November 26, 2024

Commissioner Mike Kreidler
Washington State Officer of the Insurance Commissioner
302 Sid Snyder Ave., SW
Olympia, WA 98504
EMAIL: rulescoordinator@oic.wa.gov

SENT VIA EMAIL

Re: R-2024-02 Health Care Benefit Managers – Proposed Rule

Dear Commissioner Kreidler:

I write on behalf of Pharmaceutical Care Management Association ("PCMA") in response to the Washington State Office of the Insurance Commissioner ("OIC") Proposed Rule ("Proposed Rule") for Health Care Benefit Managers ("HCBMs"), R-2024-02. Generally, this Proposed Rule would amend state law concerning the business practices of HCBMs, related to the 2024 Legislative Session enactment of Engrossed Second Substitute Senate Bill ("E2SSB") 5213 (Chapter 242, Laws of 2024). As you know, PCMA submitted comments to you regarding the Second Prepublication Draft on September 16, 2024, as well as the First Prepublication Draft on July 26, 2024. We appreciate the OIC accepting some of our requests for changes. However, PCMA continues to have grave concerns with the Proposed Rule, along with requests for changes to be made to this Proposed Rule, as well as questions about the language in this Proposed Rule.

PCMA is the national trade association representing pharmacy benefit managers ("PBMs"). PCMA's PBM member companies administer drug benefits for more than 275 million Americans, including most Washingtonians, who have health insurance through employer-sponsored health plans, including those organized under the federal Employee Retirement and Income Security Act ("ERISA") of 1974, commercial health plans, union plans, Medicare Part D plans, managed Medicaid plans, the state employee health plan, and others.

The ERISA benefit plans with which PCMA's members contract include both insured and self-funded benefit plans sponsored by businesses/employers and labor unions. PBMs use a variety of benefit management tools to help these plans provide high quality, cost-effective prescription drug coverage to plan beneficiaries.

Our primary concerns have been consistently communicated to the OIC since the rulemaking process began earlier this year with the First Prepublication Draft, followed by the Second Prepublication Draft, and not the current Proposed Rule. Those primary concerns include:

- Issues related to the Washington Legislature's intent that pharmacies be accountable for providing documentation of the "net amount" paid for prescription drugs, including transparency of all discounts and other cost reductions attributed to the drug which is completely undermined by the language of the Proposed Rule;

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- Requirements that HCBMs, including PBMs, provide information unavailable to them, information they do not control, as well as required information not supported by underlying statute;
- Allowing pharmacies to play by different and less stringent rules than all other entities in the pharmaceutical supply chain;
- Duplicative and redundant language in Washington Administrative Code ("WAC") 284-180-505 and 284-180-507;
- The applicability of the Proposed Rule to health plans via HCBMs of which the OIC has no regulatory authority; and
- A plethora of provisions in the Proposed Rule that are clearly not supported by underlying statute, E2SSB 5213.

With all that said, we strongly recommend that the OIC heed our requests for the changes requested in these comments. The OIC has gone far beyond the scope of the agency's regulatory authority. Additionally, the language in the Proposed Rule, similar to the language in the Second Draft, is a mess. There are assumptions made throughout the Proposed Rule that PBMs are privy to specific information, of which they are not. Therefore, the OIC will likely need to make substantial changes to what it is attempting to do with the Proposed Rule, and prior to finalization.

Lastly, as we move forward in a new post-*Chevron* doctrine era in which federal courts will continue to cast aspersions on government entities – especially federal and eventually state agencies – seeking to go beyond their scope of authority regarding agency rulemaking, it is PCMA's hope that the OIC takes notice. This is true to any of the language of the Proposed Rule that goes beyond the underlying statute or the scope of the OIC's rulemaking authority.

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WAC 284-180-120 Applicability and scope.

(b)(3)

This provision of the Proposed Rule would add new language to the Wahington Administrative Code ("WAC"), stating that the Chapter does not apply to the actions of HCBMs providing services to or acting on behalf of "medicare supplement or medicare advantage plans." PCMA respectfully requests that the OIC explain its change from the First Prepublication Draft to the Second Draft, also now included in the Proposed Rule, which explicitly removes from the scope of the language "self-insured health plans," "Medicare plans," "Medicaid plans," and "union plans."

As the OIC knows, the Proposed Rule contains troublesome language providing for an "opt-in" for self-insured health plans to take part in the regulatory scheme provided by the language in the Proposed Rule. However, the new language of this section appears to not take several factors into consideration. First, is it the intent of the OIC to include managed care Medicaid plans within the Proposed Rule? What is the reasoning behind splitting up Medicare supplement plans from Medicare Advantage plans, generally, in the Proposed Rule? "Union plan(s)" typically means a Taft-Hartley plan, the benefits of which may be collectively bargained. And a

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Taft-Hartley plan may be organized under federal ERISA law. PCMA and its member companies remain concerned that the “opt-in” language, now along with the new language in this section, are setting up the OIC for a raft of unintended negative consequences.

WAC 284-180-130 Definitions.

(4)

Control

In this section of the Proposed Rule, “control” is defined as the ability to directly or indirectly make decisions. It states that such “control” may be exercised “through ownership of voting securities, membership rights, or by contract” PCMA and its member companies appreciate the removal of the Second Draft language “or otherwise,” as it was not a legal term nor appropriate.

(7)

Credentialing

Credentialing is not mentioned anywhere in the underlying statute or the language of E2SSB 5213. Nor was credentialing ever part of the public debate during the legislative process for E2SSB 5213. It is entirely unclear why this term was included in the Proposed Rule. Furthermore, it is not mentioned anywhere in the remainder of the Proposed Rule language. PCMA respectfully requests that this be removed from the Proposed Rule.

(19)

Net amount

This definition **explicitly states** the Washington Legislature’s intent that pharmacies account to OIC for post-invoice discounts and rebates. However, in reviewing the language of the Proposed Rule, as well as both the Second Prepublication Draft, and First Draft, the OIC has left gaping loopholes for pharmacies to not provide documentation of what the “net amount” actually is.

PCMA insists that the OIC address this issue, as we have repeatedly requested in the past. PBMs are not privy to any of the information shared between pharmacies, their pharmacy services administrative organizations (“PSAOs”), as well as the wholesalers and pharmaceutical manufacturers pharmacies use to secure a specific drug. Thus, the OIC’s intent in this definition for “net amount” needs to consider that all the entities within the pharmaceutical supply chain have a role to play, as well as information to be shared, in order to determine the actual “net amount” for a prescription drug.

(29)

Retaliate

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The new definition in the Draft for the term “retaliate” is troublesome. As listed in this new definition, it appears that the OIC is unaware that many of these items are actions that do occur in the normal course of business.

For example, in the context of a pharmacy’s inclusion in a network, the Proposed Rule would prohibit a PBM from using certain criteria “solely” or “in part” when deciding for pharmacy network inclusion. The term, “in part,” does not appear anywhere in the underlying statute, nor was it included in the public debate during the legislative process. As is, the term, “in part” may lead to a pharmacy claiming retaliation as its defined in the Proposed Rule when it declines to accept the terms and conditions for inclusion of the pharmacy network.

During the 2024 Legislative Session, this issue was discussed extensively. And it was always the legislative intent to include restrictions on such actions, **only when** such actions were done, not implied nor a stated threat of action, in a manner inconsistent with normal business practices.

Finally, this Proposed Rule language is missing a provision from the underlying statute that should be included, as found in the Revised Code of Washington (“RCW”) 48.200.320:

> *(3) A pharmacist or pharmacy shall make reasonable efforts to limit the disclosure of confidential and proprietary information.*

Including this language helps add confidentiality, integrity and trust to the overall process.

(30)

Union plan

This new provision adds a definition for “union plan” to the Proposed Rule. Specifically, it defines a “union plan” as being organized under federal ERISA law. However, a union plan as generally understood means a Taft-Hartley plan, which itself may be organized under federal ERISA law. As previously mentioned in PCMA’s letter to you regarding the Second Draft, there are many problems with the opt-in language of both the Proposed Rule and the underlying statute. This is something that has not been attempted in any other state. And we are reiterating our concern again that the language at issue may have negative consequences for the market.

WAC 284-180-210 Registration and renewal fees.

(5)(b)

This provision of the Proposed Rule provides for an example of when a health care is exempt from the HCBM rule language. Specifically, this provision establishes a requirement that when one carrier acts as an HCBM on behalf of another carrier, the client carrier is responsible for the conduct of the other carrier that is operating as an HCBM on its behalf. PCMA respectfully requests where this new language is in the underlying statute? As is, this is another instance of the OIC enacting public-policy that should be left to the legislative process.

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WAC 284-180-230 HCBM renewal.

(2)(a)

In this provision of the Proposed Rule, the OIC seeks to amend existing law in the WAC. Specifically, the OIC seeks to compel HCBMs to share data in order to achieve renewal of registration in order to conduct business in the State of Washington. It mirrors the language of the Second Prepublication Draft, which itself updated the language of the First Draft addressing the same issue.

The new underlined language states:

> *Their Washington state annual gross income for health care benefit manager business for the previous calendar year, broken down by Washington state annual gross income received from each contracted entity, whether a carrier or another health care benefit manager, that has made payments to the health care benefit manager for services provided to covered persons in Washington state during the previous calendar year;*

The language of the Proposed Rule is not supported by the underlying statute, the language of the E2SSB 5213. Further, such information is unnecessary and outside the scope of both initial registration, as well as renewals.

