January 10, 2020

OSI Records and Docketing
New Mexico Office of Superintendent of Insurance
Attention: Mariano Romero, Room 331
1120 Paseo de Peralta
PO Box 1689
Santa Fe NM 87504-1689
via email: docketfiling@state.nm.us

Dear Mr. Romero:

I am writing to provide the Pharmaceutical Care Management Association (PCMA) comments on the New Mexico Office of the Superintendent of Insurance's (OSI) proposed rule implementing SB 415 (2019) relating to pharmacy benefit managers, enacted earlier this year. PCMA is the national trade association representing pharmacy benefit managers (PBMs), which manage prescription drug benefits for large and small employers, health insurance carriers, labor trusts, government programs, and other payers.

At the outset, we note that SB 415 established licensing requirements and a number of other new requirements for PBMs. The proposed rule, however, includes a number of provisions that fall out of scope of the law, are unnecessary to implement the law, and create new substantive provisions that the Legislature did not adopt. As you know, OSI has rulemaking authority to implement the terms of provisions in the Insurance Code, however, that authority stops short of being able to adopt rules outside the scope of the statute.

As you know, no rule established by the superintendent "shall extend, modify, or conflict" with any provision of the Insurance Code.[1] A court shall set aside an administrative agency ruling if it is found to be: (a) arbitrary and capricious; (b) not supported by substantial evidence, or (c) otherwise not in accordance with the law. *Law v. New Mexico Human Services Dep't*, 2019-NMCA-066, ¶ 11, 451 P.3d 91, 97, cert. denied (Aug. 1, 2019). The courts have defined "arbitrary and capricious" as an agency action "which is unreasonable or does not have a rational basis and is the result of an unconsidered, willful and irrational choice of conduct and not the result of winnowing and sifting process. *Saenz v. New Mexico Dept. of Human Services, Income Support Div. ex rel. Human Services Dept*., 1982-NMCA-159, ¶ 13, 98 N.M. 805, 808, 653 P.2d 181, 184; see also *Rio Grande Chapter of Sierra Club v. New Mexico Mining Comm'n*, 2003-NMSC-005, ¶ 16, 133 N.M. 97, 104, 61 P.3d 806, 61 ("A ruling by an administrative agency is arbitrary and capricious if it is unreasonable or without a rational basis, when viewed in light of the whole record").

[1] NMSA § 59A-2-9.

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Our comments are outlined by section below, and we have noted the areas that have significantly deviated from the scope of the underlying statute as prohibited by § 59A-2-9. We appreciate the opportunity to submit comments on the proposed rule and would like the opportunity discuss our comments further before the rule is finalized.

13.10.30.7 Definitions

1. Section (A) defines the term "clean claim." PCMA objects to the inclusion of this term in this rule because it is not used in the PBM law that this rule is meant to enforce. Later in the rule proposal, OSI attempts to apply carrier claims payment requirements to PBMs, but there is no statute that applied the claims payment provisions directly on PBMs. PBMs pay claims in accordance with contract terms set by carriers that hire them to manage the prescription drug benefit. Carriers are highly regulated entities, and the compliance with the appropriate statutes and rules, depending on the type of product the PBM is serving (Medicaid, state employee plan, fully-insured plan, etc.), will flow through the carrier-PBM contract. This definition and the application of the claims provisions directly on PBMs is unnecessary. If OSI includes this definition, it should be consistent with the definition of "clean claim" in the statute.[2]

2. Section (B) defines the term "eligible provider," apparently to clarify the use of the term in the "clean claim" law. This definition is unclear. PCMA suggests striking because it appears to be an unnecessary term and the term is not used in the PBM statute or the proposed rule. In the alternative, PCMA suggests further clarifying as:

   > (B)"Eligible provider" is a pharmacy that: (1) is a participating provider ~~in a health benefits plan network~~; or (2) a PBM has credentialed after assessing and verifying the provider's qualifications; or (3~~2~~) a PBM ~~health benefits plan~~ is obligated to reimburse for claims in accordance with the provisions of 59A-16-21~~state and federal law~~.

3. Section (D) defines the term "health insurance carrier" or "carrier," but it is not consistent with the existing definitions in the Insurance Code.[3] For clarity and lack of confusion for regulated entities, PCMA recommends that the OSI use the same definitions.

4. Section (E) defines "health benefits plan" or "health plan," but the language is inconsistent with the use of those terms in other areas of the Insurance Code. PCMA suggests that the definition be amended for consistency with NMSA § 59A-16-21.1.

