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PROPOSED	RULE	MAKING
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# CR-102 (June 2024) (Implements RCW 34.05.320)

Do **NOT** use for expedited rule making

OFFICE OF THE CODE REVISER STATE OF WASHINGTON FILED

DATE: October 22, 2024 TIME: 7:33 PM

WSR 24-21-158

Agency: Office of the Insurance Commissioner			Insurance Commissioner Matter R 2024-02	
⊠ Original Notice				
Supplemental Noti	ce to WSR			
□ Continuance of WS	SR			
☑ Preproposal Stater	nent of Inqu	uiry was filed as WSR 24-1	1-126	; or
Expedited Rule Ma	kingPropo	osed notice was filed as W	SR	; or
Proposal is exemp	t under RC\	N 34.05.310(4) or 34.05.33	0(1); oı	
Proposal is exemp				
				Relating to health care benefit managers, including but
Hearing location(s):	Itation of E23	SSB 5213 (Chapter 242, La	WS OF Z	024)
Date:	Time:	Location: (be specific)		Comment:
November 26, 2024		Virtual Meeting (Zoom)		Written comments are due to the OIC by 2:00 p.m. on
1000111001 20, 2021		Detailed information for atte	ending	November 26, 2024. Written comments can be emailed
		the Zoom meeting is posted	don	to <u>rulescoordinator@oic.wa.gov</u> .
		the OIC website:	ov/rol	
		https://www.insurance.wa.g ating-health-care-benefit-	jov/rei	
		managers-r-2024-		
Date of intended ado	otion: Nover	mber 27, 2024 (Note: T	his is <b>N</b>	IOT the effective date)
Submit written comm	ents to:		Assist	ance for persons with disabilities:
Name Jane Beyer			Contact Katie Bennett	
Address 302 Sid Snyd	er Ave.,SW	Olympia WA 98504	Phone	360-725-7013
Email rulescoordinator@oic.wa.gov		Fax 3	60-586-2023	
Fax 360-586-3109		TTY 3	60-586-0241	
Other		Email	Katie.Bennett@oic.wa.gov	
Beginning (date and time) Wednesday, October 23, 2024		Other		
at 12:00 a.m. Pacific Time Zone		By (da	te) November 25, 2024 by 12 noon Pacific Time Zone	
By (date and time) November 26, 2024 by 2 p.m. Pacific Time Zone		Бу (ua	te) November 25, 2024 by 12 noon Facilit Time 20ne	
	sal and its a	anticipated effects includi	ing anv	changes in existing rules: E2SSB 5213 (Chapter
				es of health care benefit managers (HCBMs) and
	•		,	aw's provisions address, among other issues, PBM
				umer access to mail order and retail pharmacies;
				n and reporting; and oversight authority of the Office of operations. Rulemaking is necessary to revise existing
				AC) and ensure that all affected entities understand
their rights and obligations under the new law.				
In addition, rulemaking related to HCBMs beyond the scope of E2SSB 5213 is necessary to ensure that OIC can effectively				
oversee HCBMs in light of recent health care industry developments like the Change Healthcare cyberattack in early 2024				
and OIC's experience regulating HCBMs.				
Reasons supporting	nronosal· 🛱	Revisions to current rules are	nppda	ed to implement F2SSB 5213 and ensure all affected
	<b>Reasons supporting proposal:</b> Revisions to current rules are needed to implement E2SSB 5213 and ensure all affected entities understand their rights and obligations under RCW 48.200.			

Statutory authority for adoption: RCW 48.200.900; RCW 48.02.060

Statute being implemented: E2SSB 5213 (Chapter 242, Laws of 2024)				
Is rule necessary	/ because of a:			
Federal Lav	w?		🗆 Yes 🛛 No	
Federal Co	urt Decision?		🗆 Yes 🛛 No	
State Court			□ Yes ⊠ No	
If yes, CITATION:				
		ny, as to statutory language, implementation, e	nforcement, and fiscal	
	ent: (person or organization) nt: □ Private. □ Public. ⊠ (	Mike Kreidler, Insurance Commissioner Governmental.		
Name of agency	personnel responsible for:			
	Name	Office Location	Phone	
Drafting	Jane Beyer	P.O. Box 40255, Olympia WA 98504-0255	360-725-7043	
Implementation Gaines	John Hayworth and Ned	P.O. Box 40255, Olympia, WA 98504-0255	360-725-7000	
Enforcement	Charles Malone	P.O. Box 40255, Olympia, WA 98504-0255	360-725-7000	
If yes, insert state The public may Name Address Phone Fax TTY Email Other	ment here: y obtain a copy of the school d	equired under <u>RCW 28A.305.135</u> ?	□ Yes ⊠ No	
Name S Address Phone Fax 360 TTY Email r Other	eliminary cost-benefit analysis Simon Casson PO Box 40255, Olympia, W 360-725-7038 0-586-3109 ulescoordinator@oic.wa.gov se explain:	may be obtained by contacting: A 98504-0255		
Regulatory Fairn	ess Act and Small Business	Economic Impact Statement		
	- · ·	vation and Assistance (ORIA) provides support in	completing this part.	
chapter 19.85 RC check the box for This rule proper adopted solely to	I, or portions of the proposal, <b>n</b> <u>W</u> ). For additional information any applicable exemption(s): osal, or portions of the proposa conform and/or comply with fe e is being adopted to conform of	<b>hay be exempt</b> from requirements of the Regulator on exemptions, consult the <u>exemption guide publis</u> al, is exempt under <u>RCW 19.85.061</u> because this re deral statute or regulations. Please cite the specific or comply with, and describe the consequences to	shed by ORIA. Please ule making is being c federal statute or	
defined by RCW 3	<u>34.05.313</u> before filing the notic osal, or portions of the propose	al, is exempt because the agency has completed the ce of this proposed rule. al, is exempt under the provisions of <u>RCW 15.65.57</u>		

