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Dear Commissioner,

This correspondence on behalf of OptumRx, Inc. ("OptumRx") concerns the Insurance Commissioner's invitation to submit comments to Stakeholder draft rule entitled "Registration and regulation of pharmacy benefit managers." We greatly appreciate the opportunity to participate in providing feedback and for your office's potential rulemaking. In addition, we will continue to make ourselves available for any questions you may have that will further educate your office as to the general nature of pharmacy benefit management and the impacts this rulemaking will have on the industry. We believe this proposed rulemaking has the potential to be a step in the right direction for this industry. In addition, we will inform you of several unintended negative consequences that were created as a result of the enactment of SB 5857 (2016). We believe that we can offer you amended language to this regulation that not only meets the goals of SB 5857, but also provides solutions that benefits all constituents, including members and pharmacies within the state of Washington.

OptumRx is a pharmacy benefit manager that administers pharmacy benefits on behalf of insurance companies, self-funded health benefit plans, Medicaid administrators, and Medicare Advantage plans, among other health care arrangements. Our services include contracting with network pharmacies and setting pricing methodologies that forecast and validate the acquisition costs of pharmacies for the purpose of their fair reimbursement while also mitigating the pharmacy costs to our clients and their members. These tools we employ, particularly in the pricing of multi-source generic drugs, are a necessity in managing drug costs that continue to rise dramatically. As you may be aware, the pharmaceutical industry has continued a trend of substantial price increases for brand and single source generic drugs; in many cases without any reasonable citation to research and development costs or general supply and demand trends. The most recent example is Mylan's Epipen, which has increased its price more than 400% to $600 for a standard two-pack. This is just one of many examples of price hikes from pharmaceutical companies that own patents or enjoy a monopoly on specific drugs where cost containment methods are nearly impossible.

For these reasons, it becomes that much more important that pharmacy benefit managers employ the most effective tools to manage costs for multi-source generic drugs and further ensure the manufacturers compete to mitigate consumers' healthcare costs when

these brand drug patents expire. It is to this end that retail pharmacies are not our adversaries, but rather serve as our strategic business partners in negotiating the best acquisition costs from pharmacy manufacturers and wholesalers. We believe retail pharmacies' compensation must be fair to allow their businesses to prosper and continue satisfying our pharmacy networks at the behest of our consumers. However we also believe our retail pharmacy partners must employ reasonable negotiating principles in ensuring they acquire these drugs at prices closely aligned with the market's true acquisition costs. Without this understanding and balance, we would be less effective in managing lower pharmacy costs for health care consumers.

**WAC 284-180-400 should be modified to permit forecasting and validation mechanisms that were intended to be employed by SB 5857.**

RCW 19.340.100(1)(a) includes in its definition of "list"

> a "list of drugs for which predetermined reimbursement costs have been established, such as a maximum allowable cost or maximum allowable cost list, or any other benchmark prices utilized by the pharmacy benefit manager and must include the basis of the methodology and sources utilized to determine multisource generic drug reimbursement amounts."

Moreover, RCW 19.340.100(2)(d) includes a transparency requirement for pharmacy benefit managers ("PBMs"). It reads as follows:

> A PBM "shall make available to each network pharmacy at the beginning of the term of a contract, and upon renewal of a contract, the sources utilized to determine the predetermined reimbursement costs for multisource generic drugs of the pharmacy benefit manager."

Within this transparency requirement is an express understanding that reflects the PBM's ability to use "sources" to set "predetermined reimbursement costs" for "multisource generic drugs." It is this very ability to utilize multiple pricing sources that allows pharmacy benefit managers to forecast and validate what the realistic acquisition cost of a multisource generic drug should be.

With this principle in mind, we believe RCW 19.340.100(4)(b) included an express contradiction that should be remediated under the OIC's rulemaking authority. It indicates that a PBM must provide as part of its appeals process when an appeal is denied:

> "…the reason for the denial and the national drug code of a drug that has been purchased by other network pharmacies located in Washington at a price that is equal to or less than the predetermined reimbursement cost for the multisource generic drug."

We do not believe it was the intention of the Washington legislature to change the very nature of the pricing methodology process by means of a formal appeal. In addition, we do not believe it meant to remove the ability of a PBM to use price containment methodologies that it previously recognized. But that's essentially the effect of the legislation without further clarification. Theoretically a pharmacy that didn't perform its due diligence in negotiating reasonable prices with its suppliers has the ability to alter an entire MAC pricing list for all similarly situated pharmacies by self-reporting invoices that are not reflective of the true acquisition costs and are unverifiable. Moreover, PBMs do not have access to pharmacies' acquisition costs, due in part to the confidential nature of their contracts with wholesalers, compounded by the off-invoice discounts common in the industry. It is also unrealistic to assume that pharmacies would be inclined to volunteer purchasing information that could be used against them in negotiating and setting MAC prices. Conversely, for those PBMs with access to a retail pharmacy's acquisition costs, i.e. a retail pharmacy is actually owned by the PBM, the acquisition costs may not be truly reflective of other independently-owned retail pharmacies who don't share the same purchasing power. Such an inequitable result was not the intention of the writers of SB 5857, and it further has the effect of potentially harming the very pharmacies it was meant to protect.