For example, does this mean that HCBMs would have to include any amounts when an individual who is not a resident of Washington travels to the state and has a prescription filled? Because of this, there is potential that such data would include out-of-state health plans covering Washington residents. To compel such data is outside the OIC's authority as a state regulatory entity.

PCMA respectfully requests that this language be removed from the Proposed Rule, for all of the above stated reasons. At a minimum, the language should be limited only to health plans/carriers based in Washington, with prescription filled in Washington.

(3)

This provision of the Proposed Rule makes changes to existing WAC law, to shorten the timeframe allowed to HCBMs with which to amend annual gross income reports. Specifically, the language at issue states:

> *Health care benefit ~~managers may amend their annual gross income report for the previous year after the date of submission, but~~ may not amend their Washington state annual gross income ~~the~~ report for the previous year later than April 15 ~~May 31st~~, of the submission year.*

While PCMA appreciates the extra two weeks provided for between the language of the First Prepublication Draft and the Second Prepublication Draft, we are uncertain why the time allowed to cure any errors is being modified and shortened. .

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However, the overarching concern is that this language is unsupported by the underlying statute, the language of E2SSB 5213. HCBMs must be allowed greater time to cure any errors via amended reports. It should be the goal of the OIC to achieve maximum compliance with those entities and industries it regulates.

PCMA respectfully requests that the OIC work with those entities who will be subject to these HCBM rules, to find a realistic timeframe for said entities to achieve compliance.

WAC 284-180-325 Required notices.

(1)

This provision of the Proposed Rule requires carriers to post on their website information that identifies its contracted HCBM, "either directly or indirectly through subcontracting." This language is unsupported by the underlying statute.

Moreover, the provision continues by stating a carrier must post such information in a "visually prominent" and "easily located" place on its website.

Nothing in the language of E2SSB 5213 mentions "subcontracting" nor "visually prominent" or "easily located." Also, requiring this granular level of detail, without defining what such terms mean, puts the OIC in a position of expecting compliance with rules that industry may not be able to comply. PCMA respectfully requests that the OIC remove this language from the Proposed Rule.

WAC 284-180-455 Carrier filings related to HCBMs.

(1)(b)(i)

This provision of the Proposed Rule imposes requirements upon health carriers for the filing of contracts it has with HCBMs. Specifically, it would also require the filing of not only contracts with HCBMs, but also the contract it has with an HCBM that then contracts or subcontracts with another HCBMs. Nowhere in the underlying statute is the filing of "subcontracts" mentioned. PCMA respectfully requests that the OIC remove this language.

WAC 284-180-460 HCBM filings.

(1)

This provision of the Proposed Rule adds language to existing law in the WAC expanding the information required by HCBMs to file with the OIC. Specifically, the language states:

> *Contracts that must be filed by a health care benefit manager shall include all contracts to provide health care benefit management services on behalf of a carrier, whether the health care benefit manager is directly of indirectly contracted with the carrier, such as*

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<u>*but not limited to health care benefit management services contracts that result from a carrier contracting with a health care benefit manager who then contracts or subcontracts with another health care benefit manager.*</u>

PCMA has concerns that this new language in the Proposed Rule is redundant. While this language mirrors that of the Second Prepublication Draft, which itself was different from that in the First Prepublication Draft, it still is a restatement of what is already in existing law via the WAC. More importantly, there is nothing in the underlying statute regarding most of this language, particularly with regarding to an HCBM who "subcontracts" with another HCBM.

PCMA respectfully requests that the OIC remove this provision, as it is unsupported by the underlying statute.

<u>WAC 284-160-465. Self-funded group health plan opt-in.</u>

This new section of law would add language via the Proposed Rule to the WAC regarding a "opt-in" for self-funded group health plans to elect to participate in certain sections of the law. As PCMA expressed throughout the legislative process on E2SSB 5213, there are unanswered questions related to the "opt-in." Because of federal preemption and other issues, the intent of the "opt-in" language may be good; however, preemption concerns and unintended consequences may be the result of laudable intent that may at the same time be misguided. This also includes intentional hurdles for self-funded groups that opt-in, but for whatever reason later choose to opt-out.

Also, while PCMA and its member companies appreciate that the Proposed Rule now makes a clarification between self-funded health plan groups that are organized under federal ERISA law, and those that are not, it is critical to note not all self-funded groups are organized under federal ERISA law. This is an important distinction that is included in the underlying statute, the language of E2SSB 5213.

And the OIC has no authority to regulate a self-funded plan operated "by an out-of-state employer that has at least one employee who resides in Washington state." Regardless of whether this language is an "opt-in" for self-funded plans, state departments of insurance around the country cannot legally offer to regulate self-funded health plans for out-of-state employer groups that each have at least one employee who resides in its state of authority. This language makes absolutely no sense, is illegal, and is a poorly thought-out public policy. At no time was this language even contemplated during the public debate within the legislative process for the underlying statute.

For example, were this language to be implemented, what is stopping the Idaho Department of Insurance from implementing similar laws for self-funded plans, operated by a Washington employer/business/labor union, which has at least one employee who resides in Idaho, from exercising its ability to regulate within the state borders of Washington?

PCMA respectfully requests that the OIC recognize the potential confusion and chaos that could be created as a result of enacting this "opt-in" language. Further, PCMA requests that the OIC

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strike the poorly thought-out public policy of regulating businesses in other states for the purposes of the "opt-in" language.

WAC 284-180-501 Pharmacy reimbursement.

This new section of the Proposed Rule states:

> *A pharmacy benefit manager may not reimburse a pharmacy in state an amount less than the amount the pharmacy benefit manager reimburses an affiliate for dispensing the same prescription drug as dispensed by the pharmacy, calculated on a per unit basis.*

This language is unsupported by the underlying statute. And it is unfortunately, another instance of the OIC creating law, where it does not have the authority. This is an issue that should be left to the legislative process. For example, in other states where similar language has been enacted via administrative rulemaking, the language also appeared in the applicable underlying statute. Whether because of an oversight or a failure to achieve its inclusion in the language of the underlying statute when it was going through the legislative process, it is not within OIC's authority granted by the Washington Legislature to require this new policy.

Specifically, RCW 48.200.280 states:

> *(k) May not reimburse a pharmacy in the state an amount less than the amount the pharmacy benefit manager reimburses an affiliate* ***for providing the same pharmacy services****; and*

PCMA respectfully requests that the OIC not disregard the legislative process and remove this provision from the Proposed Rule.

WAC 284-180-505 Appeals by network pharmacies to HCBMs who provide PBM services.

With its passage of the underlying statute, the Washington Legislature clearly intended for pharmacies to submit first-tier appeals to HCBMs (including PBMs) that are statutorily required to have an appeals process. Following this, OIC appeals are second-tier, and are to occur only after the HCBM appeals process has been completed.

As previously stated, the "net amount" of a prescription drug, especially that which a network pharmacy paid to the supplier of a drug, is the result of contracting between a pharmacy and other entities within the pharmaceutical supply chain.

What is concerning is that "net amount" is specified in this provision, but other provisions of the Proposed Rule allow pharmacies to circumvent providing proof of "net amount" by stating that their contracts will not permit them to share pricing data relying on undated ordering system screen shots, allowing attestation by pharmacies, or the ability to circumvent this accountability based on disclosure requirements contained in wholesaler or distributor contracts. This is

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disingenuous as to the intent of the appeal process, and as to what the Washington Legislature contemplated through public debate and negotiations during the legislative process.

Additionally, while PCMA and its member companies appreciate the 24-month timeframe in the for appeals in the Second Draft being decreased to 90 days in the Proposed Rule, this is still too long. Importantly, the 90-day timeline for appeals does not appear in the underlying statute. So, while we appreciate the new inclusion of this shorter timeline, the current timeline remains concerning. And most states require pharmacies to file an appeal within a specific timeframe, as they require PBMs to respond to said appeal.

PCMA respectfully requests that the OIC both correct and standardize the definition of "net amount" throughout the Proposed Rule and remove all proposed loopholes allowing pharmacies to circumvent the Washington Legislature's intent for requiring accountability and transparency by providing documentation of net prices paid for medicines. And further, we request that the OIC provide its authority for enacting a 90-day timeline for appeals, and consider requiring both the pharmacy and PBM provide the information at issue within 30 days.

(1)(a)(i)

This provision of the Proposed Rule requires a PBM to provide a telephone number for the pharmacy to contact the PBM "between 9AM and 5PM Pacific Time Zone Monday through Friday, except national holidays…" So, while PCMA and its member companies appreciate the OIC changing this from the language of the Second Draft requiring a contact to be available on weekends and holidays, this language still appears nowhere in the underlying statute. And it is really a reversion to the language of the First Draft, requiring such contact be available during "normal business hours." Ultimately, the OIC has no authority to implement such a rule. We strongly question the intent of this change between the First and Second Drafts, and then the Proposed Rule.

(1)(a)(iii)

This provision must change. Pharmacies should be mandated to submit all required data in order to process an appeal. Such language is included when pharmacies appeal to OIC (second-tier). There is no reason that pharmacies should not be required to do the same when submitting an appeal to an HCBM (first-tier). In other words, why does an PBM (or any payor entity categorized as an HCBM), have to accept as valid, an appeal that does not contain all the relevant information? There should be integrity and as much uniformity in each process, as is possible.