This rule proposal, or portions of the proposal, is exempt under <u>RCW 19.85.025(3)</u>. Check all that apply:

- <u>RCW 34.05.310</u> (4)(b)
   (Internal government operations)
- <u>RCW 34.05.310</u> (4)(c)
   (Incorporation by reference)
- RCW 34.05.310 (4)(d) (Correct or clarify language)

- RCW 34.05.310 (4)(e) (Dictated by statute)
- RCW 34.05.310 (4)(f) (Set or adjust fees)
- <u>RCW 34.05.310</u> (4)(g)
   ((i) Relating to agency hearings; or (ii) process
   requirements for applying to an agency for a lid

requirements for applying to an agency for a license or permit)

This rule proposal, or portions of the proposal, is exempt under <u>RCW 19.85.025(4)</u>. (Does not affect small businesses).
 This rule proposal, or portions of the proposal, is exempt under RCW

L This full proposal, of portions of the proposal, is exempt under RCW \_

Explanation of how the above exemption(s) applies to the proposed rule:

OIC determined that both health carriers and HCBMs are impacted by the implementation of this rule. Based on 2022 WA Employment Security Department (ESD) Covered Employment data, health carriers are not considered small businesses, as they have on average 112 employees per firm (7,163 total employees in WA / 64 average number of firms in WA). Small business is defined as a business entity, including a sole proprietorship, corporation, partnership, or other legal entity, that is owned and operated independently from all other businesses, and that has fifty or fewer employees (RCW 19.85.020). Health carriers are not considered small businesses.

OIC also considered the impact of this rule on small pharmacies. The NAIC's system classifies pharmacies as having an average of 38 employees under code 456110 – pharmacies and drug retailers. Provisions of the rule (WAC 284-180-505 and WAC 284-180-507) make changes to the process that small pharmacies must use to appeal reimbursements from PBMs. However, the small pharmacy appeals process is voluntary on the part of pharmacies. Therefore, OIC concluded that the rule provisions related to pharmacies do not constitute a cost to small businesses.

Portions of the proposal are exempt from requirements of the Regulatory Fairness Act. The following table identifies rule sections or portions of rule sections that have been determined exempt based on the exemptions provided in RCW 34.05.310

WAC Section and Title	Description of Adopted Changes	Rationale for Exemption Determination
WAC 284-180-120 Applicability and scope	Clarification of who the chapter applies to; adopting or incorporating by reference statutory provisions.	RCW 34.05.310(4)(e) and (d)
WAC 284-180-130 Definitions.	Clarification of definitions used within the chapter; dictated by statute.	RCW 34.05.310(4)(e) and (d)
WAC 284-180-210 Registration and renewal fees.	Clarifying the gross income definition, clarifying applicability.	RCW 34.05.310(4)(d)
WAC 284-180-220 Health care benefit manager registration.	Dictated by statute.	RCW 34.05.310(4)(e)
WAC 284-180-240 Providing and updating registration	Clarifying language; dictated by statute.	RCW 34.05.310(4)(d) and (e)
WAC 284-180-325 Required notices.	Does not impact small businesses as health carriers are not deemed to be small businesses.	RCW 19.85.025(4)
WAC 284-180-405 Definitions	Clarifying language.	RCW 34.05.310(4)(d)
WAC 284-180-411 Purpose of this subchapter.	Clarifying language.	RCW 34.05.310(4)(d)
WAC 284-180-455 Carrier filings related to health care benefit managers.	Does not impact small businesses as health carriers are not deemed to be small businesses.	RCW 19.85.025(4)
WAC 284-180-465 Self-funded group health plan opt-in.	No requirement for self-funded group health plans to opt in. Therefore, no cost of compliance is calculated.	RCW 19.85.025(4)
WAC 284-180-500 Applicability and scope.	Clarifying language; dictated by statute.	RCW 34.05.310(4)(e) and (d)
WAC 284-180-515 Use of brief adjudicative proceedings for appeals by network pharmacies to the commissioner.	The OIC has determined that this section does not have additional costs for businesses.	RCW 19.85.025(4)