[2] NMSA 59A-16-21.1A. As used in this section:(1) "clean claim" means a manually or electronically submitted claim from an eligible provider that: (a) contains substantially all the required data elements necessary for accurate adjudication without the need for additional information from outside of the health plan's system; (b) is not materially deficient or improper, including lacking substantiating documentation currently required by the health plan; and (c) has no particular or unusual circumstances requiring special treatment that prevent payment from being made by the health plan within thirty days of the date of receipt if submitted electronically or forty-five days if submitted manually.

[3] *See* NMSA 59A-1-8(A), defining "insurer" as "every person engaged as principal and as indemnitor, surety or contractor in the business of entering into contracts of insurance," and NMSA 59A-46-2, defining "carrier" as a health maintenance organization, an insurer, a nonprofit health care plan or other entity responsible for the payment of benefits or provision of services under a group contract"

(E) "Health ~~benefits~~ plan" ~~or "health plan"~~ is a policy or agreement entered into, offered or issued by a health insurance carrier to provide, deliver, arrange for, pay for or reimburse any of the costs of health care services.

5. Section (F) defines the term "NABP" but this term is not used in the statute or anywhere in the rule. PCMA suggests striking this term and the definition.

6. Section (J) defines "participating provider" slightly differently than how it is used in other areas of the statue.[4] While this is not a significant concern, for clarity and avoiding confusion, PCMA suggests making the language consistent or striking the provision. The term is not used in the statute and the only place it is used is in the definition of "eligible provider" above. Also, it should be noted that the statute relating to PBMs refers to providers as "network providers" or "network pharmacy providers."

   For clarity and avoiding confusion, PCMA suggests consistency wherever possible and suggests the following amendment:

   J. "Participating provider" is ~~a pharmacy that, under an expresss contract with a health insurance carrier, or with its contractor or subcontractor, has agreed to provide pharmacy services to covered persons with an expectation of receiving payment directly or indicarectly from the carrier, subject to any cost-sharing required by a plan~~ an individual or entity participating in a health plan's provider network.

7. Section (L) defines "spread pricing," but this term is not used in the statute, nor is it needed to enforce the terms of the statute. The requirements proposed later in the rule are outside the scope of the statute, in contravention to NMSA § 59A-2-9, and thus a definition is not needed. The definition of the term itself is also not an accurate description of what "spread pricing" actually is. The statute was focused on PBM licensure, access to maximum allowable cost lists, and specified prohibited contract provisions. There is no mention of "spread pricing" in the statute. PCMA suggests striking this term.

8. Section (M) defines "similarly situated" but this definition is overly broad. The definition should refer to pharmacy providers that are subject to the same reimbursement, not the broader "pricing terms." Broader pricing terms could encompass more than being eligible to receive the same MAC amount under an appeal, which is how the term is used in the statute and elsewhere in the proposed rule.

   PCMA suggests the following amendment:

   M. "Similarly situated" refers to a pharmacy provider whose PBM contract is subject to the same reimbursement for a claim ~~pricing terms~~ as a pharmacy whose appeal was granted.

[4] *See* NMSA § 59A-16-21.1.

13.10.30.8 Requirements for Licensure

9. Subsection (A)(3) requires the PBM to provide contact information for responding to complaints. PCMA is concerned that providing a contact person for the OSI appears to be redundant to subsection (A)(4), and establishing a complaint process outside the scope of the existing contractual relationships is outside the scope of the statute, prohibited by NMSA § 59A-2-9. PCMA suggests striking (A)(3).

10. Subsection (A)(6) requires a background investigation report through a vendor approved by OSI. PCMA requests that the vendor be named in the rule so PBMs are on notice as to how to comply.

11. Subsection (A)(7) requires the PBM to provide information on refusal, suspension, revocation, etc. of a registration, license or certification. The information to be provided should be limited to the last five years, which the standard for industry regulations. PCMA suggests amending (7)(a) and (b) accordingly.

12. Subsection (A)(8) requests information about whether the applicant has ever had a business relationship terminated due to alleged fraud or illegal activities. We are concerned with the use of the term "alleged." While we do not condone fraud or illegal activities, it is possible for businesses that work together to sometimes disagree on perspectives. They could potentially end up in litigation over things neither one expected at the outset of the business relationship. While litigation can result in legal *findings*, allegations, however, are simply that—allegations. They are not legal findings. For clarity and objectivity, this term should be removed, and the standard should be: "terminated due to a legal finding or judgment of fraudulent or illegal activities." In addition, we believe there should be a time limit of 5 years to the look-back period.