(1)(a)(iv)

PCMA and its member companies appreciate the OIC's inclusion of a "secure online portal" as one medium in which to conduct appeals, first provided in the language of the Second Prepublication Draft, and beyond the limited avenues provided for in the First Draft.

We also appreciate the OIC changing the language surrounding a PBM's acceptance of "a valid submission" for a pharmacy appeal submitted via email or secure online portal as allowed for in

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a contract between a PBM and pharmacy. This will add integrity to the process and require that pharmacies share some of the burden to ensure the integrity.

However, we remain concerned that if a pharmacy submits an appeal with incomplete and/or inaccurate information, this provision may still put most of the burden on the PBM to accept the appeal with no expectations from the pharmacy to properly submit an appeal.
PCMA respectfully requests that the OIC consider adding language to further strengthen this provision to enhance integrity of the pharmacy appeals process.

(2)

This provision again allows pharmacies to play by different and more lenient rules than the rest of the pharmaceutical supply chain, including HCBMs. It states that a network pharmacy “may” submit information during an appeal to show a reimbursement amount paid by a PBM is “less than the net amount that the network pharmacy paid to the supplier of the drug…” This is permissive language that puts no burden on the pharmacy to not only provide a complete submission but to also include all relevant information in order to determine the “net amount” of a drug reimbursement at issue, but also to submit inaccurate and/or incomplete appeals.

PCMA suggests the following change:

> *In order for the pharmacy benefit manager to determine the "net amount" the appealing pharmacy paid for a drug, the pharmacy benefit manager shall be permitted to request documentation that includes but is not limited to, the invoice price and any and all discounts or price concessions or estimated discounts and price concessions based on purchasing volume, payment timing, generic compliance to the manufacturer, wholesaler or buying group program, wholesaler program enrollment and any other reduction in invoice price.*

PCMA respectfully requests that the OIC change this language as noted above, in order to protect the integrity of the pharmacy appeals process. Pharmacies must submit all the necessary and required information in order for a PBM to properly process an appeal.

(2)(a)

As included in both the Second Prepublication Draft, as well as the First Draft, the OIC has again included language that allows for “an image of information” from the network pharmacy’s “wholesale ordering system.” However, this does not consider that drug prices may change daily. Therefore, any “Image” must include a date of service. Also, the pharmacy’s “wholesale ordering system” does not reflect the post-invoice discounts “net amount” paid for a drug.

Also, the invoice price presented by pharmacies does not reflect an actual acquisition price that considers discounts and incentives that pharmacies obtain from wholesalers that lower the net cost of the drug to the pharmacies.

For example, additional price concessions that pharmacies may receive include:

- Volume discounts

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- Functional discounts
- Bundle discounts
- Slotting Allowances
- Free Goods
- Marketing Funds
- Trade Show Discounts and Rebates
- Pre-payment Discounts

Therefore, requiring pharmacies to only provide an image from the ordering system as proof as in **(2)(a)** is likely to result in overpayment for that drug, given the actual net cost of the drug to the pharmacy is lower. This will inflate drug costs for health plans, employers and consumers.

PCMA respectfully requests that the OIC change this language to resolve the concerns raised above. Along with out member companies, we want the language of the Proposed Rule to follow the legislative intent that pharmacies be accountable for providing documentation related to the "net amount" (A/K/A net price) that they paid for a given drug.

(2)(c)

This new language, first unveiled by the OIC in the Second Prepublication Draft, allows for a network pharmacy to submit an attestation regarding any actions and/or peripheral information relevant to an appeal. Such language appears nowhere in the language of the underlying statute, and it therefore beyond the scope of the OIC's authority for inclusion in the Proposed Rule.

Additionally, this attestation language creates a huge loophole. For example, if a pharmacy's contract with its wholesaler prohibits any and/or all disclosures, a pharmacy will not have to provide any information as part of the appeals process. The resulting loophole is a process whereby a pharmacy may submit attestations without including any of the necessary information, including what is needed to determine "net amount." Lastly, this attestation language was never contemplated during the public debate taking place over the legislative process. For these reasons, PCMA respectfully requests the removal of this provision from the Proposed Rule as well as the ability to not provide documentation if prohibited by contract.

However, if for some misguided reason the OIC insists on keeping this language, at the very least, the conjunctive word between provisions **(2)(b)** and **(2)(c)** should be changed from "or" to "and." Doing this would enact a bare minimum of effort for pharmacies to submit complete and robust documentation.

(2)(c)(ii)

Also included as part of the new attestation language of the Proposed Rule, is this provision allowing for a network pharmacy to describe in its attestation, a narrative to support its appeal. It goes on to describe that a pharmacy may take into consideration whether it has:

> *…fewer than fifteen retail outlets within the state of Washington under its corporate umbrella and whether the network pharmacy's contract with a wholesaler or secondary*

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supplier restricts disclosure of the amount paid to the wholesaler or secondary supplier for the drug.

There is nothing in the underlying statute that mentions anything along these lines. Additionally, this language means that any pharmacies with less than fifteen (15) retail outlets within Washington would not be required to conduct any due diligence to secure the lower cost drug(s).

The language regarding a "network pharmacy's contract with a wholesaler or secondary supplier" that prohibits disclosures is counterintuitive to the entire thrust of this new law and does not meet the legislative intent of pharmacy purchasing accountability and transparency. It explicitly disallows the disclosure of information necessary to determine a drug's "net amount." It also is unsupported by the underlying statute and was never part of the public debate and negotiations during the legislative process.

This language will result in an appeals process where a network pharmacy can submit an attestation stating that it paid $X amount for a drug, without having to offer any proof.

PCMA respectfully requests that this language be removed from the Proposed Rule for all the aforementioned reasons.

(5)(a)

This Proposed Rule provision would enact burdens to be satisfied by a PBM in the event that it denies a network pharmacy's appeal. Specifically, it requires that beyond the PBM's reason for denial, it must provide the pharmacy with the "price" of a drug that has been purchased by other network pharmacies located in Washington with specific caveats. This language, first unveiled by the OIC in the Second Prepublication Draft, again ignores the fact that PBMs have absolutely no direct visibility to what a pharmacy pays a wholesaler for drugs. Generally, a PBM may know what prices a wholesaler states may be available. However, PBMs do not know what type of contract a pharmacy has with its wholesaler(s). Thus, this language is again requiring PBMs to provide unknowable information. Beyond the fact that this is impossible, the language is also unsupported by the underlying statute. Therefore, PCMA respectfully requests that it be removed from the Proposed Rule.

(5)(b)

This Proposed Rule provision puts an additional burden on a PBM to provide additional information in the event of a denial of an appeal. One issue that was not contemplated in the OIC's Proposed Rule is that a self-funded plan participating in this regulatory scheme does so with the OIC, not with a PBM. That said, how is a PBM to know and track what self-funded plans have opted-in? So, what is left, is language that is not only unsupported by the underlying statute but also holding PBMs accountable for information for which they are not in control. Lastly, the language of the Proposed Rule appears to make a mistake in that it fails to exempt other insurance lines of business not under OIC purview other than Medicare.

Further, PBMs having to provide documentation that a claim is from a self-funded plan that has "opted-in" is illogical. Self-funded plans who "opt-in" to the program must do so with OIC, not

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with a PBM. Our member companies do not have that information. PBMs should only be required to inform pharmacies of the claims that are from plans who have not “opted-in” to this regulatory scheme. Then, the pharmacies can validate that with OIC. This is also the reason the pharmacists stated they wanted PBMs to provide them with plan information upon request.

For all these reasons, PCMA respectfully requests that the OIC remove this language from the Proposed Rule.

(6)

PCMA appreciates the changes made by the OIC between the First Prepublication Draft and this Second Draft, and latest changes made to the language of the Proposed Rule.

It appears that the language of the Proposed Rule now includes language to provide the OIC Commissioner with the presumption that a “reasonable adjustment applied prospectively for a period of at least 90 days from the date of an upheld appeal is not a knowing or willful violation” of the applicable law(s). Again, PCMA and its member companies appreciate this change.

However, we remain concerned about the fact that drug prices change daily and are not controlled by PBMs. Moreover, we are concerned that the language in this provision would require PBMs to keep paying an appealed drug’s amount for 90 days. This would be even though PBMs are also required to update lists every seven (7) days. Lastly and most importantly, none of this language is supported by the underlying statute. Thus, PCMA respectfully requests that this language be removed from the Proposed Rule. If the OIC does not agree to remove this language, at a bare minimum, it should be changed to something like:

> *If an appeal is upheld, the health care benefit manager shall make an adjustment for the appealing pharmacy from the date of the initial adjudication forward and allow the pharmacy to reverse the claim and resubmit an adjusted claim without any charges.*

Making this change helps align with the legislative intent of the underlying statute. And it does not establish arbitrary timelines.

(7), (8), and (9)

The public policy set forth in these provisions of the Proposed Rule is to allow for individuals and/or entities, irrespective of their relevance to the appeals process, to be involved in it. Only a pharmacy or its contracted PSAO are the relevant entities for issues over claims and appeals with a contracted PBM.

These provisions would also require PBMs to maintain and submit information related to individuals or entities submitting appeals for which they have no information. PBMs do not know the taxpayer identification numbers, or numbers assigned to said entities by the OIC.

Next, these provisions require a single-point of contact for appeals submitted to PBMs. However, what happens if that single-point of contact for any reason leaves the position? What is the OIC’s recourse?