WAC 284-180-517 Use of brief adjudicative proceedings for appeals by network pharmacies to the commissioner.	The OIC has determined that this section does not have additional costs for businesses.	RCW 19.85.025(4)
WAC 284-180-520 Appeals by network pharmacies to the commissioner.	Clarifying language	RCW 34.05.310(4)(d)
WAC 284-180-522 Appeals by network pharmacies to the commissioner	The OIC has determined that this section does not have additional costs for businesses and is dictated by statute.	RCW 34.05.310(4)(e)

### (2) Scope of exemptions: Check one.

□ The rule proposal: Is fully exempt. *(Skip section 3.)* Exemptions identified above apply to all portions of the rule proposal. □ The rule proposal: Is partially exempt. *(Complete section 3.)* The exemptions identified above apply to portions of the rule proposal, but less than the entire rule proposal. Provide details here (consider using this template from ORIA): Section 1 above details the identified exemptions and for which sections they apply to. Portions of the proposed rule are not exempt. Those sections are described in detail in section 3 below.

□ The rule proposal: Is not exempt. (*Complete section 3.*) No exemptions were identified above.

(3) Small business economic impact statement: Complete this section if any portion is not exempt.

If any portion of the proposed rule is **not exempt**, does it impose more-than-minor costs (as defined by RCW 19.85.020(2)) on businesses?

□ No Briefly summarize the agency's minor cost analysis and how the agency determined the proposed rule did not impose more-than-minor costs.

Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses and a small business economic impact statement is required. Insert the required small business economic impact statement here:

A brief description of the proposed rule including the current situation/rule, followed by the history of the issue and why the proposed rule is needed. A description of the probable compliance requirements and the kinds of professional services that a small business is likely to need in order to comply with the proposed rule.

E2SSB 5213 (Chapter 242, Laws of 2024) amends state law concerning the business practices of health care benefit managers (HCBMs) and pharmacy benefit managers (PBMs, which are a type of HCBM). The law's provisions address, among other issues, PBM reimbursement to pharmacies for dispensing prescription drugs; consumer access to mail order and retail pharmacies; consumer out-of-pocket costs for prescription drugs; HCBM registration and reporting; and oversight authority of the Office of the Insurance Commissioner (OIC) regarding HCBM registration and operations. Rulemaking is necessary to revise existing HCBM rules at Chapter 284-180 WAC and to ensure that all affected entities understand their rights and obligations under the new law.

In addition, rulemaking related to HCBMs is necessary to ensure that OIC can effectively oversee HCBMs in light of recent developments in the health care industry.

The OIC was unable to definitively determine whether HCBMs should be classified as large businesses (more than 50 employees). The OIC used the North American Industry Classification System (NAICS) code 524292, "Pharmacy benefit management and other third-party administration of insurance and pension funds," to estimate the number of employees per firm. However, this NAICS code includes entities in addition to HCBMs and PBMs, as it captures third-party administrators of insurance and pension funds; accordingly, the code could misrepresent the true average firm sizes of HCBMs and PBMs.

Additionally, the OIC reviewed evidence suggesting that a small number of large PBM firms dominate the PBM market in Washington state and nationally. The Washington state Health Care Authority's Drug Price Transparency Program Annual Report 2023<sup>1</sup> found that "the top four PBMs in Washington account for approximately 99 percent of the total dollar value of prescription drug claims, with the top two accounting for 68% of statewide dollars." This report also found that the bottom 10 PBMs account for just one percent of Washington's PBM market. The Federal Trade Commission (FTC)'s 2024 report titled Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies<sup>2</sup> found

<sup>&</sup>lt;sup>1</sup> Washington State Health Care Authority, *Drug Price Transparency Annual Report* (Olympia, WA: Washington State Health Care Authority, 2023), <u>https://www.hca.wa.gov/assets/billers-and-providers/drug-price-transparency-annual-report-2023.pdf</u>.

<sup>&</sup>lt;sup>2</sup> **Federal Trade Commission**, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies*, July 2024, <u>https://www.ftc.gov/reports/pharmacy-benefit-managers-report</u>.

that a few large, integrated firms dominate the pharmacy benefit management market in the United States. The FTC report stated: "Over the past two decades, the PBM industry has undergone substantial change as a result of horizontal consolidation and vertical integration. The top three PBMs processed nearly 80 percent of the approximately 6.6 billion prescriptions dispensed by U.S. pharmacies in 2023, while the top six PBMs processed more than 90 percent. All of the top six PBMs are vertically integrated downstream, operating their own mail order and specialty pharmacies, while one PBM owns and operates the largest chain of retail pharmacies in the nation. Pharmacies affiliated with the three largest PBMs now account for nearly 70 percent of all specialty drug revenue."

There is evidence to suggest that, in addition to PBMs specifically, many HCBMs are large and vertically integrated businesses. For example, the U.S. House of Representatives' Committee on Energy and Commerce found that Change Healthcare, a subsidiary of UnitedHealth Group that performs HCBM functions nationally and in Washington state, "acts as a clearing house for 15 billion medical claims each year – accounting for nearly 40 percent of all claims."<sup>3</sup>

Although these findings indicate that many HCBMs and PBMs are indeed large businesses, OIC acknowledges that there may also be a subset of firms providing HCBM and PBM services who are small businesses. Because of this, the OIC assumed that HCBMs are classified as small businesses for purposes of this analysis.

