PCMA

January 29, 2016

Ms. Roseanne Mead
Iowa Securities and Regulated Industries Bureau
Iowa Insurance Division
Two Ruan Center, Fourth Floor
601 Locus Street
Des Moines IA 50319

Via email: roseanne.mead@iid.iowa.gov

Re: Discussion Draft of Notice of Intended Action to Amend Chapter 59, "Pharmacy Benefits Managers," Iowa Administrative Code

Dear Ms. Mead:

The Pharmaceutical Care Management Association (PCMA) is submitting the following comments for consideration as the Insurance Division (Division) develops amendments to Chapter 59 related to Pharmacy Benefits Managers (PBMs). PCMA is the national trade association representing America's PBMs, which administer prescription drug plans for more than 253 million Americans with health coverage provided through Fortune 500 employers, health insurance plans, labor unions, Medicaid managed care, and Medicare Part D.

Thank you for the opportunity to provide comments on the Division's discussion draft. This letter will first address the procedural posture of *PCMA v. Gerhart* and concerns over the Division's interpretation of its authority under Section 510B, given the District Court's narrow construction of Section 510B.8. Finally, it will address PCMA's concerns with the remainder of the proposed regulatory language.

***PCMA v. Gerhart* Ruling and Ongoing Litigation**

PCMA believes that it is questionable whether the Commissioner has the authority to promulgate these regulations in light of the narrow construction given to Iowa Insurance Code Section 510B.8 by the District Court in *PCMA v. Gerhart*. Not only does the proposed rule appear to ignore Judge Jarvey's opinion, it takes an incorrect position on the status of the litigation.

In its December 10, 2015 communication, the Department characterized the ruling as ending the litigation and upholding the law unchanged, apparently justifying the adoption of a rule that will significantly expand the requirements related to maximum allowable cost (MAC) pricing. That characterization simply is not accurate. As the IID is aware, the District Court indicated that the statutory language on which these proposed administrative rules are based is "so confusingly written that it defies a reasonable interpretation" and makes "determining what it affirmatively requires nearly impossible." The Court ultimately concluded that Section 510B.8 places no substantive limitations on MAC pricing and only requires PBMs to disclose certain MAC pricing information. It also appears that the statute only survived PCMA's legal challenge because of the District Court's narrow construction. That ruling is now being appealed, so clearly the litigation has not ended. Because there is still an appeal pending, status of the substantive requirements of the statute relating to MAC pricing are still very much in doubt. Until

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the Court of Appeals has an opportunity to review the rulings by the District Court, the IID's attempt to expand those substantive limitations on MAC pricing through new administrative rules is premature.

Comments on Proposed Expansion of the Commissioner's Authority

Considering the rulings by the District Court that construed Section 510B.8 narrowly, PCMA is concerned that the discussion draft proposes improper expansions to the Commissioner's authority. These proposed expansions are evident in several sections throughout the proposed regulation:

a. Proposed subrule 59.10(4)(d) states that Section 510B.8(2) permits PBMs to "establish MAC amounts…" However, the District Court's order narrowly construed the statute—supported by the language of the preamble of Section 510B.8(2) referencing "disclosure"—to have no substantive requirements, "aside from its requirement that PBMs utilize nationally-recognized data." It is unnecessary for the Division simply to re-state the language of the statute, particularly if it is being done to imply that the language permits substantive regulation beyond the Court's order.

b. Proposed subrule 59.10(4)(e) refers to a requirement that PBMs submit MAC "amounts" in Section 510B.8. There is no such language in Section 510B.8. The statute requests only information related to the *methodology*, not actual "amounts" or prices.

c. Proposed Section 59.10(4)(e) attempts to establish substantive rules about how MAC prices are determined. The proposed requirement that MAC prices be "available at that price" to multiple pharmacies in Iowa is an expansion of the statute's language, which requires only that disclosure is made of certain data sources upon which MAC prices are developed. In the statute, the term "available for purchase locally" modifies the term "drugs," not the term "prices." Nowhere in the statute does it set a requirement that a particular product is available at a particular price. This is a new substantive requirement that falls outside of the District Court's order, which states the only substantive requirement is that PBMs use nationally-recognized data in determining reimbursement amounts.

d. Proposed subrule 59.10(4)(e)(3) requires a PBM to disclose to the Commissioner, 90 days prior to use, any data source on which it establishes maximum reimbursement amounts that differs from data sources disclosed previously. However, section 510B.8 does not require the filing of MAC pricing information *prior to use*. This requirement is substantive in nature and is inconsistent with the interpretation of Section 510B.8 in *PCMA v. Gerhart.* A "prior to use" filing requirement falls outside the statute's only substantive requirement—to use nationally-recognized data in the development of MAC reimbursement amounts—and is thus inconsistent with the Court's interpretation.