    PCMA suggests the following amendment:

    A statement of whether the applicant ~~ever~~ in the most recent five years had a business relationship terminated for any ~~alleged~~ legal finding or judgment of fraudulent or illegal activities in connection with the administration of a pharmacy benefits plan and a description of each termination.

13. Subsection (A)(10) provides OSI with broad authority to obtain information from licensed PBMs. We understand that there will be times when additional information may be needed from a PBM to determine its compliance with the licensing statute. The authority should specifically indicate that the information being requested from the PBM is *relevant* to the enforcement of the *statute*. Any further requirement would be inconsistent with the underlying law.

    PCMA suggests the following amendment:

(11) Any other relevant information deemed necessary by the superintendent in evaluating the application to evidence compliance with Chapter 59A, Article 61 NMSA 1978 ~~or the requirements of rules promulgated by the superintendent~~.

14. The proposed rule does not clearly set forth due process rights in the event that OSI denies a license renewal. In addition, PCMA suggests clearer language on the deadline for submission of a license renewal.

    PCMA suggests the following amendment:

    D. License renewal. An application for renewal shall be submitted no later than ~~by~~ October 1 of each year. A renewal application shall include the non-refundable fee for annual continuation of a license required by Paragraph (2) of Subsection AA of Section 59A-6-1 NMSA 1978, as well as updates to any items required by the initial application for licensure. For disapprovals or denials of a renewal licensure by the superintendent, the superintendent will provide written notice to the applicant that the licensure renewal was denied and state the reason or basis for the denial, along with the right to adjudicatory proceedings, as required by NMSA 1978, §12-8.

15. The rule does not clearly outline due process rights in the event that negative action is taken against the license applicant during the initial review and application process.

    PCMA suggests the following language:

    F. Denial of a license application triggers due process requirements as outlined in NMSA 59A-4 et seq.

13.10.30.10 OSI Complaint Process

16. PBMs support—and have existing processes for—pharmacies being able to appeal reimbursements and communicate with the PBM regarding disputes. However, the proposed rule establishes a new complaint process that is not contemplated by the statute, including the ability to circumvent existing, contractually agreed-to complaint processes. This complaint process can lead to enforcement proceedings for the PBM, but it is unclear where the authority to do so exists. PCMA strongly objects to the creation of this new OSI complaint process that is outside the scope of the law as prohibited by NMSA § 59A-2-9 and interferes with existing private contracts. Without further explanation about the statutory authority and rational basis for creating this complaint process it is difficult to know how this is linked to the statute, especially since there was no discussion of this in the legislative arena.

    Without having an opportunity to discuss with the OSI about the underlying problems it is trying to address (and having not discussed a proposed complaint process in the legislature), it is difficult to suggest an appropriate alternative. Because this addition is arbitrary and not based on the underlying statute (which is focused on licensure, MAC

reimbursement list transparency, and specified contract terms), PCMA suggests striking this section from the regulation. However, we would like the opportunity to talk with the OSI about the underlying concerns and to educate the OSI as to existing procedures for pharmacies to lodge complaints or reimbursement appeals.

13.10.30.11 Payment of Claims

17. PBMs support timely payment of claims and this is part of the standard process for PBMs as they serve their clients in various commercial and public programs. However, including this in the regulation is an expansion of the statute. This requirement was discussed at length in stakeholder meetings during the legislative process, and a previous draft of the legislation had requirements for prompt payment. The group discussed that these provisions were not needed because there is already prompt payment statute in place and the PBMs as a downstream entity of carriers fell under that statute. This rule is arbitrarily extending the terms of the statute to PBMs, which is unnecessary, because to the extent the PBM is serving a plan covered by this statute, these timely claims payment requirements would already flow through to the PBMs through its client contracts. This is another area that the OSI has exceeded its statutory charge, as prohibited by NMSA § 59A-2-9, especially because this was discussed during the process and the legislature chose not to include it. PCMA suggests that this requirement be stricken.

13.10.30.12 Maximum Allowable Cost Appeals

18. Section (A) establishes the right of the pharmacy to file a MAC appeal through a PSAO. PCMA suggests clarifying the timeframes in the rule.

    PCMA suggests the following amendment:

    A. Submission of appeal. A pharmacy may submit a MAC appeal <u>within 21 business days after a pharmacy receives notice of the reimbursement amount</u> through a PSAO or directly to the PBM.

19. Section (B) establishes business hours for the phone number to be manned to deal with MAC appeals. The business hours proposed – 8:00 – 5:00 p.m. Mountain Time – are inconsistent with some companies' existing business hours for these purposes. PCMA suggests that instead, the licensees be able to set an 8 hour timeframe that is clearly stated so network pharmacies are notified as to the operating hours. In addition, the statute calls for an email address or website for the purpose of submitting appeals. PCMA suggests consistency with the statute (NMSA § 59A-61-4(D)(5)).