OIC also considered the impact of this rule on small pharmacies. The NAIC's system classifies pharmacies as having an average of 38 employees under code 456110 – pharmacies and drug retailers. Provisions of the rule (WAC 284-180-505 and WAC 284-180-507) make changes to the process that small pharmacies must use to appeal reimbursements from PBMs. However, the small pharmacy appeals process is voluntary on the part of pharmacies. Therefore, OIC concluded that the rule provisions related to pharmacies do not constitute a cost to small businesses.

This analysis evaluates the cost of compliance and any potential impacts on revenue associated with the proposed rule. Impacts on small businesses are discussed in sections 4 and 5, and steps to reduce the impacts to small businesses are discussed in section 6.

Parts of this analysis refer to HCBMs where others reference pharmacy benefit managers (PBMs). Under RCW 48.200.020, "health care benefit manager" includes, but is not limited to, health care benefit managers that specialize in specific types of health care benefit management such as pharmacy benefit managers. Chapter 48.200 RCW and E2SSB 5213 include provisions that are limited in application to pharmacy benefit managers.

Identification and summary of which businesses are required to comply with the adopted rule using the North American Industry Classification System (NAICS).

# SBEIS Table 1. Summary of Businesses Required to comply to the Adopted Rule

NAICS Code	NAICS Business Description	Number of businesses in WA	Minor Cost Threshold
524292	Pharmacy Benefit Management and Other Third Party Administration of Insurance and Pension Funds	160	\$28,510.46

The number of HCBMs in Washington is determined from the list of entities that have registered with the OIC. To conduct business in Washington, a HCBM must register with the Commissioner and annually renew the registration (RCW 48.200.030). HCBMs are a subset of the businesses included in the NAICS code 524292, which includes third party administration of insurance and pension funds.

Analysis of probable costs of businesses in the industry to comply to the adopted rule and includes the cost of equipment, supplies, labor, professional services, and administrative costs. The analysis considers if compliance with the adopted rule will cause businesses in the industry to lose sales or revenue.

WAC 284-180-230 Health care benefit manager renewal.

Description:

This section amends how HCBMs should report information related to Washington state annual gross income when completing the annual registration renewal. Under current regulation, the HCBMs must submit their Washington state annual gross income for health care benefit manager business for the previous calendar year. The proposed rule requires the renewing HCBM to submit their Washington state annual gross income broken down by Washington state annual gross

<sup>&</sup>lt;sup>3</sup> United States House of Representatives, Committee on Energy and Commerce, *What We Learned: Change Healthcare Cyber Attack*, May 2024, https://energycommerce.house.gov/posts/what-we-learned-change-healthcare-cyber-attack

income received from each entity with which the health care benefit manager has contracted during the previous calendar year.

# Cost(s):

The OIC calculated the cost associated with providing the WA state annual gross income received from each contracted entity by assuming the number of hours it will take HCBM staff to compile and submit the information, and by relying upon legal and clerical worker labor rates as published by the U.S. Department of Labor Employee Benefits Security Administration.<sup>4</sup> Using these components, the OIC estimated the cost of submitting the annual gross income broken down by contracted entity for year one after the proposed rule would go into effect, and the cost in subsequent years.

Currently, the OIC requires HCBMs to submit an Annual Report at renewal. The Annual Report asks HCBMs to enter the following information:

- The amount of Washington state annual gross Health Care Benefit Manager income for the year.
- The number of entities that the Registrant provides HCBM services to in the state of Washington.
- Whether the Registrant has any new entities that they provide HCBM services to that were not previously reported.
- Whether the Registrant has any new persons and entities with ownership or controlling interests.
- Whether there are any changes in ownership interests that have not been previously reported.
- Any updates to the contact persons.
- Any other material changes to report.
- Whether the Registrant has committed any violations in WA or any other state or has been the subject of an order from a department of insurance or other federal or state agency.
- Whether the HCBM committed any act not previously reported in the renewal application that would result in denial, suspension, or revocation of a registration.

The OIC will develop an updated reporting template to capture Washington state annual gross income 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 OIC estimates that each HCBM will file three to five contracts.<sup>5</sup> Each reported income document is estimated to take 30 minutes for a lawyer to review, and an additional 30 minutes for a clerical worker to submit to the OIC via the annual report. This equates to (5 contracts) x (0.5 hours) x (\$165.71) = \$414.28 for a lawyer's services, and (5 contracts) x (0.5 hours) x (\$65.99) = \$164.98 for a clerical worker's services, per submitting HCBM.

Average number of	Lawyer labor rate	Clerical worker labor	Total average cost
contracts		rate	per HCBM
5	\$165.71 * 0.5 hrs	\$65.99 * 0.5 hrs	\$579.26

### WAC 284-180-460 Health care benefit manager filings.

### Description:

Under the proposed rule, HCBMs would be required to file all contracts to directly or indirectly provide health care benefit management services on behalf of a carrier. This requirement is implementing RCW 48.200.040, which requires HCBMs to file with OIC "in the form and manner prescribed by the commissioner, every benefit management contract and contract amendment between the health care benefit manager and a health carrier, provider, pharmacy, pharmacy services administration organization, or other health care benefit manager, entered into directly or indirectly in support of a contract with a carrier or employee benefits programs, within 30 days following the effective date of the contract or contract amendment." The proposed rule restates the statutory requirement and adds an illustrative example of which contracts must be filed.