   Furthermore, the statute does not grant the Commissioner authority to *approve* the use of specific data or sources upon which the PBMs' MAC pricing methodologies are developed, so there is no rational reason for obtaining the information in advance.

PCMA

Comments on Remainder of Discussion Draft

1. **The proposed definition of "complaint" in amended section 191-59.2 is overly broad and disregards the common understanding of the word "complaint."**

   The proposed regulation includes as a "complaint" any "written communication…that makes an inquiry, comment on, contest, or appeal; requests information; or expresses a grievance." This is a significant expansion of any common definition of a complaint, which would normally imply some sort of dissatisfaction or unacceptability. There are a number of problems with this expanded definition:

   - Not every comment, inquiry or request of information is a statement of dissatisfaction. Communications could be positive, negative, or neutral in nature. A simple email communication relating to ordinary course, day-to-day matters could be considered a "complaint" under this definition. Inquiries clearly are not "complaints" and should be not counted as complaints.
   - This expansion of the definition will artificially inflate the number of recorded complaints against PBMs because it will include any comment—regardless of whether it is positive, negative, or neutral—and will paint an unfairly negative picture of PBM activities in Iowa. This result will be exacerbated by the proposed inclusion of "PSAO" in the definition of "pharmacy," because in the event a single issue is discussed with both a PSAO and a pharmacy, these communications ("complaints") would be double-counted.
   - The expanded definition will increase the number of communications to record and report, increasing the administrative burden on both PBMs and IID, taking time away from any legitimate issues—true complaints—that need to be addressed.

2. **The inclusion of the term "PSAO" in the definition of "pharmacy" in amended rule 191-59.2 inappropriately broadens the statutory definition and confuses the use of the term "pharmacy" in other areas of Chapter 59.**

   It is unclear for what purpose the IID includes PSAOs in the definition of "pharmacy." A "pharmacy" is defined in Section 510B.1 as it is defined in Iowa Code section 155A.3, which is "a location where prescription drugs are compounded, dispensed, or sold by a pharmacist and where prescription drug orders are received or processed in accordance with the pharmacy laws." A pharmacy is a location or a site, but PSAOs are administrative entities. PSAOs do not compound, dispense, or sell prescription drugs. Nor do PSAOs receive or process prescription drug orders or appear in the pharmacy laws as regulated entities. The inclusion of "PSAO" in the definition of "pharmacy" is an expansion of the statute beyond that which was reasonably contemplated by the legislature, and further, will confuse the term "pharmacy" as used in other areas of the regulations.

   For example, section 59.4 addresses audits of pharmacies. PSAOs were not contemplated as "pharmacies" in these provisions. Also, section 59.5 regulates termination and suspension of contracts with pharmacies. This regulation is intended to provide rights to pharmacies, likely in the context of participating in health plan networks to provide plan members access to pharmacy benefits. PBMs may have contracts with a PSAO in addition to a contract with a pharmacy, and these pharmacy rights (e.g., 60-day notice of contract

termination, right to independent third party review of contract termination) should not extend to PSAOs.

3. **The proposed amended rule 191-59.4(1)"b" that replaces "pharmacist" with "pharmacy" in the context of audit consultation ignores and confuses the role of a consulting pharmacist in audits.**

   The proposed language changes the term "pharmacist" to "pharmacy" in the context of consultations during pharmacy audits. Although PCMA understands that this amendment is likely made to be consistent with the proposed definition of "pharmacy" that includes "pharmacist," this change illustrates why the terms "pharmacy," "pharmacist," and "PSAO" should not fall under one definition. An audit of a pharmacy cannot be done in consultation with a non-person entity, or a PSAO, which is an administrative entity that does not provide professional consultation. An audit must be done in consultation with an individual who is appropriately professionally licensed. This change makes the requirement that an actual person (pharmacist) be consulted for audits awkward and unclear. The definitions of "pharmacy" and "pharmacist" should remain as the existing rule sets forth.

4. **The proposed amendment to rule 191-59.4(1)"j"(6) causes confusion about the range of instances where a corrective action plan (CAP) is used and encourages contract terminations instead encouraging PBMs and pharmacies to work together to address issues.**

   The proposed language proposes a definition of "corrective action plan" that is limited to "agreements entered into by a pharmacy benefits manager and a pharmacy which is intended to promote accurate submission and payment of pharmacy claims." However, corrective action plans are used in other areas. For example, PBMs have clinical programs that promote patient safety. If a pharmacy is violating terms and conditions that could impact patient care, PBMs must be able to take action, by placing that pharmacy on a corrective action plan or moving to terminate the contract. This proposed change to the rule would have the likely unintended consequence of providing a PBM only one option: terminating the contract, instead of allowing the PBM to work with the pharmacy to come into compliance and fix the patient care issues.