    B. Appeals mechanism. A PBM shall provide a mechanism for submitting MAC appeals, including the dedicated phone number pursuant to Paragraph (5) of Subsection D of Section 59A-61-4 NMSA 1978. The phone number shall be manned at a minimum during ~~the hours of~~ <u>8 hours per business day that is clearly stated so network pharmacies are notified of operating hours</u>~~:00 a.m. to 5:00 p.m., mountain time~~. Information about MAC appeals mechanisms shall be

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included~~prominently displayed~~ in any contract or manual provided by a PBM to a pharmacy.

20. Section (D) Response to appeal. PCMA is concerned about the language used throughout section (D). The language should be consistent with the statute—the information that needs to be provided to the pharmacy is only in the case of a *denied* MAC appeal, not every appeal.

    The reference in subsection (D)(1) to "source or sources used" should be stricken because it is not triggered by the appeals process (*See* NMSA § 57A-61-4(D)(1), indicating that as part of its general MAC pricing policy, the PBM must provide this information upon the network pharmacy's request). The language "to determine pricing for the MAC list specific to that provider" and "how it was applied to the MAC price at issue" should be stricken as well, because the words are inappropriately governing appeals and they go beyond the statute, as prohibited by NMSA § 59A-2-9. The statute is silent on providing information related to *how* the sources were applied to the MAC reimbursement. PCMA suggests that the language be amended for consistency with the statute at 59A-61-4(D).

    Subsection (D)(2) requires the response to a MAC appeal with the "date of the last update" of the MAC list for that drug. While MAC lists must be updated at least every 7 business days according to the statute (59A-61-4), this information is not required to be provided to the pharmacy upon denial of the MAC appeal. In addition, PBMs do not necessarily keep track of the timing of updates by individual drug, so pulling the information for complying with this term may be impossible. Thus, this provision should be stricken.

    Subsection (D)(3) is problematic because PBMs do not have insight into individual pharmacy purchasing ability and cannot document what individual pharmacies can purchase and for what rate. Pharmacy purchase prices from wholesalers are private business arrangements between pharmacies and wholesalers. PBMs are unsure how to comply with this provision and suggests that it be stricken.

    PCMA suggests the following amendment to Section (D) to ensure consistency with the statute:

    D. Response to a denied appeal. The PBM's response to a denied MAC appeal shall include:
    (1) the ~~source or sources used, including~~ NDC and name of supplier that has the product available for purchase in New Mexico at or below the maximum allowable cost~~, to determine pricing for the maximum allowable cost list specific to that provider and how it was applied to the maximum allowable cost (MAC) price at issue~~;
    ~~(2) the date of the last MAC list update for the drug which is subject of the MAC appeal;~~

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~~(3) documentation evidencing that the drug was available for purchase by a pharmacy in New Mexico at the MAC price from a national or regional wholesaler at the time of claim submission;~~
~~(4)~~ (2) any other information the PBM deems relevant to the MAC appeal.

21. Section (E) provides for a default reimbursement rate when the PBM does not comply with the timeframes for MAC appeals, set at the NADAC amount. PCMA does not object to the MAC appeal being granted if the PBM fails to meet the timeframes, as required by the statute. However, the statute does not call for the OSI to establish reimbursement rates and thus, this requirement is an expansion of the statute as prohibited by NMSA § 59A-2-9. From a policy perspective, the default rate is inappropriate. There may not be a NADAC price for every NDC, and NADAC is not necessarily a reliable benchmark for reimbursements. NADAC is a voluntary survey conducted by the Centers for Medicare and Medicaid Services and NADAC prices do not take into account off-invoice discounts that the pharmacy received from its supplier and reduce the pharmacy's net cost for the drug. These discounts reduce the net cost of the drug to the pharmacy, so a NADAC price may be inflated over the pharmacy's actual cost. Regardless, licensed PBMs should be complying with the law and providing a default rate in the event they violate the statute seems counterproductive. The OSI has sufficient enforcement mechanisms if a PBM has failed to comply with its statutory obligations and conditions of licensure. PCMA suggests that the second sentence of (E) be stricken and the following amendment to be made for clarity on timing.

    E. Nonresponse to appeal. The MAC appeal shall be deemed granted if the PBM does not respond within 14 <u>business</u> days pursuant to Paragraph (6) of Subsection D of Section 59A-61-4 NMSA 1978. ~~The PBM shall pay the MAC appeal at the NADAC price in effect on the date of the fill plus any contracted dispensing fee~~.