### Cost(s):

The OIC currently receives all contract filings in the System for Electronic Rate and Form Filing (SERFF). This is a system developed and maintained by the National Association of Insurance Commissioners (NAIC). HCBMs currently each submit approximately three contract filings per year. The OIC is unable to accurately determine how many contract filings this rule would require, given the current statutory obligation of HCBMs to file contracts entered into directly or indirectly in support of a contract with a carrier or employee benefits program. For this analysis, the OIC assumes that the filing of the additional contracts will require a lawyer three hours to review and a clerical worker two hours to upload into SERFF.

Occupation	Labor Rate	Hours	Total Cost
Lawyer	\$165.71	3	\$497.13

<sup>&</sup>lt;sup>4</sup> U.S. Department of Labor, "Rulemaking for 2024" (April 2024), <u>https://public-inspection.federalregister.gov/2024-08068.pdf</u>.

<sup>&</sup>lt;sup>5</sup> Based on 572 HCBM contract filings received in 2023, from 172 submitting HCBMs. 572/172 = 3.3. With additional rule language requiring entities that are both directly and indirectly contracted, this number could be higher; therefore the OIC estimates five filings per HCBM.

Clerical worker	\$65.99	2	\$131.98
			\$629.11 <sup>6</sup>

WAC 284-180-505 Appeals by network pharmacies to health care benefit managers who provide pharmacy benefit management services.

### Description:

The rule language proposed by the OIC would amend several subsections within WAC 284-180-505. The proposed rule requires:

- That a PBM allow a pharmacy to appeal a reimbursement if the claim was adjudicated by the PBM within the past 90 days.
- A PBM to have a phone number available 9 a.m. to 5 p.m. Pacific Time Monday through Friday, except national holidays, for purposes of pharmacy appeals.
- A PBM to provide the pharmacy with the price of a drug purchased by other network pharmacies, for purposes of denying a pharmacy appeal.
- A PBM to provide documentation to show that a claim is not subject to RCW 48.200 (the chapter) when the PBM is denying a claim for this reason. RCW 48.200.280(4)(b) requires a PBM to provide the reason that an appeal is denied; therefore, the PBM already has an obligation to provide a reason. If the denial is based upon the fact that an appeal is for a plan not subject to the chapter, the PBM will have made that determination already. The proposed rule merely requires that the PBM specifically share the results of their research with the pharmacy.
- That when a pharmacy's appeal is upheld, the PBM must make a "reasonable adjustment" that includes, at minimum, the payment of the claims at the net amount the pharmacy paid the supplier. The proposed rule provides that the OIC will presume 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 chapter 48.200 RCW under RCW 48.200.290. If a therapeutically equivalent interchangeable product becomes available during the period that a reasonable adjustment is in effect, the adjustment may reflect the cost of that product from the date it becomes available to the end of the prospective reasonable adjustment period.

# Cost(s):

The proposed rule sets a clear and uniform timeframe or "lookback period" by allowing pharmacies to appeal a reimbursement if the claim was adjudicated by the PBM within 90 days of the claim's adjudication (and otherwise meets the requirements for appeals). To determine the marginal cost to PBMs resulting from this requirement, the OIC would need to know the length of the lookback period that pharmacies generally use in appealing a reimbursement to a PBM. In other words, the OIC would need to know whether, and how, the proposed 90-day lookback period is different from current practice in the absence of this provision. However, the OIC understands that for this type of appeal (first tier appeal), the lookback period the pharmacy may use is determined by contractual arrangement between the PBM and the pharmacy. Because these contract terms are not well known, the OIC could not estimate the cost of this proposed amendment to PBMs.

The OIC did review a sample of final orders and decisions for "second tier" appeals from the Office of Administrative Hearings (OAH) from 2019-2024. This sample suggested, but did not prove, that the "lookback period" used by pharmacies was approximately 30 days in 2024 and longer from 2019-2023. However, this review was not definitive and did not capture the "first tier" appeals, in which a pharmacy appeals directly to a PBM. Therefore, OIC did not have enough information to estimate the cost of this amendment on PBMs.

Currently, under WAC 284-180-505(1)(a)(i) PBMs are required to have a telephone number by which the pharmacy may contact the PBM during "normal business hours" and speak with an individual responsible for processing appeals. The OIC assumes that normal business hours include 9 a.m. – 5 p.m. Pacific Time. Therefore, there is no marginal cost associated with this provision.