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Finally, these provisions, along with the rest of the section, expire on December 31, 2025. PCMA respectfully requests that the OIC provide its reasoning for varying expiration dates with overlapping rule language, and strike all of the aforementioned language in these provisions for the reasons stated.

WAC 284-180-507 Appeals by network pharmacies to HCBMs who provide PBM services.

(1)(a)

This provision of the Proposed Rule would add language to existing law regarding network pharmacy reimbursement appeals. Specifically, the language states:

> *A network pharmacy, or its representative, may appeal the reimbursement amount for a drug to a health care benefit manager providing pharmacy benefit management services (first tier appeal) if the reimbursement amount for the drug is less than the net amount the network pharmacy paid to the supplier of the drug and the claim was adjudicated within the past 90 days.*

This language is not supported by the underlying statute. Further, all the concerns expressed above regarding **WAC 284-180-505**, are also applicable here. And PCMA respectfully requests that this language be stricken because it is unsupported by the underlying statute, it allows pharmacies to play by different rules than other entities in the pharmaceutical supply chain, and it would make Washington stand out as an unreasonable standard in which to conduct business compared to nearly all other states. PCMA and its member companies again appreciate the OIC shortening the timeframe at issue from twenty-four months to 90 days. However, this provision needs to be stricken.

(1)(b)

Similar to the Proposed Rule language in **WAC 284-180-505**, this provision allows for a pharmacy to be represented by not only a PSAO, but also an "other entity." PBMs have contracts with pharmacies and/or PSAOs. If finalized, this language would require PBMs to accept appeals from said "other entity" that may not be working on behalf of a pharmacy. PCMA respectfully requests that this language be stricken from the Proposed Rule.

(1)(c)

This Proposed Rule language states that a PSAO may submit an appeal to a PBM on behalf of multiple pharmacies if the "PBM has contracts with the pharmacies on whose behalf the PSAO is submitting the claims." There is nothing in the underlying statute that supports this language. Thus, PCMA respectfully requests that this section be removed from the Proposed Rule.

Additionally, regarding provision **(1)(c)(iii)**, it is imperative that the OIC understand that reimbursement amount varies by contract. Just because multiple pharmacies are in a network and dispense the same drug, does not mean they are reimbursed the same amount. The reimbursement is according to the contract at issue. Thus, all the language in section **(1)(c)** should be stricken.

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(2)

This provision of the Proposed Rule requires that a PBM provide within four (4) business days of receiving a pharmacy's request – prior to an appeal – to provide the pharmacy with:

> *a current and accurate list of bank identification numbers, processor control numbers, and pharmacy group identifiers for health plans and for self-funded group health plans that have elected under RCW 48.200.330 to participate in RCW 48.200.280, 48.200.310, and 47.200.320 with which the pharmacy benefit manager either has a current contract or had a contract that has been terminated within the past 12 month to provide pharmacy benefit management services*.

This language puts a burden on PBMs that does not appear in the underlying statute. It also is too short of a timeframe in which to achieve compliance. The timeframe is also unreasonable and punitive. Furthermore, PCMA is confused by the intent and/or objective of this language. And the bank identification numbers at issue are not necessarily something a PBM can provide without permission from a client.

PCMA respectfully requests that the OIC collaborate with stakeholders to achieve negotiated language that allows for a reasonable timeframe, as well as strike the language pertaining to bank identification numbers.

(4)

This new language in the Proposed Rule requires that a PBM reconsider the reimbursement amount to a pharmacy. Why should a PBM have to reconsider a reimbursement amount if the claim at issue is for a health plan outside the scope of the OIC's authority? Similarly, why should a PBM have to reconsider if a pharmacy and/or PSAO submit an incomplete and/or inaccurate appeal? PCMA respectfully requests that this provision be stricken from the Proposed Rule.

WAC 284-180-517 Use of brief adjudicative proceedings for appeals by network pharmacies to the commissioner.

This new section in the Proposed Rule, first unveiled by the OIC in the Second Prepublication Draft, establishes a procedure for OIC to conduct adjudicative proceeding regarding a network pharmacy's appeal of a PBM"s decision. It states that the language does not apply to adjudicative proceedings under WAC 284-02-070, including "converted brief adjudicative proceedings."

And while the language of the Proposed Rule has changed for the drug at issue has been added to include a drug "subject to predetermined reimbursement costs for multisource generic drugs (reimbursement)" for a first-tier appeal, this does not address the aforementioned concerns.

PCMA respectfully requests that the OIC explain its intent for inserting a caveat to the OIC's adjudicative proceedings.

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WAC 284-180-522 Appeals by network pharmacies to the commissioner.

This new section in the Proposed Rule, first unveiled by the OIC in the Second Prepublication Draft, further details appeals by network pharmacies submitted to PBMs and the OIC's involvement in an appeal to the agency. Specifically, the language sets forth the (1) grounds for appeal, the (2) timeframes governing appeals to the OIC, and (3) the relief the OIC may provide. The new section also establishes notice requirements, along with standards for appearance and practice at a brief adjudicative proceeding. Lastly, the language sets forth a method of response, standards for hearings by telephone, information related to a presiding officer for the proceedings, the entry of orders, and filing instructions. With all of this new administrative procedure law, PCMA respectfully requests that the OIC better explain its reasoning for not having an effective date until January 1, 2026, beyond the fact that **WAC 284-180-520** expires on December 31, 2025 – thus **WAC 284-180-522** presumably taking its place in the WAC.

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In sum, PCMA's respectfully requests that the OIC adhere to the language of the underlying statute, as well as its rulemaking authority as a state regulatory entity. We further urge the OIC to make changes to the Proposed Rule in order to ensure the integrity of all of the processes at issue. And hope that the OIC will help us understand the intent of certain provisions contained within the Proposed Rule by answering our questions.

PCMA looks forward to working with the OIC on this issue. Please contact myself or my colleague, Tonia Sorrell-Neal (tsorrell-neal@pcmanet.org), PCMA's Senior Director of State Affairs, for further discussion.

Sincerely,

Peter Fjelstad

Peter Fjelstad
Assistant Vice President, State Regulatory & Legal Affairs

Enclosure (2)
PCMA's comment letter on the First Prepublication Draft – July 26, 2024
PCMA's comment letter on the Second Prepublication Draft – September 16, 2024

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September 16, 2024

Commissioner Mike Kreidler
Washington State Officer of the Insurance Commissioner
302 Sid Snyder Ave., SW
Olympia, WA 98504
EMAIL: rulescoordinator@oic.wa.gov

SENT VIA EMAIL

Re: R-2024-02 Health Care Benefit Managers – Second Prepublication Draft

Dear Commissioner Kreidler:

I write on behalf of Pharmaceutical Care Management Association ("PCMA") in response to the Washington State Office of the Insurance Commissioner ("OIC") Second Prepublication Draft ("Draft") for Health Care Benefit Managers ("HCBMs"), R-2024-02. Generally, this Draft would amend state law concerning the business practices of HCBMs, related to the 2024 Legislative Session enactment of Engrossed Second Substitute Senate Bill ("E2SSB") 5213 (Chapter 242, Laws of 2024). As you know, PCMA submitted comments to you regarding the First Prepublication Draft on July 26, 2024. We appreciate the OIC accepting some of our requests for changes. However, PCMA continues to have concerns with this Draft, along with requests for changes to be made to this Draft, as well as questions about the language in this Draft.

PCMA is the national trade association representing pharmacy benefit managers ("PBMs"). PCMA's PBM member companies administer drug benefits for more than 275 million Americans, including most Indianans, who have health insurance through employer-sponsored health plans, including those organized under the federal Employee Retirement and Income Security Act ("ERISA") of 1974, commercial health plans, union plans, Medicare Part D plans, managed Medicaid plans, the state employee health plan, and others.

The ERISA benefit plans with which PCMA's members contract include both insured and self-funded benefit plans sponsored by businesses/employers and labor unions. PBMs use a variety of benefit management tools to help these plans provide high quality, cost-effective prescription drug coverage to plan beneficiaries.

Below is a brief outline of PCMA's concerns, requests for changes, and questions for the OIC regarding its Second Prepublication Draft. At the outset, we would like to note that much of the language in the Second Draft contains redundant language from the First Draft. For example, that language of WAC 284-180-505 in the First Draft substantially overlaps with the language of WAC 284-180-507 in the Second Draft, yet both sections remain. Furthermore, issues related to the "net amount" of a drug at issue, the information unavailable to PBMs or HCBMs, and allowing pharmacies to play by different and less stringent rules, are littered throughout the language of the Second Draft. And much of this language is either the same, or substantially similar. Therefore, for the sake of brevity, we have attempted to consolidate our comments on the Second Draft to focus on what language is new, but often, it relates to the same issues, as with the language of the First Draft.

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WAC 284-180-120 Applicability and scope.

(b)(3)

This provision of the Draft would add new language to the Wahington Administrative Code ("WAC"), stating that the Chapter does not apply to the actions of HCBMs providing services to or acting on behalf of "medicare supplement or medicare advantage plans." PCMA respectfully requests that the OIC explain its change from the First Prepublication Draft explicitly removing from the scope of the language "self-insured health plans," "Medicare plans," "Medicaid plans," and "union plans."