22. Section (F) indicates that within one day of granting an appeal, the PBM shall notify the pharmacy and similarly situated network pharmacies and their PSAOs that a MAC appeal was granted. The proposed rule appears to combine some of the statutory requirements into one section (F). PCMA suggests that for clarity, the terms and process used in the regulation match the terms and process outlined in the statute.

    NMSA 59A-61-4((D)(7)) requires the PBM to do three things: (1) *notify* the challenging pharmacy and its PSAO that the appeal is granted; (2) *make the change in MAC effective* for the appealing pharmacy and each other network pharmacy; (3) *Permit the appealing pharmacy to reverse and rebill the claim.* (D)(9) also requires the PBM within one *business* day of granting or denying a network pharmacy's appeal, notify all network pharmacies of the decision, and (D)(10) requires the PBM to "*allow other similarly situated network pharmacies to reverse and rebill* again for like claims that formed the basis of the granted appeal." Although we believe that it is unnecessary to re-state statutory requirements in regulation, if the sections are going to be restated, we suggest mirroring the actual language in the statutory sections (D)(6)-(11) to be clear that the rule is consistent.

PCMA suggests the following amendment:

F. Notice of granting an appeal.
(1) If a MAC appeal is granted or deemed granted, a PBM shall, ~~within one day~~, notify the challenging pharmacy and ~~any similarly situated network pharmacy and their~~ its PSAO~~(s)~~, if any, that ~~a~~ the ~~MAC~~ appeal was granted~~,~~ and ~~update~~ make the change in the maximum allowable cost effective for the appealing pharmacy and for each other pharmacy in its network, and permit the appealing pharmacy ~~and any similarly situated pharmacy~~ to ~~resubmit~~ reverse and rebill the claim ~~at the updated price~~ or claims that formed the basis of the appeal.
(2) Within one business day of granting or denying a network's pharmacy appeal, notify all network pharmacies of the decision.
(3) Upon granting an appeal, allow other similarly situated network pharmacies to reverse and rebill again for like claims that formed the basis of the granted appeal.

23. Section (G), relating to failing to respond to an appeal, appears to restate the requirement outlined in (E), which we believe is an expansion of the underlying law as prohibited by NMSA § 59A-2-9. PCMA reiterates its comment on (E) here. PCMA suggests striking section G.

24. Section (H) requires the PBM to provide a reimbursement list to a pharmacy or superintendent with seven business days. The rule should be clear that the reimbursement list is a MAC list.

    PCMA suggests the following amendment:

    H. Request for maximum allowable cost ~~reimbursement~~ list. A PBM shall provide access to a maximum allowable cost ~~reimbursement~~ list to a each of its network pharmacies or the superintendent within seven business ~~seven~~ days upon request.

13.10.30.13 – Submission of a MAC Appeal

25. Section (A) outlines the requirements for a "complete" appeal. Specifically, subsections (A)(6) and (7) call for drug name and drug strength to be on the appeal, respectively. These elements are unnecessary to list out separately as the NDC and other information listed provide sufficient information to identify the claim appealed. In addition, subsection (A)(8) indicates that a pharmacy would be required to submit the "purchase price of drug." Pharmacies receive discounts on the purchase of drugs that are not reflected on the invoice price and the net price should be reported.

PCMA requests that (6) and (7) be stricken, and (8) be amended to reflect off-invoice discounts by amending the language as such:

(8) net purchase price of drug (whole dollar with two decimal places)

26. PCMA is concerned that the list provided is not exhaustive of the information that would be required to complete an appeal. Information such as contact information, carrier, ID number, and provider number (PCN) are all elements that would need to be provided to process an appeal. It is possible that additional information could be needed in the future. While PBMs do not want to serve as a barrier to pharmacy appeals, it is important that the *necessary* information is provided.

    To reflect the need to obtain the appropriate information necessary to process the appeal, PCMA suggests that an additional element be listed:

    (12) any other data necessary to file an appeal, as required by the PBM-Pharmacy or PSAO contract.

27. Section (B) limits the PBM from requiring additional information to process a MAC appeal. Because of the additional fields of information that the PBM may need to process an appeal, PCMA is concerned about this provision. While we do not want to construct barriers to appealing reimbursements in the event the PBM has missed the mark significantly on reimbursement, there may be information that OSI is not considering during this rulemaking that may be necessary for processing of an appeal, either now or in the future. Setting a requirement without leaving any opening for change eliminates the ability to be nimble and respond to industry evolution. We understand that PBM requests for information would need to be necessary to process the appeal and to avoid unnecessary requests that construct barriers to processing an appeal. Thus, PCMA suggests striking this subsection, or amending to ensure that the PBM is able to obtain other information that is necessary to process the appeal.