OIC considers the cost to a PBM of providing a network pharmacy with the price of a drug that has been purchased by other network pharmacies located in Washington at a price less than or equal to the predetermined reimbursement cost for a drug to be minimal. RCW 48.200.280(4(b) already requires, for denied appeals, that the PBM provide "the national drug code of a drug that has been purchased by other network pharmacies located in Washington at a price that is equal to or less than the predetermined reimbursement cost..." Under the proposed rule, the PBM would be sharing the results of its research with the pharmacy. This change could potentially impact the market for PBM services by changing the relative leverage that

<sup>&</sup>lt;sup>6</sup> Labor rates based on 2023 labor cost data. 2023 wage rates estimated from the published 2019 labor costs by the U.S. Department of Labor: https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/rules-and-regulations/technical-appendices/labor-cost-inputs-used-in-ebsa-opr-ria-and-pra-burden-calculations-june-2019.pdf

pharmacies, their representatives, and PBMs have in negotiating contracts. However, the OIC is unable to quantify the precise impact of this change.

The proposed language specifically defines what the reasonable adjustment must include if the PBM upholds the network pharmacy's appeal. RCW 48.200.280(5)(a) already requires a PBM to make a reasonable adjustment; the proposed language stipulates that 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. The proposed rule provides that the OIC will presume 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 chapter 48.200 RCW under RCW 48.200.290. If a therapeutically equivalent interchangeable product becomes available during the period that a reasonable adjustment is in effect, the adjustment may reflect the cost of that product from the date it becomes available to the end of the prospective reasonable adjustment period.

According to public information released by the Health Care Authority, as of 2020, a vast majority of pharmacy appeals to PBMs were denied (96%), meaning that this amended language would only apply to a small subset of upheld appeals, assuming the denial rate remains relatively stable.<sup>7</sup> The OIC is unable to establish the baseline for how the "reasonable adjustment" as described in WAC 284-280-505(6) is currently interpreted. For second tier appeals, the OIC reviewed Administrative Law Judge (ALJ) orders to determine how ALJs interpret reasonable adjustments. From the orders reviewed, the reasonable adjustment is the difference between the original payment by the PBM to the pharmacy and the price the pharmacy paid the wholesaler or supplier. The sample OIC reviewed does not indicate what "reasonable adjustment" a PBM is making as a part of the first tier appeals. However, OIC's review of these orders does indicate that the proposed rule's definition of reasonable adjustment is in line with current practice as seen in the OAH orders. Therefore, there is a cost associated with the provision explicitly defining reasonable adjustment, although the OIC is unable to accurately estimate the cost. The OIC assumes that the cost is not significant, considering that second tier appeal practices are already in line with the proposed language.

It is important to note that any cost associated with this provision is based on the number of appeals made to the PBMs. Between 2018 and 2020, 38% of appeals were made to only two PBMs.<sup>8</sup> Smaller PBMs are less likely to receive as many appeals compared to larger PBMs, and therefore the smaller PBMs are less likely to bear a significant cost due to this provision.

284-180-505 proposed rule cost elements	Annual cost per PBM
A claim must be adjudicated within the past 90 days	Undetermined
Phone number available 9-5 PT on weekends and holidays	No cost
PBM must provide pharmacy with the price of a drug	Undetermined – low cost of compliance, with unknown impacts to PBM revenue
Defining "reasonable adjustment"	Undetermined – Likely low cost, with reduced cost burden for smaller businesses.

WAC 284-180-507 Appeals by network pharmacies to health care benefit managers who provide pharmacy benefit management services.

Description:

This section goes into effect January 1, 2026, at which point WAC 284-180-505 is no longer effective.

This section allows a pharmacy services administrative organization (PSAO) to submit an appeal to a PBM on behalf of multiple pharmacies under certain conditions. Under RCW 48.200.280(3), as amended by E2SHB 5213, a pharmacy or its representative may submit an appeal. This proposed rule language clarifies how a representative of a pharmacy may submit an appeal. It is possible that allowing a PSAO to submit an appeal for multiple pharmacies would have the effect of increasing the overall number of appeals that PBMs receive, because they could be receiving appeals from multiple pharmacies instead of one.

Prior to a pharmacy filing an appeal, upon request by a pharmacy or pharmacist, a PBM must provide, within four business days of receiving the request, a current and accurate list of bank ID numbers, processor control numbers, and pharmacy group identifiers for health plans and for self-funded group health plans that have elected to participate. The language in the proposed rule is incorporated into the rule directly from RCW 48.200.280(4), as amended by E2SHB 5213, with the exception of the addition of a four-day time frame for the PBM to provide the information to the pharmacy. Because the requirement to

 <sup>&</sup>lt;sup>7</sup> Washington State Health Care Authority, Drug Price Transparency Annual Report (Olympia, WA: Washington State Health Care Authority, 2023), <u>https://www.hca.wa.gov/assets/billers-and-providers/drug-price-transparency-annual-report-2023.pdf</u>.
 <sup>8</sup> Ibid.

provide the information upon request is statutory, the only possible additional cost to a PBM would be providing the information in four days, rather than a longer prior of time. OIC is unable to determine whether the four day standard creates any cost obligation that would be in addition to the costs associated with implementing the statutory requirement.

### Cost(s):

Because the enacting statute states that a pharmacy's representative may submit an appeal, and given the fact that cost associated with this provision on PBMs is likely minimal, the OIC is unable to precisely determine the cost to PBMs. The OIC assumes that any marginal cost above what is already dictated under statute is minimal.