As the OIC knows, this Draft contains troublesome language providing for an "opt-in" for self-insured health plans to take part in the regulatory scheme provided by the language in the Draft. However, the new language of this section appears to not take several factors into consideration. First, is it the intent of the OIC to include managed care Medicaid plans within the Draft? What is the reasoning behind splitting up Medicare plans, generally, in the new Draft? "Union plan(s)" typically means a Taft-Hartley plan, the benefits of which may be collectively bargained. And a Taft-Hartley plan may be organized under federal ERISA law. So, what is a "union plan?" PCMA and its member companies remain concerned that the "opt-in" language, now along with the new language in this section, are setting up the OIC for a raft of unintended negative consequences.

WAC 284-180-130 Definitions.

(4)

Control

In this section of the draft, "control" is defined as the ability to directly or indirectly make decisions. It states that such "control" may be exercised "through ownership of voting securities, membership rights, by contract, or otherwise." PCMA and its member companies respectfully request that "or otherwise" be explicitly defined or removed. This is not a legal term, nor is it a policymaking term of art. It is inappropriate to use words or phrases that have no clear meaning either because they are not explicitly defined in the agency rulemaking at issue, or in some other chapter of existing state states or administrative code.

(7)

Credentialing

Credentialing is not mentioned anywhere in the underlying statute, the language of E2SSB 5213. Nor was credentialing ever part of the public debate during the legislative process for E2SSB 5213. Furthermore, it is not mentioned anywhere in the remainder of the Draft language. PCMA respectfully requests that this be removed from the Draft.

(19)

Net amount

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This definition explicitly states the OIC's intent is to account for post-invoice discounts and rebates. However, in reviewing the language of both this Second Prepublication Draft, as well as the First Prepublication Draft, the OIC has left gaping loopholes for pharmacies to not provide documentation of what the "net amount" actually is.

PCMA respectfully requests that the OIC address this issue, as we have repeatedly requested in the past. PBMs are not privy to all of the information shared between pharmacies, their pharmacy services administrative organizations ("PSAOs"), as well as the wholesalers and pharmaceutical manufacturers at issue for a specific drug. Thus, the OIC's intent in this definition for "net amount" needs to consider that all the entities within the pharmaceutical supply chain have a role to play, as well as information to be shared, in order to determine the actual "net amount" for a prescription drug.

(29)

Retaliate

The new definition in the Draft for the term "retaliate" is troublesome. As listed in this new definition, it appears that the OIC is unaware that some of these items are actions that may occur in the normal course of business.

For example, in the context of a pharmacy's inclusion in a network, the Draft would prohibit a PBM from using certain criteria "solely" or "in part" when deciding for pharmacy network inclusion. The term, "in part," does not appear anywhere in the underlying statute, nor was it included in the public debate during the legislative process. As is, the term, "in part" may lead to a pharmacy claiming retaliation as its defined in the Draft when it declines to accept the terms and conditions for inclusion of the pharmacy network.

During the 2024 Legislative Session, this issue was discussed extensively. And it was always the legislative intent to include restrictions on such actions to exclude a pharmacy from a network, **only when** such actions were done in a manner inconsistent with normal business practices.

WAC 284-180-210 Registration and renewal fees.

(5)(b)

This provision of the Draft provides for an example of when a health care is exempt from the HCBM rule language. Specifically, this provision establishes a requirement that when one carrier acts as an HCBM on behalf of another carrier, the client carrier is responsible for the conduct of the other carrier that is operating as an HCBM on its behalf. PCMA respectfully requests where this new language is in the underlying statute? As is, this is another instance of the OIC enacting public-policy that should be left to the legislative process.

WAC 284-180-230 HCBM renewal.

(2)(a)

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In this provision of the Draft, the OIC seeks to amend existing law in the WAC. Specifically, the OIC seeks to compel HCBMs to share data in order to achieve renewal of registration, in order to conduct business in the State of Washington. It updates the language of the First Prepublication Draft addressing the same issue.

The new underlined language states:

> *Their Washington state annual gross income for health care benefit manager business for the previous calendar year, broken down by Washington state annual gross income received from each contracted entity, whether a carrier or another health care benefit manager, that has made payments to the health care benefit manager for services provided to covered persons in Washington state during the previous calendar year;*

The new language in the Draft is not supported by the underlying statute, the language of the E2SSB 5213. Further, such information is unnecessary and outside the scope of both initial registration, as well as renewals.

For example, does this mean that HCBMs would have to include any amounts when an individual who is not a resident of Washington travels to the state and has a prescription filled? Because of this, there is potential that such data would include out-of-state health plans covering Washington residents. To compel such data is outside the OIC's authority as a state regulatory entity.

Lastly, as we move forward in a new era in which federal courts will continue to cast aspersions on government entities seeking to go beyond their scope of authority regarding agency rulemaking, it is PCMA's hope that the OIC takes notice. This is true to any of the language of the Draft that goes beyond the underlying statute or the scope of the OIC's rulemaking authority.

PCMA respectfully requests that this language be removed from the Draft, for all of the above stated reasons. At a minimum, the language should be limited only to health plans/carriers based in Washington, with prescription filled in Washington.

(3)

This provision of the Draft makes changes to existing WAC law, to shorten the timeframe allowed to HCBMs, with which to amend annual gross income reports. Specifically, the language at issue states:

> *Health care benefit ~~managers may amend their annual gross income report for the previous year after the date of submission, but~~ may not amend their Washington state annual gross income ~~the~~ report for the previous year later than April 15 ~~May 31st~~, of the submission year.*

PCMA appreciates the extra two weeks provided for between the language of the First Prepublication Draft and the Second Prepublication Draft.

However, the overarching concern is that this language is unsupported by the underlying statute, the language of E2SSB 5213. HCBMs must be allowed greater time to cure any errors

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via amended reports. It should be the goal of the OIC to achieve maximum compliance with those entities and industries it regulates.

PCMA respectfully requests that the OIC work with those entities who will be subject to these HCBM rules, to find a realistic timeframe for said entities to achieve compliance.

WAC 284-180-325 Required notices.

(1)

This provision of the Draft requires carriers to post on their website information that identifies its contracted HCBM, “either directly or indirectly through subcontracting.” This language is unsupported by the underlying statute.

Moreover, the provision continues by stating a carrier much post such information in a “virtually prominent” and “easily located” place on its website.

Nothing in the language of E2SSB 5213 mentions “subcontracting” nor “virtually prominent” or “easily located.” Also, requiring this granular level of detail, without defining what such terms mean, puts the OIC in a position of expecting compliance for rules that industry may not be able to comply. PCMA respectfully requests that the OIC remove this language from the Draft.

WAC 284-180-455 Carrier filings related to HCBMs.

(1)(b)(i)

This provision of the Draft imposes requirements upon health carriers for the filing of contracts it has with HCBMs. Specifically, it would also require the filing of not only contracts with HCBMs, but also the contract it has with an HCBM that then contracts or subcontracts with another HCBMs. Nowhere in the underlying statute is the filing of “subcontracts” mentioned. PCMA respectfully requests that the OIC remove this language.

WAC 284-180-460 HCBM filings.

(1)

This provision of the Draft adds language to existing law in the WAC expanding the information required by HCBMs to file with the OIC. Specifically, the language states:

> *Contracts that must be filed by a health care benefit manager shall include all contracts to provide health care benefit management services on behalf of a carrier, whether the health care benefit manager is directly of indirectly contracted with the carrier, such as but not limited to health care benefit management services contracts that result from a carrier contracting with a health care benefit manager who then contracts or subcontracts with another health care benefit manager.*

PCMA has concerns that this new language in the Draft is redundant. While the language is different from that in the First Prepublication Draft, it still is a restatement of what is already in

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existing law via the WAC. Also, there is nothing in the underlying statute regarding most of this language, particularly with regarding to an HCBM who “subcontracts” with another HCBM.

PCMA respectfully requests that the OIC remove this provision, as it is unsupported by the underlying statute.

WAC 284-160-465. Self-funded group health plan opt-in.

This new section of law would add language via the Draft to the WAC regarding a “opt-in” for self-funded group health plans to elect to participate in certain sections of the law. As PCMA expressed throughout the legislative process on E2SSB 5213, there are unanswered questions related to the “opt-in.” Because of federal preemption and other issues, the intent of the “opt-in” language may be good; however, preemption concerns and unintended consequences may be the result of laudable intent that may at the same time be misguided. This also includes potential hurdles for self-funded groups that opt-in, but for whatever reason later choose to opt-out.

Also, the Draft makes no clarification between self-funded health plan groups that are organized under federal ERISA law, and those that are not. Not all self-funded groups are organized under federal ERISA law. This is an important distinction that is included in the underlying statute, the language of E2SSB 5213.

And the OIC has no authority to regulate a self-funded plan operated “by an out-of-state employer that has at least one employee who resides in Washington state.” Regardless of whether this language is an “opt-in” for self-funded plans, state departments of insurance around the country cannot legally offer to regulate self-funded health plans for out-of-state employer groups that each have at least one employee who resides in its state of authority. This language makes absolutely no sense, is illegal, and is a poorly thought-out public policy. At no time was this language even contemplated during the public debate within the legislative process for the underlying statute.

For example, were this language to be implemented, what is stopping the Idaho Department of Insurance from implementing similar laws for self-funded plans, operated by a Washington employer/business/labor union, which has at least one employee who resides in Idaho, from exercising its ability to regulate within the state borders of Washington?

PCMA respectfully requests that the OIC clarify that the “opt-in” language refers to self-funded plans organized under federal ERISA law. Further, PCMA requests that the OIC strike the poorly thought-out public policy of regulating businesses in other states for the purposes of the “opt-in” language.

WAC 284-180-505 Appeals by network pharmacies to HCBMs who provide PBM services.