    PCMA suggests the following amendment:

    B. No additional information required. A MAC appeal shall be deemed complete if it contains the information contained in Subsection A of this section. A PBM shall ~~not~~ only require or request additional information if it is necessary in order to process the appeal.

13.10.30.14 – Searchable Online Database of Drug Prices

28. The underlying statute this proposal is implementing requires PBMs to provide OSI the MAC list and sources upon request, not access to a searchable online database. This is a significant expansion of the statue prohibited by NMSA § 59A-2-9, overly prescriptive as to the mechanism to provide information on MAC lists, and it is unclear whether any current PBM system would support such a process. In addition, the superintendent would not have the plan-specific information needed to look up the relevant maximum allowable cost for a particular drug. Finally, the searchable database is unnecessary, as

there OSI may simply make a request directly to the PBM as allowed by statute. The statute was intentionally made not prescriptive on the mechanism for sharing the information, as long as it is prompt (*See* NMSA § 59A-4-3). PCMA would like to work with OSI on detailing a simple mechanism to promptly provide this information if the OSI requests it.

In addition, some of the subsections within this section are concerning from a systematic perspective. First, under "search requirements" (C), it is unclear what is meant by "date of fill" in a searchable database of drugs and reimbursement rates. "Date of fill" would be an element for a specific claim (a field on a claim), but not for a general MAC list search. A pharmacy would be using this portal to review current MAC list reimbursement rates so "date of fill" will be irrelevant to the search. Therefore, we request that this requirement be stricken.

Also, some of the elements of (D)—the "drug information" required to be maintained—do not make sense. Specifically, requiring the NADAC amount (4) is irrelevant to the contractual pricing amounts between a PBM and a pharmacy or its PSAO. NADAC is a survey managed by the Centers for Medicare and Medicaid Services, and is not a data set managed by PBMs or necessary to maintain for the processing of all prescription drug claims.

Section (E) requires the PBM to have instructions for searching the MAC list and instructions for "requesting the sources used to establish the MAC price." PCMA does not object to the requirement that instructions for requesting the sources be provided to pharmacies. We do, however, support consistency with the statute in the language used, and the introduction of new terms to be avoided.

Finally, subsection (F) requires a "prominent link to request the sources used to establish the MAC price." We believe this is too prescriptive of a requirement. As required in subsection (E), the explanation on how to receive the sources, if they are not already provided in the provider manual, as some PBMs do currently, is already required in the provider manual. Again, network pharmacies have access to real-time reimbursement amounts *at any time*, and the licensed PBMs will provide the information required by the statute to the superintendent upon request.

PCMA suggests the following amendment to this section:

13.10.30.14 SEARCHABLE ONLINE DATABASE OF DRUG PRICES:
A. Update timeframe. A PBM shall update its MAC list at least once every seven days pursuant to Paragraph (2) of Subsection (D) of Section 59A-61-4 NMSA 1978.
B. Searchable Online database required. A PBM shall establish a searchable online database that will allow a pharmacy ~~and the superintendent~~ to search MAC list prices for a particular drug. The PBM's provider manual shall include instructions for accessing the price list on their website. The provider manual shall be transmitted to a newly joined pharmacy within 10 business days from the date of execution of a contract with the PBM. A PBM

shall provide an updated version of its provider manual within 30 days of any revisions to all network pharmacies.

C. Search requirements. The database shall be searchable by NDC ~~or drug name, and date of fill for~~ and a specific network plan identifier.

D. Drug information. The information provided for the drug shall contain:

(1) NDC;
(2) NDC description;
(3) MAC list price;
~~(4)~~ ~~NADAC price per unit; and~~
(5) ~~effective date~~.

E. Instructions Required. The provider manual shall contain instructions for searching the MAC list and contain instructions for requesting the sources used to ~~establish the MAC price~~ determine MAC pricing for the MAC list. A network pharmacy may request the sources through a PBM's website, e-mail, facsimile or letter if they are not already included in the provider manual. The PBM shall respond with ~~each derivative~~ the sources within ten business days from the date of the request.

F. Website requirements. The PBM's website shall contain a ~~prominet~~ link to request the sources used to determine the MAC pricing for the MAC list~~establish the MAC price~~, if the sources are not already included in the provider manual or listed on the PBM's MAC website.

