December 6, 2016

Ms. Bianca Stoner
Senior Health Policy Analyst
Office of the Insurance Commissioner
Olympia WA 98504

Via email: rulesc@oic.wa.gov

Re: Proposed Rulemaking - Registration and Regulation of Pharmacy Benefit Managers, Rule No. 2016-07

Dear Ms. Stoner:

The Pharmaceutical Care Management Association (PCMA) is submitting the following comments for consideration as the Office of the Insurance Commissioner (OIC) develops its rules relating to Registration and Regulation of Pharmacy Benefit Managers. PCMA is the national trade association representing America's PBMs, which administer prescription drug plans for more than 266 million Americans with health coverage provided through Fortune 500 employers, health insurance plans, labor unions, Medicaid managed care, Medicare Part D, Federal Employees Health Benefit Programs, and other public programs.

Thank you for the opportunity to provide comments on the OIC's Proposed Rule. We also appreciated the opportunity to provide verbal comments at the stakeholder meeting held in August and appreciate your efforts to develop a fair, understandable regulatory scheme that fits within the four corners of the statute. However, we remain concerned about a number of items, which are outlined below.

1) **Proposed Section 284-180-130**. Definitions.

   a) (3) "Net Amount." PCMA appreciates the inclusion of off-invoice discounts in the definition of "net amount," however, we remain concerned that the inclusion of "taxes, fees, or other costs" as a part of the drug acquisition cost does not reflect the typical contracting relationships between payers, PBMs, PSAOs, and pharmacies. Reimbursements to pharmacies consist of both ingredient costs and dispensing fees. Dispensing fees are intended to reimburse for the pharmacy's costs related to dispensing the drugs that are not the actual ingredient. This proposed language could encompass fees which are already accounted for in the dispensing fee, fees of which the payer has no knowledge, and/or fees the PBM has not contracted to cover in its reimbursements. Additionally, the terms "fees" and "other costs" are overly broad and provide no notice to the PBM as to what these costs might encompass. And finally, PBMs have no way of knowing the value of purchase discounts that pharmacies receive from suppliers, as PBMs are not privy to the terms of their purchase arrangements. PCMA requests the following amendment:

Pharmaceutical Care Management Association
325 7th Street, NW, 9th Floor
Washington, DC 20004
www.pcmanet.org

(3) “Net amount” means the invoice price that the pharmacy paid to the supplier for a prescription drug that it dispensed~~, plus any taxes, fees, or other costs~~, inclusive of all discounts and other cost reductions attributable to the drug.

b) (6) “Readily available for purchase.” PCMA is concerned that PBMs have no knowledge of whether specific wholesalers have stock of specific drugs. Pharmacies control the inventories in their own stores and seek relationships with wholesalers who can meet the demands of those locations. The use of the term “readily available for purchase” in the statute implies that PBMs control this process, and they do not. Many other states have a similar requirement that pharmacies be provided an NDC that is “readily available for purchase.” However, the term is rarely (if ever) defined, as its meaning is commonly understood in the industry. However, if the term must be defined, PCMA requests the following definition:

“Readily available for purchase” means drugs that have not been designated as in short supply by manufacturers and/or are not obsolete and are available for purchase by Washington pharmacies from national or regional wholesalers.

2) **Proposed Section 284-180-210**. Registration and renewal fees. This proposal establishes registration renewal fees based on PBM annual gross business income for the previous calendar year. PCMA believes that the meaning of “annual gross business income” is vague and overly broad and instead supports a reasonable, uniform, flat fee for all PBMs to fund the OIC’s activities related to this statute. Further, we do not believe that basing PBM registration and renewal fees on income unrelated to PBM business in the State of Washington appropriately accounts for the administrative efforts expended in the OIC’s oversight of PBMs. However, if OIC moves forward with assessing fees based on prior year’s income, we suggest moving the due date for financials to later in the year, after all audited corporate financials and tax filings are complete. PCMA requests the following amendment:

Section 284-180-210(4): No later than ~~March~~ May 1 of each year, pharmacy benefit managers must report.…

