



August 26, 2016

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

Via email: rulesc@oic.wa.gov

Re: 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 rule 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 Stakeholder Draft. At the outset, PCMA would like to briefly explain the relationships between parties that are in the pharmacy supply chain. Payers, such as health plans, labor unions, large employers, and state governments often contract with pharmacy benefit managers to manage the pharmacy component of the health benefit on the payer's behalf. Payers dictate the terms of the contracts with the PBMs, and the PBMs perform the functions required of them. One of the key functions for a PBM in the context of this relationship is to contract with pharmacies that will dispense pharmaceuticals to the payer's members, enrollees, or employees.

In building a network of pharmacies for their payer clients, PBMs enter into contracts on the payer's behalf with pharmacies, and agree to reimbursement terms, which include ingredient costs (for the actual pharmaceutical dispensed), and dispensing fees (for the administrative costs of dispensing the drug).

Most small pharmacies join together into buying groups called Pharmacy Services Administrative Organizations (PSAOs) that negotiate on pharmacies' behalf to secure favorable contract terms with PBMs on the reimbursement side, and favorable price terms on the purchase of drugs from wholesalers. There are three major wholesalers across the country that sell most of the pharmaceuticals in the country. These wholesalers distribute pharmaceuticals across the country; distribution is not limited to specific states or regions. The terms of the contracts between payers/PBMs and pharmacies are confidential, and the prices that pharmacies pay for drugs from wholesalers are not known to the payers/PBMs.

These complicated, competitive relationships make the pharmacy supply chain operate in a delicate balance. Regulatory action that impacts just one segment of the supply chain, without



addressing the impact of the action on the others can throw off this delicate balance and cause one or more entity to profit significantly or lose significantly.

Given this context, PCMA has the following comments on the stakeholder draft:

- 1) Proposed Section 284-180-130(2). PCMA has concerns regarding the definition of “Generally Available for Purchase.” While the proposal refers to “wholesalers *within* the state of Washington” (emphasis added), RCW 19.340.100(2)(b) refers to wholesalers *that serve pharmacies* in Washington” (emphasis added). These are two distinct concepts and the rule should be clarified to indicate that wholesalers do not need to be located in Washington State, but wholesalers need to be serving pharmacies in Washington State.
- 2) Proposed Section 284-180-130(3). PCMA is concerned that the rule’s definition of “net amount or drug acquisition cost” does not reflect the typical contracting relationships between payers, PBMs, PSOs, and pharmacies. Specifically, the rule calls for the inclusion of taxes, fees, or other costs as a part of the “net amount or drug acquisition cost.” This language could encompass fees that the payer has no knowledge of, and/or has not contracted to cover in its reimbursements.
- 3) Proposed Section 284-180-130(6) defines “reasonable adjustment” as “an amount that is sufficient to cover the pharmacy’s cost of purchasing the drug at the time of reimbursement.” This definition would give pharmacies a guaranteed return on the sale of generic pharmaceuticals by adopting a cost-based reimbursement scheme. The concept of cost-based reimbursement is inappropriate in the generic drug marketplace. It does not take into account what is appropriate under marketplace conditions, nor does it take into account the pharmaceuticals that are reimbursed *above* the net cost to the pharmacy—the pharmaceuticals on which the pharmacy makes a profit, of which there are many. Cost-based reimbursement invites a race to the highest price. If a manufacturer or wholesaler knows that the cost of its product will be covered—regardless of how high the price is—there is little incentive for that manufacturer or wholesaler to keep prices low. In addition, cost-based reimbursement that is based on invoice price invites secret off-invoice discounts or other incentives, which makes “cost” an even more challenging concept to determine.

Additionally, the Washington Legislature considered but rejected cost-based reimbursement in SB 5857, when it adopted terms such as “reasonable” and “fair and equitable” in the statutory structure. It also acknowledged that what “other” pharmacies had paid for a drug is relevant in the overall reimbursement equation (See RCW 19.340.100(4)(b)). We understand that the Legislature did not provide further clarification on these terms, but cost-based reimbursement was rejected, and what is reasonable in the marketplace should be part of the analysis. And finally, as written, the proposed definition does not take into account the discounts or other incentives pharmacies obtain from wholesalers that, overall, reduce the net cost of the drug to the pharmacy.

- 4) Proposed Section 284-180-130(8) defines “unsatisfied” as the pharmacy not receiving the cost of purchasing the drug, but does not take into account discounts or other incentives that the pharmacy obtains. Again, this definition suggests that cost-based reimbursement is the expectation. In addition, PCMA believes that defining “unsatisfied” is unnecessary in this proposal.



- 5) Proposed Section 284-180-310(1)(b) requires information about appeals to be submitted to the OIC upon request. PCMA has two concerns with this requirement.
 - a) The requirement to provide information to the OIC regarding appeals is too broad. The requirement should extend only to information necessary to process an appeal.
 - b) In addition, because appeals of reimbursement relate to confidential pricing and contract terms, all information submitted to the OIC under this should remain confidential and not subject to public disclosure.
- 6) Proposed Section 284-180-310 and 320 refer to records that must be provided to the OIC upon request, and the associated deadlines for submission. These sections should be clarified to state the authority the OIC has to review records is limited to those that are related to the appeals that SB 5857 granted authority to the OIC to review, and PBM registration materials. Specifically, 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 SB 5857, namely records related to registration and information about appeals.
- 7) Proposed Section 284-180-400 requires PBMs to post information about the appeals process on their websites. Specifically, it requires information describing the PBM’s response time for responding to calls related to appeals. Posting this information is unnecessary and serves no purpose for the pharmacy. In addition, response times will ebb and flow depending on the day and the workload. Thus, the information posted would likely be inaccurate or outdated by the time it is posted. Providing days and times the pharmacy can contact the PBM is sufficient to provide the pharmacy with adequate notice.
- 8) 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 with the underlying expectation that reasonable market conditions (i.e., what other pharmacies have paid for the drug) are appropriate to consider in this context, and we understand that this language mirrors the statute, we are concerned that this section may be impossible for PBMs to comply with. PBMs know only their own reimbursements and average pharmaceutical prices (based on market surveys, etc.). PBMs do not know how much pharmacies have *actually paid* for pharmaceuticals, so there is no way for PBMs to provide this information with denials of appeals. PCMA is considering additional comments on this section.
- 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. PCMA is still reviewing these sections and considering additional comments on the OIC’s authority to keep this information confidential.



We appreciate the opportunity to provide comments on this Notice 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,

A handwritten signature in black ink that reads "April C. Alexander". The signature is fluid and cursive, with a long horizontal stroke at the end.

April C. Alexander
Senior Director, State Affairs