As previously stated, the “net amount” of a prescription drug, especially that which a network pharmacy paid to the supplier of a drug is the result of contracting between a pharmacy and other entities within the pharmaceutical supply chain.

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What is concerning is that “net amount” is specified in this provision, but other provisions of the Draft allow pharmacies to circumvent providing proof of “net amount” by stating that their contracts will not permit them to share pricing data. This is disingenuous as to the intent of the appeal process, and as to what the Washington Legislature contemplated through public debate and negotiations during the legislative process. Furthermore, a 24-month timeline for appeals does not appear in the underlying statute. So, while we appreciate the new inclusion of a finite timeline, which did not appear in the First Prepublication Draft, the current timeline remains concerning.

PCMA respectfully requests that the OIC both correct and standardize the definition of “net amount” throughout the Draft. And further, we request that the OIC provide its authority for enacting a 24-month timeline for appeals.

(1)(a)(i)

This provision of the Draft requires a PBM to provide a telephone number for the pharmacy to contact the PBM “between 9AM and 5PM Pacific Standard Time every day, including weekends and holidays…” This language appears nowhere in the underlying statute, and the OIC has no authority to implement such a rule. Previously, such a phone number was required to be operated during normal business hours. We strongly question the intent of this change.

PCMA respectfully requests that this provision revert to its former language, requiring operation of a telephone number during normal business hours. Further, we request the reasoning for including weekends and holidays for the operation of such a telephone number.

(1)(a)(iv)

PCMA and its member companies appreciate the OIC’s inclusion of a “secure online portal” as one medium in which to conduct appeals, beyond the limited avenues provided for in the First Prepublication Draft.

However, this provision requires that a PBM accept “as a valid submission” a pharmacy appeal submitted via email or secure online portal as allowed for in a contract between a PBM and pharmacy.

How can a PBM be expected to accept an appeal, if an appealing pharmacy does not include all of the required and/or relevant information necessary to process an appeal? This provision puts the entire burden of pharmacy appeals onto a PBM, without requiring any due diligence of pharmacies. For example, if a pharmacy submits an appeal with incomplete and/or inaccurate information, this provision puts the burden on the PBM to accept the appeal with no expectations from the pharmacy to properly submit an appeal. This undermines the entirety of the appeals process. What would be left, is an appeals process with no integrity.

PCMA respectfully requests that the OIC either strike or change this language because of the fact that it does nothing other than impugn the integrity of the pharmacy appeals process.

(2)

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This provision again allows pharmacies to play by different any more lenient rules than the rest of the pharmaceutical supply chain, including HCBMs. It states that a network pharmacy "may" submit information during an appeal to show a reimbursement amount paid by a PBM is "less than the net amount that the network pharmacy paid to the supplier of the drug…" This is permissive language that puts no burden on the pharmacy to not only provide the relevant information in order to determine the "net amount" of a drug reimbursement at issue, but also to submit inaccurate and/or incomplete appeals.

PCMA respectfully requests that the OIC change this language in order to protect the integrity of the pharmacy appeals process.

(2)(a)

As included in the First Prepublication Draft, the OIC has again included language that allows for "an image of information" from the network pharmacy's "wholesale ordering system." However, this does not consider that drug prices may change daily. Therefore, any "Image" must include a date. Also, the pharmacy's "wholesale ordering system" does not reflect the "net amount" paid for a drug.

PCMA respectfully requests that the OIC change this language to resolve the concerns raised above.

(2)(c)

This new language in the Second Prepublication Draft allows for a network pharmacy to submit an attestation regarding any actions and/or peripheral information relevant to an appeal. Such language appears nowhere in the language of the underlying statute, and it therefore beyond the scope of the OIC's authority for inclusion in the Draft.

Additionally, this attestation language creates a huge loophole. For example, if a pharmacy's contract with its wholesaler prohibits any and/or all disclosures, a pharmacy will not have to provide any information as part of the appeals process. The resulting loophole is a process whereby a pharmacy may submit attestations without including any of the necessary information, including what is needed to determine "net amount," Lastly, this attestation language was never contemplated during the public debate taking place over the legislative process. For these reasons, PCMA respectfully requests the removal of this provision from the Draft.

(2)(c)(ii)

Also included as part of the new attestation language of the Draft, is this provision allowing for a network pharmacy to describe in its attestation, a narrative to support its appeal. It goes on to describe that a pharmacy may take into consideration whether it has:

> *…fewer than fifteen retail outlets within the state of Washington under its corporate umbrella and whether the network pharmacy's contract with a wholesaler or secondary supplier restricts disclosure of the amount paid to the wholesaler or secondary supplier for the drug.*

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There is nothing in the underlying statute that mentions anything along these lines. Additionally, this language means that any pharmacies with less than fifteen (15) retail outlets within Washington would not be required to conduct any due diligence to secure the lower cost drug(s).

The language regarding a "network pharmacy's contract with a wholesaler or secondary supplier" that prohibits disclosures is counterintuitive to the entire thrust of this new law. It explicitly disallows the disclosure of information necessary to determine a drug's "net amount." It also is unsupported by the underlying statute and was never part of the public debate and negotiations during the legislative process.

Eventually, this language will lead to an appeals process where a network pharmacy can submit an attestation stating that it paid $X amount for a drug, without having to offer any proof.

PCMA respectfully requests that this language be removed from the Draft, for all the aforementioned reasons.

(5)(a)

This Draft provision would enact burdens to be satisfied by a PBM in the event that it denies a network pharmacy's appeal. Specifically, it requires that beyond the PBM's reason for denial, it must provide the pharmacy with the "price" of a drug that has been purchased by other network pharmacies located in Washington with specific caveats. This new Second Prepublication Draft language again ignores the fact that PBMs are not privy to what a pharmacy pays a wholesaler for drugs. Generally, a PBM may know what prices a wholesaler may state is available. However, PBMs do not know what type of contract a pharmacy has with its wholesaler(s). Thus, this language is again requiring PBMs to provide unknowable information. Beyond the fact that this is impossible, the language is also unsupported by the underlying statute. Therefore, PCMA respectfully requests that it be removed from the Draft.

(5)(b)

This Draft provision puts an additional burden on a PBM to provide additional information in the event of a denial of an appeal. One issue that was not contemplated in the OIC's Draft is that a self-funded plan participating in this regulatory scheme does so with the OIC, not with a PBM. That said, how is a PBM to know and track what self-funded plans have opted-in? So, what is left, is language that is not only unsupported by the underlying statute but also holding PBMs accountable for information for which they are not in control. Lastly, the new language of the Second Prepublication Draft appears to make a mistake in not exempting more than Medicare.

For all these reasons, PCMA respectfully requests that the OIC remove this language from the Draft.

(6)

PCMA appreciates the changes made by the OIC between the First Prepublication Draft and this Second Draft. As the change addresses situations when a generic drug is introduced to the market. However, it does not resolve the issue that drug prices change daily and are not

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controlled by PBMs. If enacted, the language in this provision would require PBMs to keep paying an appealed drug's amount for 90 days. This would be even though PBMs are also required to update lists every seven (7) days. And none of this language is supported by the underlying statute. PCMA respectfully requests that this language be removed from the Draft.

(7), (8), and (9)

The public policy set forth in these provisions of the Draft is to allow for individuals and/or entities, irrespective of their relevance to the appeals process, to be involved in it. Only a pharmacy or its contracted PSAO are the relevant entities for issues over claims and appeals with a contracted PBM.

These provisions would also require PBMs to maintain and submit information related to individuals or entities submitting appeals for which they have no information. PBMs do not know the taxpayer identification numbers, or numbers assigned to said entities by the OIC.

Next, these provisions require a single-point of contact for appeals submitted to PBMs. However, what happens if that single-point of contact for any reason leaves the position? What is the OIC's recourse?

Finally, these provisions, along with the rest of the section, expire on December 31, 2025. PCMA respectfully requests that the OIC provide its reasoning for varying expiration dates with overlapping rule language, and strike all of the aforementioned language in these provisions for the reasons stated.

WAC 284-180-507 Appeals by network pharmacies to HCBMs who provide PBM services.

(1)(a)

This provision of the Draft would add language to existing law regarding network pharmacy reimbursement appeals. Specifically, the language states:

> *A network pharmacy, or its representative, may appeal the reimbursement amount for a drug to a health care benefit manager providing pharmacy benefit management services (first tier appeal) if the reimbursement amount for the drug is less than the net amount the network pharmacy paid to the supplier of the drug and the claim was adjudicated within the past twenty four months.*

This Draft language is not in the underlying statute. Further, all the concerns expressed above regarding **WAC 284-180-505**, are also applicable here. And PCMA respectfully requests that this language be stricken because it is unsupported by the underlying statute, it allows pharmacies to play by different rules than other entities in the pharmaceutical supply chain, and it would make Washington stand out as an unreasonable standard in which to conduct business compared to nearly all other states.

(1)(b)

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Similar to the Draft language in **WAC 284-180-505**, this provision allows for a pharmacy to be represented by not only a PSAO, but also an "other entity." PBMs have contracts with pharmacies and/or PSAOs. If finalized, this language would require PBMs to accept appeals from said "other entity" that may not be working on behalf of a pharmacy. PCMA respectfully requests that this language be stricken from the Draft.

(1)(c)(iii)

This Draft language is part of a larger provision that states that a PSAO may submit an appeal to a PBM on behalf of multiple pharmacies if the "PBM has contracts with the pharmacies on whose behalf the PSAO is submitting the claims."