On a related note, PCMA is concerned that there is no penalty for pharmacies filing frivolous appeals or filing appeals in bad faith. Given the number of pharmacy claims each year, pharmacies could file thousands of appeals that result in reimbursement determinations being upheld, but that require OIC’s time and expense to review. For example, the State of Oregon recently issued a report[1] wherein it stated that of the 24,000 MAC complaints made to the Oregon Department of Insurance (“DOI”) in 2015, one third (8,000) were related to Medicare Part D claims and, therefore, were not subject to the state’s MAC law, and of the more than 44,000 complaints received in 2016, more than one third (over 14,000) were related to Medicare Part D claims and, therefore, not subject to the state’s MAC law. These findings indicate that the pharmacies or their representatives filing the appeals failed to

[1] *See* 2016 Report of the Department of Consumer and Business Services on Recommendations for Rulemaking Regarding Pharmacy Benefit Manager Compliance to the Seventy-Eighth Legislative Assembly (available at http://dfr.oregon.gov/public-resources/committees-workgroups/Documents/pharmacy-benefit-manager/pbm-report-recommendation-draft.pdf).

exercise any due diligence in removing ineligible appeals before submitting them to the Oregon DOI. Rather, the pharmacies placed the onus on the DOI and the PBMs to parse through the information. Without any disincentives for pharmacies filing bad faith or frivolous appeals, the OIC would have to expend its resources reviewing/adjudicating these appeals and the associated costs would be unjustly passed to the PBMs to fund the OIC's activities. Pharmacies incur no risk, whatsoever, for filing bad faith or frivolous appeals, since the PBMs will be supporting all of the costs associated with the appeals. PCMA is not seeking to establish a barrier to legitimate pharmacy appeals, but fairness calls for some disincentive to file frivolous appeals. Accordingly, PCMA requests that the OIC consider imposing a penalty for pharmacies filing frivolous appeals or bad faith appeals and/or limiting the number of appeals that a pharmacy may file on a monthly basis under the OIC's authority in section 284-18-420(3) "other actions deemed fair and equitable."

Finally, whether the OIC adopts a uniform flat fee or proceeds with the currently proposed fee basis, PCMA requests a new subsection (7), as follows, that nonetheless limits fees to those that are *reasonable and necessary* to fund the registration and appeals provisions required by the statute:

(7) Fees collected from PBMs shall be limited to the amount reasonable and necessary to fund the registration, renewal, and appeals provisions required by this chapter.

3) **Proposed Sections 284-180-310 and 320.** These sections refer to records that must be provided to the OIC upon request, and the associated deadlines for submission. PCMA and its member companies support the OIC's fair and equitable enforcement of the underlying statute, but believe access to PBM records that are unrelated or unnecessary to determine the appeals is unreasonable and falls outside the scope of the OIC's authority. We respectfully request that this language be clearly and affirmatively limited to the scope of the statute.

Specifically, these sections should be clarified to state the OIC's authority to review records is limited to those materials that are related to the appeals that the underlying statute granted authority to the OIC to review, or to the review of PBM registration and renewal materials. The proposed Section 284-180-310 states that PBMs "must maintain records and make them available to the commissioner upon request. Records include, but are not limited to…" The term "but are not limited to" is an expansion of the statutory authority and should be stricken. In addition, proposed Section 284-180-320 refers to records for inspection "for a purpose other than to resolve an appeal under RCW 19.340.100(6)…" This section should be clarified to be consistent with the enforcement authority granted the OIC by the underlying statute, namely records related to registration and information about appeals. PCMA requests the following amendment:

(1) Pharmacy benefit managers must maintain and make them available to the commissioner upon request. Records include~~, but are not limited to~~:
(a)…

In addition, subsection (1)(b) should be limited to information that is necessary to determine appeals, not information "about" appeals. PCMA requests the following amendment:

"[i]nformation ~~about~~ necessary to determine appeals under chapter 19.340 RCW.

Pharmaceutical Care Management Association
325 7th Street, NW, 9th Floor
Washington, DC 20004
www.pcmanet.org

4) **Proposed Section 284-180-320**. Deadline to provide copies of records. This section refers to records that must be submitted to the OIC. PCMA requests the following amendment:

"…then the records are due at the date indicated on the extension. Records shall be requested only when necessary for PBM registration, renewal, or appeals determination."

