Office of the Insurance Commissioner
302 Sid Snyder Ave., SW, Suite 200,
Olympia, WA 98504

August 30, 2016

RE: National Community Pharmacists Association (NCPA) Comments to the Office of the Insurance Commissioner (OIC) of Washington State on Proposed Rule R 2016-07 regarding registration and regulation of pharmacy benefit managers

Submitted To: rulescoordinator@oic.wa.gov

Dear Washington State OIC:

The National Community Pharmacists Association (NCPA) offers the following comments regarding the registration and regulation of Pharmacy Benefit Managers (PBMs) in Washington State (proposed rule R 2016-07.) NCPA has offered input on several successful legislative efforts to provide greater regulation and oversight of the PBM industry nationwide, including but not limited to Washington State's S.B. 6137 and ESSB 5857. Washington State has taken numerous steps to reform and regulate the PBM industry over the past few years. NCPA believes that ensuring that the final regulations governing such oversight effectively advance the intent and goals of the empowering legislation/statute. NCPA has worked with many other state Departments of Insurance on similar efforts, and is happy to provide the following comments to the OIC based on the lessons learned through such experience.

NCPA thanks the OIC for proposing such comprehensive regulations. NCPA strongly supports proposed rule R 2016-07 and feels that each of its provisions take necessary and appropriate steps to effectively implement ESSB5857. From a national perspective, NCPA has seen that PBMs often circumvent or ignore the underlying intent of legislation such as S.B.6137 and ESSB 5857 due to a lack of precise and comprehensive regulations. We offer the following comments in an effort to ensure the intent of the law is protected:

1) Applicability and scope:
NCPA strongly recommends that the "Applicability and scope" section of the proposed regulations clarify that the provisions of the regulations, in their entirety, impact both the contracting relationship between a pharmacy and a PBM and also the pharmacy's contracting agent such as a Pharmacy Services Administrative Organization (PSAO) and a PBM. Many independent community pharmacies contract with PBMs through an intermediary contracting agent, such as a PSAO, and these entities manage many aspects of a pharmacy's contracting relationship and administrative duties, including reimbursement appeal processes. Legislation in other states that lacks this clarifying language has allowed the PBMs to circumvent the law by arguing that it does not apply to pharmacy appeals submitted by PSAOs on behalf of pharmacies. Therefore, NCPA strongly urges that the state include such language to ensure an effective and properly functioning system.

2) Applicability and scope:
NCPA respectfully requests that the exemption of self-insured health plans be struck from the proposed regulation. It is not a legal requirement that state law(s) such as those requiring generic-drug pricing transparency exclude self-insured plans. In fact in the state of Iowa, where the PBM community filed a lawsuit challenging Iowa's transparency law, a federal court concluded that ERISA does not preempt the state from requiring such transparency and reporting for self-insured plans. NCPA believes that Washington should not exclude self-insured plans from this law/regulation and to do so would undermine the intent and applicability of the empowering law.

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1) **Definitions:**
NCPA recommends that the definition of "Corporate Umbrella" be amended to the following:

"Corporate umbrella" means all entities including, but not limited to, subsidiaries and affiliates operating under common control or ownership."

2) NCPA recommends that the definition of "Generally available for purchase" be clarified with the following:

"Generally available for purchase" means available for purchase by multiple pharmacies not under common ownership or control from national or regional wholesalers servicing pharmacies in the state of Washington."

3) NCPA recommends that the definition of "Net amount or drug acquisition coast" be clarified with the following:

"Net amount of drug acquisition cost means the invoice price that the pharmacy paid for a prescription drug that it dispensed, plus any taxes, fees or other costs."

4) NCPA recommends that the definition of "Readily available for purchase" be clarified with the following language:

"Readily available for purchase" means manufactured supply that is held in stock and available for order by more than one pharmacy, not under common control or ownership in Washington State in Washington State."

5) NCPA strongly recommends that the definition of "Retaliate" include language referencing instances when a PBM targets particular pharmacy providers with PBM/Pharmacy Audits. NCPA believes that pharmacy providers must have an avenue to contact the OIC and provide reasoning behind their claim that a PBM has targeted them in a retaliatory nature through PBM auditing processes.