First, it is imperative that the OIC understand that reimbursement amount varies by contract. Just because multiple pharmacies are in a network and dispense the same drug, does not mean they are reimbursed the same amount. The reimbursement is according to the contract at issue. Thus, PCMA respectfully requests that this language be stricken.

(2)

This provision of the Draft requires that a PBM provide within four (4) business days of receiving a pharmacy's request – prior to an appeal – to provide the pharmacy with:

> *a current and accurate list of bank identification numbers, processor control numbers, and pharmacy group identifiers for health plans and for self-funded group health plans that have elected under RCW 48.200.330 to participate in RCW 48.200.280, 48.200.310, and 47.200.320 with which the pharmacy benefit manager either has a current contract or had a contract that has been terminated within the past 12 month to provide pharmacy benefit management services.*

This language puts a burden on PBMs that does not appear in the underlying statute. It also is too short of a timeframe in which to achieve compliance. The timeframe is also unreasonable and punitive. PCMA respectfully requests that the OIC work with stakeholders to achieve negotiated language that allows for a reasonable timeframe.

(4)

This new language in the Draft requires that a PBM reconsider the reimbursement amount to a pharmacy. Why should a PBM have to reconsider a reimbursement amount if the claim at issue is for a health plan outside the scope of the OIC's authority? Similarly, why should a PBM have to reconsider if a pharmacy and/or PSAO submit an incomplete and/or inaccurate appeal? PCMA respectfully requests that this provision be stricken from the Draft.

WAC 284-180-517 Use of brief adjudicative proceedings for appeals by network pharmacies to the commissioner.

This new section in the Second Prepublication Draft establishes a procedure for OIC to conduct adjudicative proceeding regarding a network pharmacy's appeal of a PBM"s decision. It states

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that the language does not apply to adjudicative proceedings under WAC 284-02-070, including "converted brief adjudicative proceedings."

PCMA respectfully requests that the OIC explain its intent for inserting a caveat to the OIC's adjudicative proceedings.

WAC 284-180-522 Appeals by network pharmacies to the commissioner.

This new section in the Second Prepublication Draft further details appeals by network pharmacies submitted to PBMs and the OIC's involvement in an appeal to the agency. Specifically, the language sets forth the (1) grounds for appeal, the (2) timeframes governing appeals to the OIC, and (3) the relief the OIC may provide. The new section also establishes notice requirements, along with standards for appearance and practice at a brief adjudicative proceeding. Lastly, the language set forth a method of response, standards for hearings by telephone, information related to a presiding officer for the proceedings, the entry of orders, and filing instructions. With all of this new administrative procedure law, PCMA respectfully requests that the OIC provide its reasoning for not having an effective date until January 1, 2026.

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In sum, PCMA's respectfully requests that the OIC adhere to the language of the underlying statute, as well as its rulemaking authority as a state regulatory entity. We further urge the OIC to make changes to the Second Draft in order to ensure the integrity of all of the processes at issue. And hope that the OIC will help us understand the intent of certain provisions contained within the Second Draft by answering our questions.

PCMA looks forward to working with the OIC on this issue. Please contact myself or my colleague, Tonia Sorrell-Neal (tsorrell-neal@pcmanet.org), PCMA's Senior Director of State Affairs, for further discussion.

Sincerely,

Peter Fjelstad

Peter Fjelstad
Assistant Vice President, State Regulatory & Legal Affairs

Enclosure (1)

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July 26, 2024

Commissioner Mike Kreidler
Washington State Officer of the Insurance Commissioner
302 Sid Snyder Ave., SW
Olympia, WA 98504
EMAIL: rulescoordinator@oic.wa.gov

SENT VIA EMAIL

Re: R-2024-02 Health Care Benefit Managers – First Prepublication Draft

Dear Commissioner Kreidler:

I write on behalf of Pharmaceutical Care Management Association ("PCMA") in response to the Washington State Office of the Insurance Commissioner ("OIC") First Prepublication Draft ("Draft") for Health Care Benefit Managers ("HCBMs"), R-2024-02. Generally, this Draft would amend state law concerning the business practices of HCBMs, related to the 2024 Legislative Session enactment of Engrossed Second Substitute Senate Bill ("E2SSB") 5213 (Chapter 242, Laws of 2024). Currently, PCMA has several concerns with the Draft, along with requests for changes to be made to the Draft, as well as questions about the language in the Draft.

PCMA is the national trade association representing pharmacy benefit managers ("PBMs"). PCMA's PBM member companies administer drug benefits for more than 275 million Americans, including most Indianans, who have health insurance through employer-sponsored health plans, including those organized under the federal Employee Retirement and Income Security Act ("ERISA") of 1974, commercial health plans, union plans, Medicare Part D plans, managed Medicaid plans, the state employee health plan, and others.

The ERISA benefit plans with which PCMA's members contract include both insured and self-funded benefit plans sponsored by businesses/employers and labor unions. PBMs use a variety of benefit management tools to help these plans provide high quality, cost-effective prescription drug coverage to plan beneficiaries.

Below is a brief outline of PCMA's concerns, requests for changes, and questions for the OIC.

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WAC 284-180-230 HCBM renewal.

(2)(a)

In this provision of the Draft, the OIC seeks to amend existing law in the Washington Administrative Code ("WAC"). Specifically, the OIC seeks to compel HCBMs to share data in order to achieve renewal of registration, in order to conduct business in the State of Washington.

The new underlined language states:

> *Their Washington state annual gross income for health care benefit manager business for the previous calendar year, broken down by Washington state annual gross income received from each entity with which the health care benefit manager has contracted during the previous calendar year;*

The new language in the Draft is not supported by the underlying statute, the language of the E2SSB 5213. In fact, it does not even appear in the underlying statute. Further, such information is unnecessary and outside the scope of both initial registration, as well as renewals.

There is also potential that such data would include out-of-state health plans covering Washington residents, because of the language stating: “each entity with which the HCBM has contracted.” To compel such data is outside the OIC’s authority as a state regulatory entity.

Lastly, as we move forward in a new era in which federal courts will continue to cast aspersions on government entities seeking to go beyond their scope of authority regarding agency rulemaking, it is PCMA’s hope that the OIC takes notice. This is true to any of the language of the Draft that goes beyond the underlying statute or the scope of the OIC’s rulemaking authority.

PCMA respectfully requests that this language be removed from the Draft, for all of the above stated reasons.

(3)

This provision of the Draft makes changes to existing WAC law, to shorten the timeframe allowed to HCBMs, with which to amend annual gross income reports. Specifically, the language at issue states:

> *Health care benefit ~~managers may amend their annual gross income report for the previous year after the date of submission, but~~ may not amend their Washington state annual gross income ~~the~~ report for the previous year later than April 1 ~~May 31st~~, of the submission year.*

PCMA is concerned that the OIC is shortening the period with which an HCBM may amend its gross annual income report. This shortening appears to be unsupported by the language of the underlying statute, E2SSB 5213. Moreover, PCMA argues that the shortening of the period would allow registered HCBMs less time with which to cure any errors via amended reports. It should be the goal of the OIC to achieve maximum compliance with those entities and industries it regulates.

PCMA respectfully requests that the OIC provide its reasoning for shortening this period, as well as consider the ramifications this current language may have should it be finalized.

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WAC 284-180-460 HCBM filings.

(1)

This provision of the Draft adds language to existing law in the WAC expanding the information required by HCBMs to file with the OIC. Specifically, the language states:

> *Contracts that must be filed by a health care benefit manager shall include all contracts to directly or indirectly provide health care benefit management services on behalf of a carrier, such as but not limited to health care benefit management services contracts that result from a carrier contracting with a health care benefit manager who then contracts or subcontracts with another health care benefit manager.*

PCMA has concerns that this new language in the Draft is redundant. It appears to be a restatement of what is already in existing law via the WAC, particularly the language that precedes it in the provision at issue.

PCMA respectfully requests that the OIC clarify its intent with this new language, as it appears redundant, and therefore possibly bad public policy.

WAC 284-160-465. Self-funded group health plan opt-in.

This new section of law would add language via the Draft to the WAC regarding a "opt-in" for self-funded group health plans to elect to participate in certain sections of the law. As PCMA expressed throughout the legislative process on E2SSB 5213, there are unanswered questions related to the "opt-in." Because of federal preemption and other issues, the intent of the "opt-in" language may be good; however, preemption concerns and unintended consequences may be the result of laudable intent that may at the same time be misguided. This also includes potential hurdles for self-funded groups that opt-in, but for whatever reason later choose to opt-out.

Also, the Draft makes no clarification between self-funded health plan groups that are organized under federal ERISA law, and those that are not. Not all self-funded groups are organized under federal ERISA law. This is an important distinction that is included in the underlying statute, the language of E2SSB 5213.

PCMA respectfully requests that the OIC clarify that the "opt-in" language refers to self-funded plans organized under federal ERISA law.

WAC 284-180-505 Appeals by network pharmacies to HCBMs who provide PBM services.

(1)

This provision of the Draft would add language to existing law regarding network pharmacy reimbursement appeals. Specifically, the language states:

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A network pharmacy, or its representative, may appeal the ~~a~~ reimbursement amount for a drug to a health care benefit manager providing pharmacy benefit management services (first tier appeal) if the reimbursement amount for the drug is less than the net amount the network pharmacy paid to the supplier of the drug and the claim was paid during the term of the current or immediate past contract between the network pharmacy and the pharmacy benefits manager.