5) **Proposed Section 284-180-400(1)** refers to a pharmacy "provider contract." This term does not reflect the norms in the industry, because pharmacies are not always considered "providers." A term that reflects the norms in the industry and ensures greater consistency with the underlying law and other sections of the regulation should be adopted. PCMA requests the following amendment:

"A pharmacy benefit manager must include in the pharmacy ~~provider contract~~ network agreement and on the pharmacy benefit manager's website…"

6) **Proposed Section 284-180-400(5)** requires a PBM, upon denying a pharmacy's appeal, to "provide the reason for the denial and the NDC of a drug that has been purchased by other network pharmacies located in the state of Washington at a price less than or equal to the predetermined reimbursement cost for the…drug." While we agree that market conditions (e.g., what other pharmacies have paid for the drug) are appropriate to consider in this context, and we acknowledge that this language mirrors the statute, we are concerned that it likely would be impossible for PBMs to comply with this section. PBMs use various sources to determine drug reimbursement, including, but not limited to, average pharmaceutical prices and other publicly available information. However, PBMs have no way of knowing how much pharmacies have *actually paid* for pharmaceuticals and, therefore, could not provide this information if appeals are denied. PCMA proposes the following amendment, which mirrors language adopted by a number of other states:

(5) If the pharmacy benefit manager denies the network pharmacy's appeal, the pharmacy benefit manager must provide the network pharmacy with a reason for the denial and the national drug code of a drug that ~~has been~~ may be purchased by network pharmacies from regional or national wholesalers at a price less than or equal to the predetermined reimbursement cost for the multisource generic drug.

7) **Proposed Sections 284-180-400 (2) and (7)**, and **284-180-420(5)** refer to representatives filing appeals and appearing at proceedings on behalf of pharmacies. The language in 400(7) and 420(5) lists several types of representatives, most of whom would have no contractual or legal standing to assert a pharmacy's rights. Moreover, these appeals take administrative time and expense to respond to, and it is important that only legitimate appeals get the protections of this process. PCMA does not oppose entities that have a personal stake in the outcome requesting appeals when they are legitimately concerned about a reimbursement that is covered by the statute. Thus, the appealing entity should be the entity with which the PBM holds the contract. PCMA requests the following amendment:

284-180-400 (7) If otherwise qualified, the following may file an appeal with a pharmacy benefit manager:
The pharmacy or entity that has entered into a network agreement on the pharmacy's behalf with the pharmacy benefit manager that is the subject of the appeal.
(strike all other entities)

8) **Proposed Section 284-180-420(1)(b)(iv)** authorizes the OIC to request "additional" information from pharmacists when reviewing an appeal. We believe these requests should be limited to information that is necessary to adjudicate the appeal. PCMA requests the following amendment:

   (1)(b)(iv) Any additional information the commissioner may require that is necessary for the review of the appeal.

9) The proposed rule should clearly state that all contracts, reimbursement terms, and appeals information will be kept confidential and not subject to public disclosure. Public disclosure of pricing and reimbursement terms can damage competition, invite collusion among market participants, and ultimately harm consumers by inflating prices. In addition, there may be state and federal protections of proprietary and trade secret information that protect documents submitted to the OIC. PCMA believes that protection of proprietary information is of utmost importance, and PBMs must retain the ability to defend against improper public disclosure of sensitive materials. Thus, PCMA requests the following amendment:

   If a Public Records Act request to view information submitted by a PBM to the OIC under this chapter is received by the OIC, the OIC shall, within 24 hours of the request, and before any release of the requested information, notify in writing the pharmacy benefit manager whose documents are the subject of the request. The pharmacy benefit manager may seek a protective order or other appropriate remedy or, in the pharmacy benefit manager's sole discretion, agree to the release of some or all of the information requested. If the PBM has notified in writing the OIC that it is seeking a protective order or other judicial remedy, the OIC shall not release any of the requested information in which the pharmacy benefit manager claims an interest while such request is pending. The OIC will reasonably cooperate with the pharmacy benefit manager's efforts to prevent disclosure. In the event that no protective order or other remedy is obtained in a timely manner so as to avoid a violation of the Public Records Act, the OIC will nonetheless furnish only such information as is legally required.

We appreciate the opportunity to provide comments on this Notice and we welcome the opportunity to speak with you 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

Pharmaceutical Care Management Association
325 7th Street, NW, 9th Floor
Washington, DC 20004
www.pcmanet.org