13.10.30.15 Historical MAC List Database

29. The proposed rule creating a requirement to develop an historical MAC list database is a new substantive requirement not contemplated by the statute, in contravention to NMSA § 59A-2-9. While we understand the importance of ensuring pharmacy access to current reimbursement rates so they know what they will be reimbursed for dispensing drugs to plan enrollees, requiring the PBMs to develop a unique historical record of all MAC reimbursement rates for the previous five years is a significant overreach. There is no explanation of why this would be needed, especially since pharmacies have a limited, specified time period for filing appeals.

    The amount of data that is required by this regulation is excessive. There are thousands of generic drugs that could be eligible for inclusion on a MAC list, and generic drug prices can fluctuate as often as daily, depending on the market dynamics for that drug. Having to maintain a database for five years of price fluctuations would take significant resources to develop, and the value to anyone, including pharmacies and OSI, is dubious.

    States that have instituted appeals or complaint processes for pharmacy reimbursement have seen an extremely low number of appeals. The work that would be required to set up a system like this with no real value, and not required by the statute, would be a significant waste of resources. In addition, it is unclear what value tracking the reasons drug are removed from the MAC list would have, or the date they came on to the list, came off the list, or became obsolete, especially for a five-year period.

It is also unclear where the statute requires a PBM's provider manual to contain instructions for accessing the list of drugs removed from its MAC list. A MAC list is a list of drugs for which reimbursement is eligible under a particular plan. If a drug is not on the list, it does not meet the requirements of the statute or there is another reason, and it is not eligible for reimbursement. The only statutory requirements on whether or not a drug is eligible to be on a MAC list are those listed in the statute. If the drug does not meet the requirements of the statute, it cannot be on the MAC list. Outside of that, the statue is silent on "why" a drug is on a MAC list.

To the extent that pharmacies claim they need this type of information, If pharmacies want to track the reimbursements they've received over a period of five years for dispensing drugs to plan enrollees covered under this statute, they have the ability to do so with the information they currently have. They also know what they've paid their suppliers for the drugs, so they can do analysis for their own businesses about costs and revenues. It was not the intent of the legislature to create a way for PBMs to provide the IT systems to support business analytics for pharmacies, but this is what this regulatory proposal seeks to do.

We are similarly confused about how this historical database would be necessary or helpful to OSI to enforce the terms of the statute. There was no discussion in the legislature of policy reasons for this type of information and no expectation of having this information be required.

Finally, subsection (F) indicates that the superintendent and network pharmacies shall have access to this database. The statute says that the MAC list needs to be available to pharmacies and OSI upon request. There is no requirement that historical data like this be provided.

This is the type of information that the legislature could have made the policy choice to require, but it did not. It is a clear extension of the statute as prohibited by NMSA § 59A-2-9. For the reasons stated above, PCMA strongly objects to this entire section and requests that this section be stricken.

13.10.30.16 Annual Report by PBM

30. Again, it is unclear where the statute establishes a requirement that a PBM submit an annual report regarding the items listed in the proposed rule. The only reporting requirement PBMs included in the statute was for network adequacy. The legislature had the opportunity to make a policy decision to require other types of reporting as it drafted its MAC, appeals, and licensure law, but it opted not to. Much of the information proposed to be required is confidential and proprietary, and it is unclear what the OSI will do with the information if it's submitted.

31. Subsection (B)(8) requires a PBM to report a description of the carrier's method of informing covered persons of changes to the drug formulary. It is unclear why this requirement would fall to the PBM and not on the health carrier, since the carrier maintains all enrollee notification responsibilities.

32. Subsection (B) (9) requires PBMs to annually report the contract templates for pharmacies, provider manuals, and carriers. This request is outside the scope of the statute. If the legislature intended to require submission of contracts, it could have, but it opted not to. In addition, PCMA is not aware that there are "templates" for carrier contracts. Each carrier determines unique contract provisions for its PBM if it chooses to hire one.

33. Subsection (B) (10) requires the PBM to report information regarding the enrollee population for the health carriers it is providing services for. This information is duplicative of the information already being provided to the OSI by the health carriers. This is unnecessary information and will be out of context with the rest of the health benefit. PCMA objects to this reporting requirement and requests that it be stricken from the rule.

