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.

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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:

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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.

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

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