These are a few of the many reasons why these pricing methodology tools we employ based on source information are more effective measures for establishing predetermined reimbursement costs than reliance on an isolated network pharmacy's acquisition cost that may not be truly indicative of other pharmacies' purchasing power. We believe there's a middle ground here that supports cost containment methodologies that protect consumers while also fairly compensating retail pharmacies. We also believe that the independent appeal processes put in place by the state and the OIC will act as a reasonable check and balance to the PBM in ensuring it is able to justify its MAC list pricing. To that end we recommend the following underlined amendment to WAC 284-180-400:

> (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 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 multisource generic drug. "Multisource generic drug" is defined in RCW 19.340.100(1)(c). <u>In the event the pharmacy benefit manager is contractually prohibited from obtaining acquisition costs of other network pharmacies, or that the actual acquisition costs of network pharmacies are not a reasonable reflection of the acquisition cost for a drug, the pharmacy benefit manager may cite regional or national pricing sources that result in an accurate acquisition cost for a given national drug code.</u>

This additional language should remain consistent with the legislature's intention to tie MAC pricing to a pharmacy's acquisition cost but also provide the flexibility to forecast and validate the acquisition costs with predictive modeling based on national and local pricing sources.

**We support the OIC's proposed appeal requirements as they may curtail waste and/or abuse of process.**

As it relates to the formal appeal requirements, we are supportive of the OIC's language that includes exhaustion of PBMs' internal appeal processes. WAC 284-180-420(1)(a) states as follows:

> "A network pharmacy or its representative may appeal a pharmacy benefit manager's decision to the commissioner if it meets all the following requirements: (a) The pharmacy benefit manager's decision must have denied the network pharmacy's appeal, or the network pharmacy must be unsatisfied with the outcome of its appeal to the pharmacy benefit manager,"

OptumRx is generally supportive of rules that require pharmacies to exhaust internal appeal processes. When pharmacies don't avail themselves of the internal processes, we find that regulatory complaints significantly tie up additional and unnecessary resources for all parties involved in many cases that could have been resolved internally. For this purpose, we strongly encourage the OIC to consistently enforce the petition prerequisites for pharmacies found in WAC 284-180-420(1)(b)(i).

**Pharmacy Petition Requirements Should Include Enough Information to Identify the Claim(s).**

WAC 284-180-420(1)(b)(i) currently includes requirements a pharmacy must meet in order to bring a petition for review with the OIC. In many cases, we find that when pharmacies bring appeals to regulators, they don't provide enough information within their appeals that allow PBMs to be able to identify the claims. This confusion leads to formal responses with requests for additional information that other state regulators are required to broker. This waste of resources can be avoided when pharmacies disclose enough information for PBMs to identify the claims subject to dispute. For this reason, we recommend the following additional requirement under WAC 284-180-420(1)(b)(i) as follows:

> D. All documents and information necessary for the purpose of identifying the claim(s) that were processed by the pharmacy benefit manager, and subject to this request for petition; and
>
> E. Any additional information that the commissioner may require.

**Each Request for Petition Should Be Focused on One Specific National Drug Code (NDC) Subject to Dispute.**

The analysis for claims that are brought by pharmacies will not always be the same, as the rationale for MAC list pricing is going to vary based on each NDC that was priced by the PBM. If each request for petition can be based on a single NDC, it will better focus the application process and allow for better specificity for the reasons the pharmacy brought the petition. For these reasons we recommend the following additional language:

> WAC 284-180-420(1)(b)(ii) Each petition for review must only include claims brought for one national drug code at a time.

**OptumRx Supports the Time Limits for Petition Following Internal Appeal Process**

We support provisions that require a pharmacy or its agents to file complaints within a fixed period of time. Occasionally, OptumRx receives regulatory complaints that were previously investigated through the regulatory complaint process only to have found those claims resubmitted several months later. Without any clear time limits or finality in the independent review or regulatory complaint process, OptumRx and regulators alike incur needless administrative resources to identify duplicative claims. For that reason, we are supportive of WAC 284-180-420(1)(d) which states:

> "The network pharmacy must file the petition for review with the commissioner within thirty days of receipt of the pharmacy benefit manager's decision,"

We believe these types of time limits will require the complainants to adhere to time limits and focus on those complaints that are truly worthy of the independent review process.

In conclusion, we believe that these regulations are a step in the right direction as they can potentially clarify implementation confusion associated with SB 5857; namely that pricing mechanisms utilizing national and local sources are valid tools when true acquisition costs are not certain. In addition, we believe the appeal provisions have the ability to focus complainants on issues that are within the jurisdiction of the OIC, issues that have been through the internal appeal process, and won't create needless administrative waste. Moreover, we want to welcome any questions the OIC has that will better inform their understanding and rulemaking.

Sincerely,

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