5. **The timeframe for application to existing contracts set forth in proposed subrule 59.5(1) fails to allow sufficient time for PBM compliance.**

   Subrule 59.5(1) requires PBMs to include in pharmacy contracts information relating to which national compendia are used for development of maximum reimbursement amounts for any contracts existing January 1, 2016. Given that the rule is no less than several weeks away from being completed, this timeframe is too short. The rule should allow for a reasonable ramp-up period for PBMs to come into compliance, and should apply only to contracts entered into *after* this rule is adopted in its final form.

6. **The use of the term "complaint" in proposed rule 59.5(3) is overly broad.**

   As stated above, a pharmacy's "comment on" a maximum reimbursement amount is not necessarily an expression of dissatisfaction, and should not be considered a complaint.

7. **The proposed new subrule 59.8(3)(b) requires PBMs to provide information to the IID that the PBM may not have.**

   Proposed subrule 59.8(3)(b) requires the PBM to provide the National Drug Code number (NDC) and the names of the manufacturers of the prescription drugs that are related to the inquiry when responding to the IID. However, the rule does not specify that the IID must provide sufficient detail in its communication with the PBM so that the PBM may identify which NDC and manufacturers are applicable, making it potentially impossible to comply. This section should be clarified to require the NDC number and manufacturer only when the Commissioner has provided enough information in the inquiry for the PBM to identify these facts.

8. **The proposed requirement in new subrule 59.8(4) to record and report "complaints" will artificially inflate the number of true issues.**

   New subrule 59.8(4) requires PBMs to record and report complaints to the Commissioner. As stated above, the term "complaint" is overly broad. Reporting all communications will artificially inflate the number of true grievances or problems. Also, reporting the Commissioner's inquiries (subrule 59.8(3)) is unnecessary. Not only will the Commissioner already have a record of these inquiries (making reporting on these redundant), if a complaint on a single matter is made by a pharmacy and/or a PSAO, and/or the Commissioner, the matter could be counted three times but have no substantive differences. This potential for over-counting complaints is unproductive, will exaggerate issues, and will create costly administrative work by PBMs and the IID that will add no value to Iowans.

9. **The requirement to disclose proprietary information imposed by proposed subrule 59.10(3) is not required by Section 510B.8 and will damage competition in the pharmacy benefit management market.**

   New subrule 59.10(3) requires disclosure of *all* payments, and the nature, type, and amounts of all other revenues that the pharmacy benefit manager receives. This would include "rebates," "administrative fees collected by manufacturers," "pharmacy network fees" and "any other fee" collected for an "administrative function." This new subrule represents a dramatic expansion of the requirements of Section 510B.8, contrary to the narrow construction by the District Court in the PCMA litigation, which requires only that the PBM "submit *information* to the commissioner *related to the PBM's pricing methodology* for maximum reimbursement amount." (emphasis added). It also goes well beyond the statutory authority to regulate PBMs that is actually granted to the Commissioner by the Legislature in Chapter 510B.

   Additionally, as a matter of public policy, requiring PBMs to disclose highly confidential and proprietary contract information, showing price negotiation strategies with manufacturers and pharmacies, will damage competition. The Federal Trade Commission (FTC) has stated that similar disclosure provisions "may increase the cost of PBM services because it will preclude health plans and PBMs from entering into efficient (i.e., cost effective) contracts for the administration of pharmacy benefits; and second, they may have the unintended consequence of publicizing proprietary business information in a way that could foster

collusion among third parties."[1] The FTC has further warned several states that legislation requiring PBM disclosure could increase costs and "undermine the ability of some consumers to obtain the pharmaceuticals and health insurance they need at a price they can afford."[2]

10. The proposed rule does not adequately protect confidential and proprietary information from public disclosure.

As stated above, the information relating to PBM pricing methodology that this rule seeks is highly confidential and proprietary, the inappropriate sharing or disclosure of which could eliminate competitive forces in the pharmacy benefit management market. Public disclosure would pave the way for inappropriate use of PBM pricing methodology information by competitors to gain an edge in purchasing, contracting, and bidding for business. It is imperative that the information provided to the IID is held in strict confidence and withheld from public disclosure.

PCMA suggests the following amendment: *All information related to a PBM's pricing methodology for maximum reimbursement amounts provided to IID under this section is deemed confidential and not subject to public disclosure.*

We appreciate the opportunity to provide comments on the discussion draft and we welcome the opportunity to have a dialogue about these changes. Please do not hesitate to contact me at 202-756-5743 if you have any questions.

Sincerely,

April C. Alexander
Senior Director, State Affairs

[1] FTC letter to Senator James L. Seward, New York Senate (March 31, 2009).

[2] FTC letter to Rep. Patrick T. McHenry, U.S. Congress (July 15, 2005); FTC letter to Assembly member Greg Aghazarian on California's AB 1960 (September 3, 2004); *see also* FTC letter to Senator James L. Seward, New York Senate (March 31, 2009).