The four-day timeline imposed by this rule could have cost impacts that include:

- Increased labor costs: hiring additional staff or reallocating existing staff;
- Administrative costs: changes to internal workflows, automation, or software that may be required to accelerate the document submission process;
- Opportunity costs: If staff are reallocated from their other duties to meet the deadline, the cost of their foregone time performing other tasks.

Because the OIC is unable to determine the baseline cost, the OIC could not quantify the cost associated with this section of the proposed rule. The OIC does assume there is a cost associated with this requirement.

### Summary of all Cost(s):

WAC Section and Title	Probable Cost (or Cost Range)
284-180-230 Health care benefit manager renewal.	\$579.26
284-180-460 Health care benefit manager filings.	\$629.11

# Analysis on if the proposed rule may impose more than minor costs for businesses in the industry. Includes a summary of how the costs were calculated.

While some of the costs of the proposed rule can be estimated, there are some that are indeterminate and variable, given several unknown parameters. Because of the unknown costs, the OIC assumes that the proposed rule imposes more than minor costs for businesses in the industry.

# Determination on if the proposed rule may have a disproportionate impact on small businesses as compared to the 10 percent of businesses that are the largest businesses required to comply with the proposed rule.

### Explanation of the determination

The OIC examined the potential cost on small and large businesses. Based on data from the WA Employment Security Department (ESD), the OIC used the average of 15 employees to represent employment at an average small business, and 195 employees to represent employment at an average large business (greater than 50 employees).

WAC section and title	Avg cost per employee at small businesses	Avg cost per employee at large businesses
284-180-230 Health care benefit manager renewal.	\$38.62	\$2.97
284-180-460 Health care benefit manager filings.	\$41.94	\$3.23
284-180-505 Appeals by network pharmacies to health care benefit managers who provide pharmacy benefit management services.	<ul> <li>"reasonable adjustment" cost per appeal</li> </ul>	<ul> <li>"reasonable adjustment" cost per appeal</li> </ul>

For the potential cost of providing a reasonable adjustment under the proposed language, the OIC assumes that the cost is "per appeal." Larger PBMs that control a significant portion of the marketplace received many more appeals from pharmacies. Because of this, smaller businesses are more likely to have fewer or no appeals, and therefore have a reduced or no cost associated with the reasonable adjustment language. Therefore, the OIC determined that this cost element does not have a disproportionate impact on small businesses. The other cost elements, including the requirement to submit annual gross income broken out by each entity with which the health care benefit manager has contracted during the previous calendar year, the requirement to file all contracts to provide health care benefit management services, and the requirement to have a pharmacy appeal phone available do have a disproportionate impact on smaller businesses. If the proposed rule has a disproportionate impact on small businesses, the following steps have been identified and taken to reduce the costs of the rule on small businesses.

RCW 19.8	85.030(2) Requirements	
Sub-		
section	Method	OIC Response
a)	Reducing, modifying, or eliminating substantive regulatory requirements	OIC considered reducing, modifying, or eliminating substantive regulatory requirements in the proposal. None of these elements can be further reduced and still meet the stated objective of the implementing statute upon which the rule is based. The OIC does not specify how many employees are necessary to ensure a phone number is available for pharmacy appeals in an attempt to minimize the burden. Additionally, in considering potential costs to small HCBMs and PBMs as the result of this rule, OIC reviewed external research in Section 1 showing that Washington's market for HCBM services is highly concentrated among large businesses, with small HCBMs affecting a very small share of the market. Accordingly, OIC generally expects the costs associated with this rule to fall primarily on large businesses, with a much smaller impact on small businesses.
b)	Simplifying, reducing, or eliminating recordkeeping and reporting requirements	OIC is developing a streamlined reporting process to simplify the requirement of reporting gross income. Additionally, the reporting of HCBM contracts is done through SERFF, an existing framework that health carriers and HCBMs already utilize. The OIC is using familiar reporting tools and attempting to streamline the reporting process as much as possible to reduce the reporting burden for small businesses.
c)	Reducing the frequency of inspections	The rule serves to clarify reporting requirements and the pharmacy appeal process. The rule does not address the frequency of inspections.
d)	Delaying compliance timetables	The rule does not address compliance timetables.
e)	Reducing or modifying fine schedules for noncompliance; or	The rule does not affect fines for noncompliance.
f)	Any other mitigation techniques, including those suggested by small businesses or small business advocates.	OIC will continue to work with HCBMs/PBMs to identify and implement actions to lessen impacts to small businesses.