This Draft language is not in the underlying statute. At present, a PBM has 30 days to process and appeal. A pharmacy should have the same period to file the appeal after the claim is adjudicated. If this language in the Draft goes unchanged, it would also create a significant administrative burden. Nearly all maximum allowable cost ("MAC") laws across the county provide for a reasonable limit of time with which a pharmacy has to appeal.

PCMA respectfully requests that this language be stricken because it is unsupported by the underlying statute, it allows pharmacies to play by different rules than other entities in the pharmaceutical supply chain, and it would make Washington stand out as an unreasonable standard in which to conduct business compared to nearly all other states.

(2)

This provision in the Draft would require that a PBM provide certain information to a pharmacy or pharmacist prior to an appeal. Specifically, the language states:

Before a pharmacy files an appeal pursuant to this section, upon request by a pharmacy or pharmacist, a pharmacy benefit manager must provide a current and accurate list of bank identification numbers, processor control numbers, and pharmacy group identifiers for health plans and for self-funded group health plans that have elected to participate in sections 5, 7, and 8 of this act through WAC 284-180-465 with which the pharmacy benefit manager either has a current contract or had a contract that has been terminated within the past 12 months to provide pharmacy benefit management services.

While this language appears in the underlying statute, PCMA and its member companies do not understand the intent of requiring information mentioned in the provision. One concern is that a PBM is generally not allowed to provide said information without the consent of a health plan or self-funded group health plan. Pharmacies are paid by a PBM, not directly by a health plan. So why then would a PBM need to provide a client health plan's bank identification numbers?

PCMA respectfully requests that the OIC provide the intent of compelling such information from a PBM.

(3)(a)(i)(D)

This provision in the Draft requires that a PBM recognize an email submission of an appeal or information regarding an appeal, to be a valid submission. Specifically, the language states:

<u>Submission by a pharmacy of an appeal or information regarding an appeal to the email address included in the contract under this subsection must be accepted by the pharmacy benefit manager as a valid submission.</u>

Generally, pharmacy appeals are conducted through a secure online portal. This language would deviate from that practice. In doing so, it may jeopardize making public not only confidential and proprietary information, but also the protected health information ("PHI") or personally identifiable information ("PII") of any individual patient involved. This is because secure online portals have been set up to establish a safe and secure process for appeals. Emails are unable to provide such security.

Further, this language in the Draft does not contemplate that an email submission may not have all the required information to process an appeal. This is another reason to use the appeal portal, as it is secure, and also ensures submission of all required information to process an appeal.

Moreover, appeals allowed via email may establish a new process that allows for pharmacy services administrative organizations ("PSAOs") to abuse the appeals and complaint processes. PSAOs are entities that contract with pharmacies to manage issues related to the administrative needs of pharmacies, including appeals. The largest PSAOs are owned and operated by the largest wholesale distributors (i.e., wholesalers) of prescription drugs. PBMs and pharmacies, as well as PSAOs and wholesalers are entities within the pharmaceutical supply chain, along with manufacturers.

If the language in this provision of the Draft is finalized it may allow PSAOs to impugn the integrity of the appeals process by sending thousands of complaints and/or what are known as batch appeals at one time.

Finally, during the discussion and debate of this issue within the legislative process, the represented intent of providing an email for appeals was so pharmacies had a mechanism to contact PBM appeals departments. It was **never** intended to be used as a submission vehicle for appeals. The language of the Draft is both unsupported by the underlying statute, as well as beyond the scope of the OIC's authority as a state regulatory entity. It also contradicts legislative intent. Therefore, requiring that a PBM accept emails as valid appeal submissions is wholly unlawful.

PCMA respectfully requests that this language be removed from the Draft. Beyond the aforementioned problems with email, this language is unsupported by the underlying statute.

(4), (4)(a), and (4)(b)

These provisions in the Draft would expand the list of information a network pharmacy is allowed to use to support its appeals with a PBM. Specifically, the language states:

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Documents or information that may be submitted by a network pharmacy to show that the reimbursement amount paid by a pharmacy benefit manager is less than the net amount that the network pharmacy paid to the supplier of the drug include but are not limited to:

(a) An image of information from the network pharmacy's wholesale ordering system;

(b) Other documentation showing the amount paid by the network pharmacy.

PBMs need a copy of the invoice that reflects all post-invoice discounts. Otherwise, it is not possible to achieve the standard of "net price" paid. So, an image or screenshot from a wholesale ordering system is inadequate. PBMs need information for the specific drug on or near the date of service.

Also, the language of this provision in the Draft does not appear in the underlying statute. As used in this provision, the term, "may," is permissive. Therefore, it does not bind a pharmacy to any standard. The use of "may" could result in pharmacies not submitting anything to PBMs. Such permissible language is not consistent with underlying statute, which states that pharmacies must submit documentation. The underlying statute also clearly defines "net price" to include post-invoice rebates and discounts.

The definition of "net amount" in **WAC 284-180-130** demonstrates the legislative intent was clearly meant to ensure pharmacies reported all post-invoice discounts or rebates the pharmacies receive. Screenshots and other images from a pharmacy's ordering system will not work.

Furthermore, the invoice price presented by pharmacies does not reflect the actual acquisition price that considers discounts and incentives that pharmacies obtain from wholesalers that lower the net cost of the drug to the pharmacies.

For example, additional price concessions that pharmacies receive include:

- Volume discounts;
- Functional discounts;
- Bundle discounts;
- Slotting Allowances;
- Free Goods;
- Marketing Funds; and
- Trade Show Discounts and Rebates

Therefore, requiring pharmacies to only provide an invoice as proof as in **(4)(a)** is likely to result in overpayment for that drug, given the actual net cost of the drug to the pharmacy is lower. This will inflate drug costs for health plans, employers and consumers.

PCMA respectfully requests that this Draft language change to include something along the lines of the following:

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In order for the pharmacy benefit manager to determine the net amount, the appealing pharmacy paid for a drug, the pharmacy benefit manager shall be permitted to request documentation that includes but is not limited to, the invoice price and any and all estimated and actual discounts or price concessions based on purchasing volume, payment timing, generic compliance to the manufacturer, wholesaler or buying group program, wholesaler program enrollment and any other reduction in invoice price.

(8)(a)

This provision of the Draft would impose requirements on a PBM regarding additional information sharing with a network pharmacy denied an appeal. Specifically, the language states:

> *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~~ drug and the name of the wholesaler or supplier from which the drug was available for purchase at that price on the date of the claim or claims that are subject of the appeal. ~~"Multisource generic drug" is defined in RCW 19.340.100 (1)C.~~*

This language in not supported by the underlying statute. PBMs do not contract with any particular pharmacy's wholesaler or supplier. Thus, a PBM is not privy to the price that a particular pharmacy would pay for a drug at any given time. And to include this language in the Draft is inconsistent with how pharmacy-wholesaler contracting actually works.

PCMA respectfully requests that this language be stricken from the Draft.

(8)(b)

This provision in the Draft imposes obligations on a PBM in the event of a pharmacy appeals denial. Specifically, the language states:

> *If the pharmacy benefit manager bases its denial on the fact that one or more of the claims that are the subject of the appeals is not subject to RCW 48.200.280 and this chapter, it must provide documentation clearly as such in its denial notice.*

This language is unsupported by the underlying statute. Therefore, it is beyond both the scope of the law, as well as the OIC's authority to implement.

PCMA respectfully requests that this language be removed from the Draft.

(9)

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This provision in the Draft would impose requirements on a PBM In the event that it upholds a pharmacy appeal. Specifically, the language states:

> *If the pharmacy benefit manager upholds the network pharmacy's appeal the pharmacy benefit manger must make a reasonable adjustment no later than one day after the date of the determination. The reasonable adjustment must include, at a minimum, payment of the claim or claims at issue at the net amount paid by the pharmacy to the supplier of the drug.*

As previously stated in PCMA's comments on provision **(4)** of the Draft, as well as elsewhere, the OIC needs to make changes to the Draft in order to allow a PBM to determine what the "net amount" at issue is. Also, the language in this provision of the Draft does not appear in the underlying statute.

Moreover, no other state has enacted language similar to this unsupported adjustment language. Part of the reason that no other state has adopted such language is because it is generally recognized that the cost of drugs changes daily. Therefore, it is not appropriate to require a PBM to continue to reimburse at a higher rate for any period of time when prices fluctuate so much. Doing so results in overpayments.

That said, does this mean the OIC wants to require that PBMs pay brand-drug reimbursement rates even when a generic is available? What if an appeal was filed when the drug cost was really high and then new generics become available with much lower price points? This would require a PBM to continue to reimburse at the higher level for 90 days.

PCMA respectfully requests that the OIC remove and/or change this language in the Draft.

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In sum, PCMA's respectfully requests that the OIC adhere to the language of the underlying statute, as well as its rulemaking authority as a state regulatory entity. We further urge the OIC to make changes to the Draft in order to ensure the integrity of all of the processes at issue. And hope that the OIC will help us understand the intent of certain provisions contained within the Draft by answering our questions.

PCMA looks forward to working with the OIC on this issue. Please contact myself or my colleague, Tonia Sorrell-Neal (tsorrell-neal@pcmanet.org), PCMA's Senior Director of State Affairs, for further discussion.

Sincerely,

Peter Fjelstad

Peter Fjelstad
Assistant Vice President, State Regulatory & Legal Affairs

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