6) NCPA recommends that the proposed rule include language within Section 284-180-240(2) requiring information such as a specific contract individual's name at a PBM responsible for the registration and compliance of the PBM's operations, the title of that individual, a direct telephone contact number and the Tax ID of the PBM. Including this language would result in the final rule being consistent with the empowering statutory language. It will also prevent any delay in directly contacting an individual charged with ensuring PBM compliance with the law and regulation in a timely manner.

7) NCPA strongly recommends that the OIC require additional information be included as part of a PBM's registration and registration renewal process. It is vital that the state have the information necessary to determine the overall influence and impact of a PBM within Washington State. This information should include, but not be limited to (at the discretion of the Commissioner): PBM financial records, number of Washington State citizen/patient lives managed at the time of PBM registration, number of pharmacies with which the PBM contracts within Washington State at the time of registration and renewal, names of PSAOs which a PBM contracts through, and any current or pending legal or enforcement actions against the PBM in any state.

8) **New Section 284-180-340**
NCPA requests that section (1) be amended to clarify the following:
A violation is knowing and willful for the purposes of chapter 19.340 RCW when the person, corporation, third-party administrator of prescription drug benefits, pharmacy benefit manager, or business entity who committed…" We believe this clarifies that PBMs fall under the provisions of this section and also results in the section being consistent with earlier provisions.

9) **New Section 284-180-400**
NCPA strongly requests that the definition of "Net amount" be amended to address concerns when a pharmacy or their contracting agent may submit an appeal for below-cost reimbursement to a PBM. We also request that this new section clarify that:

"A pharmacy may appeal a reimbursement to a pharmacy benefit manager ("first tier appeal") if the reimbursement for the drug is less than the invoice price that the pharmacy paid for the prescription drug that is dispensed, plus any taxes, fees or other costs."

10) **New Section 284-180-400 1.a.(i)-(iv)**
NCPA strongly requests that the OIC revisit these provisions and provide greater detail as to the timeframes for which a pharmacy must report information to the PBM related to an appeal, and more importantly, the timeframes in which a PBM must respond to a pharmacy's requests. Each provision through these sections should include greater clarity as to required timeframes for response/action. A consistent issue that independent community pharmacies face is the lack of response or delayed response from a PBM to a reimbursement appeal. This was a primary concern which NCPA's national model legislation of generic pricing transparency was attempting to address. NCPA strongly encourages the OIC to work with interested pharmacy stakeholders in Washington State to identify specific times in which pharmacy outreach must be responded to, hours that PBM staff must be available to discuss appeal requests, timeframes for which e-mails will be responded to, etc. NCPA feels the greater detail that can be provided within these provisions, the less challenges will be encountered when a final regulation is implemented.

11) **New Section 284-180-400 1.a.(iv)b-c**
NCPA strongly requests that the OIC require any PBM provided "description of the actions that a network pharmacy must take to file an appeal" to be reviewed by the OIC in coordination with pharmacy stakeholders. NCPA believes that a reasonable process must be implemented that is both thorough yet not overly cumbersome, and time consuming. The OIC should have authority to ensure that reasonable standards be implemented that advance the intent of the law/regulation. NCPA has coordinated with a number of state Insurance Departments over the past few years that have implemented such standards including standardized forms indicating what information is required and the appropriate processes and information to file an appeal. NCPA would be happy to provide the OIC with examples of such efforts, or contact information for our state partners and Insurance Department contacts.

12) **New Section 284-180-400(3)**
NCPA has serious concerns with the provision indicating that if a PBM response is not received by a pharmacy or their contracting agent in the required timeframe that the appeal will be "deemed denied." NCPA was the national organization responsible for developing the model legislation that 35 states have now enacted into law, and that has been introduced in the U.S. Congress. A primary goal of this legislation, driven by a national call to address the issue, was that PBMs would simply not respond to pharmacies request for appeals in a reasonable timeframe, if at all. We believe that including a provision that in essence codifies the very violation that the law/regulation is attempting to address is counterproductive to the overall goal of the law/regulation. We respectfully request that the last sentence of section (3) be struck from the final regulation.

