end of 2017 by one of the accrediting organizations noted above, and another 179 accredited by two or more organizations. That total of 729 locations is almost double the number of accredited locations in 2015.¹

Why Should You Care?

- If you care about improved outcomes for patients and lower health care costs, then you should care about accreditation. You should question why pharmacies are pushing self-interested legislation to restrict or prohibit PBMs and health plans from requiring accreditation as a condition for participating in their pharmacy networks, when their own industry leadership groups, including the NABP, have partnered to establish an accrediting body (the CPPA). Why should pharmacies be accredited? To quote the CPPA, an “accredited pharmacy practice improves patient outcomes and contributes to overall lower healthcare costs.”²

¹ Drug Channels, 10 April 2018, <https://www.drugchannels.net/2018/04/exclusive-record-number-of-specialty.html>

² The Center for Pharmacy Practice Accreditation, <https://www.pharmacypracticeaccredit.org/>