13.10.30.17 Retaliation

34. This section establishes a vague standard ("a pattern") where it is unlawful to audit pharmacies under certain circumstances. PCMA is concerned about ensuring that there are not barriers erected to the ability finding fraud, waste, and abuse. One of the important functions of a PBM is to audit pharmacies and try to ensure that the pharmacies in the network are not acting fraudulently or doing other things in contravention to the requirements of the plan or the program the PBM is serving. Plans that choose to work with PBMs to perform these functions rely on them to help ferret out fraud, waste, and abuse. Establishing a vague standard that provides no reasonable notice as to what might be a "pattern" is unreasonable. Auditing laws have been in place for years and they are meaningful activities that PBMs provide, to identify anomalies and outlier service providers. This section appears to be punitive in nature, is arbitrary, not supported by any sort of evidence that it is needed, and out of the scope of the statute in contravention to NMSA § 59A-2-9. PCMA suggests striking this section.

13.10.30.18 Audit

35. The proposed rule indicates that the superintendent has the authority to examine audits of pharmacies conducted by PBMs to determine whether they are in compliance with NM audit laws. The existing audit law is not in the Insurance Code and the OSI does not have authority to enforce this section of the law, and in doing so, would be arbitrarily extending its jurisdiction. PCMA objects to this provision and suggests striking subsection (B).

13.10.30.19 Compensation

36. These two provisions do not seem to be consistent and it is unclear what the intent is. On one hand the plan may not work with a PBM that isn't licensed, but on the other hand, the PBM must pay pharmacies regardless of being licensed. A PBM is only paying pharmacies if it is providing services to a carrier (or other) client. PCMA suggests striking this section.

13.10.30.20 Responsibilities of the Health Insurance Carrier

37. PCMA is not concerned with the underlying intent of these provisions, which appears to be to ensure that the plan retains the ultimate responsibility of any services it relies on a PBM to deliver. However, we are concerned that by listing out the elements of oversight the OSI will inadvertently miss some necessary elements of plan oversight. It is standard practice for the carrier to retain responsibility for any and all functions that it chooses to contract out to a PBM, because the carrier cannot relieve itself of its legal/regulatory obligations regardless of whether it chooses to provide those services directly (in house) or it contracts with a PBM to provide those services. PCMA suggests that to be clear that the plan retains responsibility for all services, in every case, the language of the rule should be clear and broad.

    For clarity, PCMA suggests the following amendment:

    A. Oversight required. ~~If a health insurance carrier utilizes the services of a PBM, the carrier shall ensure an adequate pharmaceutical network, timely and fair claims payment to pharmacies, appropriate appeals procedures, and lack of retaliation against pharmacies and appropriate formulary development and tier structures.~~ Assignment of the responsibilities of the carrier to a PBM as to any ~~of these~~ matters shall be set forth in the written agreement between the PBM and the carrier.

38. Subsection (C) requires a health plan to maintain documents for a specified time period. PCMA suggests that the language be clarified to require the carrier to produce relevant records to ensure compliance with the statute.

13.10.30.21 Maintenance of Information

39. This section requires the PBM to maintain its records in accordance with the timeframes and requirements outlined in this section. PCMA requests that clarification be made within the rule that the records that are the subject of this rule are those relevant to enforcement of the underlying statute. In addition, PCMA suggests clarifying information that clearly articulates protections around trade secrets and proprietary information.

    PCMA suggests the following amendment:

    Every PBM shall maintain…adequate books and records of all transactions <u>governed by the Pharmacy Benefits Manager Regulation Act</u> between it, health insurance carriers and pharmacies. Such books and records shall be maintained in accordance with prudent standards of insurance record keeping. The superintendent shall have access to such books and records for the purpose of examination, audit and inspection. Any trade secrets, <u>as defined by §57-3A</u> contained therein shall be deemed confidential, except that the superintendent may use such information in any proceedings instituted against the PBM. <u>However, the superintendent must take necessary steps to ensure that the PBM's trade secrets are not publicly disclosed in any administrative or other legal</u>

proceeding. Specifically, the superintendent must ensure that trade secrets are not included in any public motions, reports and/or recommendations, and/or findings of fact. Necessary steps include, but are not limited to, redacting trade secrets and/or filing documents containing or attaching trade secrets under seal. The health insurance carrier shall retain the right to continuing access to such books and records to permit the carrier to fulfill all of its contractual obligations to insured persons, subject to any restrictions in the written agreement between the insurance carrier and the PBM regarding the proprietary rights of the parties in such books and records

13.10.30.22 Discrimination Prohibited

40. PCMA supports the underlying intent of this section but believes that federal law in this area already applies and this section is unnecessary.[5] PCMA suggests striking this provision.

Thank you for the opportunity to provide comments on this proposal. Please contact me at aalexander@pcmanet.org if you would like to discuss our comments further. Thank you.

Sincerely,

April Alexander
General Counsel and Vice President, State Regulatory Affairs

[5] 42 U.S.C. § 18116

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