13) **New Section 284-180-400(5)**

NCPA strongly requests that in addition to "a National Drug Code (NDC) of a drug that has been purchased by other network pharmacies in the state of Washington at a price less than or equal to the predetermined reimbursement cost for the multi-source general drug" the OIC should also require the PBM to provide the specific source where the drug may be purchased from a wholesaler licensed in Washington at a price at or below the maximum allowable cost.

14) **New Section 284-180-400(6)**

NCPA requests that language in Section 6 regarding "reasonable adjustment" be clarified, and that additional standards be required so that there is a minimum benchmark that the PBM must meet when approving a price adjustment. Section 5 and 6 of this draft regulation are indisputably the most critical to the intent of the law, yet often they are the most challenging provisions to properly enforce. States across the nation have found it necessary to include additional specificity within such provisions to protect the intent of the law. The following language is provided directly from a state that amended their previously existing pricing generic pricing transparency law at approximately the same time as Washington passed its law, and is also currently going through the rulemaking process simultaneously with Washington State. We offer it as an example of the level of specificity that some states have found necessary to address the lack of compliance for the intent of the law and as an example that NCPA respectfully requests Washington State to follow.

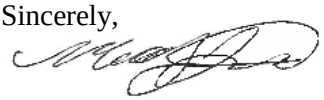
If a price update is warranted as a result of an appeal granted under subsection (X) of this section, the pharmacy benefit manager shall:
(a) Make the change in the maximum allowable cost to the initial date of service the appealed drug was dispensed;
(b) Adjust the maximum allowable cost of the drug for the appealing pharmacy and for all other contracted pharmacies in the network of that pharmacy benefit manager that filled a prescription for patients covered under the same health benefit plan to the initial date of service the appealed drug was dispensed;
(c) Individually notify all other contracted pharmacies in the network of that pharmacy benefit manager that a retroactive maximum allowable cost adjustment has been made as a result of a granted appeal effective to the initial date of service the appealed drug was dispensed;
(d) Adjust the drug product reimbursement for contracted pharmacies that resubmit claims to reflect the adjusted maximum allowable cost if applicable to their contract;
(e) Allow the appealing pharmacy and all other contracted pharmacies in the network that filled prescriptions for patients covered under the same health benefit plan to reverse and resubmit claims and receive payment based on the adjusted maximum allowable cost from the initial date of service the appealed drug was dispensed; and
(f) Make retroactive price adjustments in the next payment cycle.

15) **New section 284-180-420(1)**

NCPA strongly supports the inclusion of the language "a network pharmacy or its representative" within this provision. As stated earlier within our comments, it is critical that throughout the final regulation the provisions apply to actions directly from a pharmacy, or their representative, contracting agent, etc., such as a PSAO. In a number of states, PBMs have attempted to challenge or ignore the laws and regulation on the grounds that they do not specifically include language referencing the contracting agent relationship and including such language has become a top tier priority for community pharmacy. Tennessee revisited their law this past legislative session and amended it exclusively to include a provision that clarifies that their law applies to both the relationship between a pharmacy and the PBM, as well as a PSAO on behalf of a pharmacy and the PBM. In summary, NCPA strongly supports the inclusion of this language within this specific section, but also again requests that this language be applied throughout the entire law/regulation.

NCPA respectfully requests that you carefully consider the above recommendations as you progress through this rulemaking process. We are here to provide our support to ensure the effective implementation of the law and would be happy to provide our assistance as you consider finalizing the proposed regulation. We encourage the OIC to work closely with pharmacy stakeholders of Washington to ensure that the challenges they face are fully understood when considering amendment the proposed draft. If you have any questions about the information contained in this letter or wish to discuss in greater detail, please do not hesitate to contact me at matt.diloreto@ncpanet.org or at (703) 600-1223.

Sincerely,



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