#### Additional steps OIC has taken to lessen impacts

Several steps were taken during the preproposal period to reduce costs to comply with the proposed rule:

- OIC will not change the HCBM registration and renewal fees as described in WAC 284-180-210. The first
  prepublication draft contemplated increasing the initial registration fee from \$200 to \$750, and increasing the renewal
  fee to a minimum of \$1,000 up from a minimum of \$500. These changes were not incorporated into the proposed rule
  (CR-102).
- OIC will not require PBMs to have an appeal phone number available on the weekends and during national holidays.
- The second prepublication draft contemplated allowing pharmacies to use a "lookback period" of 24 months after a claim is adjudicated to appeal a drug reimbursement (WAC 284-180-505 and WAC 284-180-507). OIC revised this lookback period to 90 days, which may lessen the impact of appeals on PBMs.
- OIC has added rule language in WAC 284-180-505 and WAC 284-180-507 specifying that pharmacy appeals may
  use secure online portals a more administratively efficient method of sending information that PBMs indicated they
  currently use for appeals.
- Regarding the reasonable adjustment that a PBM must provide to a pharmacy, WAC 284-180-505 and WAC 284-180-507 contain provisions that may protect a PBM from having to field repeated appeals and from being at risk of violating Chapter 48.200 after the original reasonable adjustment is made.

#### Description of how small businesses were involved in the development of the proposed rule.

OIC engaged in fully transparent rulemaking, involving all interested parties. OIC developed and shared draft proposed rules and circulated them for interested party feedback. The feedback received was taken into consideration and incorporated where feasible. All businesses within an industry, including small businesses, were involved throughout these processes. Feedback was submitted by interested parties and trade associations representing interested parties.

#### The estimated number of jobs that will be created or lost in result of the compliance with the proposed rule.

OIC does not anticipate that the compliance with the proposed rule will lead to a significant number of job creations or cuts. Employers will be able to meet the proposed requirements using existing staff without new hires. Similarly, it is unlikely that employers would need to dismiss employees as a direct result of the proposed rule amendments.

The public may obtain a copy of the small business economic impact statement or the detailed cost calculations by contacting:

Name Simon Casson Address PO Box 40255, Olympia, WA 98504-0255 Phone 360-725-7038 Fax 360-586-3109 TTY Email rulescoordinator@oic.wa.gov Other

Signature:

Date: October 22, 2024

Name: Mike Kreidler

Title: Insurance Commissioner

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AMENDATORY SECTION (Amending WSR 21-02-034, filed 12/29/20, effective 1/1/22)

WAC 284-180-120 Applicability and scope. (1) This chapter applies to:

(a) <u>H</u>ealth care benefit managers as defined in RCW 48.200.020, and health carriers who contract with health care benefit managers; and

(b) Pharmacy benefit managers who contract with pharmacies on behalf of health carriers, medicaid managed care organizations, and employee benefits programs as defined in RCW 48.200.020.

(2) Effective January 1, 2026, RCW 48.200.280, 48.200.310, and 48.200.320 and WAC 284-180-500, 284-180-507, 284-180-517, and 284-180-522 apply to self-funded group health plans that have elected to participate under RCW 48.200.330.

(3) This chapter does not apply to the actions of health care benefit managers providing services to, or acting on behalf of((:

(a) Self-insured health plans;

(b) Medicare plans;

(c) Medicaid; and

(d) Union plans)) medicare supplement or medicare advantage plans.

AMENDATORY SECTION (Amending WSR 21-02-034, filed 12/29/20, effective 1/1/22)

WAC 284-180-130 Definitions. Except as defined in other subchapters and unless the context requires otherwise, the following definitions apply throughout this chapter:

(1) "Affiliate" or "affiliated employer" has the same meaning as the definition of affiliate or affiliated employer in RCW 48.200.020.

(2) <u>"Annual gross income" means the sum of all amounts paid dur-</u> ing a calendar year by any entities with which a health care benefit manager has contracted for the provision of health care benefit management services in Washington state.

(3) "Certification" has the same meaning as the definition of certification in RCW 48.43.005.

((<del>(3)</del>)) <u>(4)</u> "Control" means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a person, such as through ownership of voting securities, membership rights, or by contract.

(5) "Corporate umbrella" means an arrangement consisting of, but not limited to, subsidiaries and affiliates operating under common ownership or control.

(((4))) (6) "Covered person" has the same meaning as in RCW 48.43.005.

(7) As used in RCW 48.200.020 and 48.200.280, "credentialing" means the collection, verification, and assessment of whether a health care provider meets relevant licensing, education, and training requirements.

(8) "Employee benefits programs" has the same meaning as the definition of employee benefits program in RCW 48.200.020.

((<del>(5)</del>)) <u>(9)</u> "Generally available for purchase" means available for purchase by multiple pharmacies within the state of Washington from national or regional wholesalers.

((((()))) (10) "Health care benefit manager" has the same meaning as the definition of health care benefit manager in RCW 48.200.020.

((<del>(7)</del>)) <u>(11)</u> "Health care provider" or "provider" has the same meaning as the definition of health care provider in RCW 48.43.005.  $((\frac{(8)}{12}))$  (12) "Health care services" has the same meaning as the

definition of health care services in RCW 48.43.005.

((-(9))) (13) "Health carrier" or "carrier" has the same meaning as the definition of health carrier in RCW 48.43.005.

((<del>(10)</del>)) <u>(14)</u> "Laboratory benefit manager" has the same meaning as the definition of laboratory benefit manager in RCW 48.43.020.

((<del>(11)</del>)) <u>(15) Effective January 1, 2026, "list" has the same</u> meaning as the definition of list in RCW 48.200.280, as amended by section 5, chapter 242, Laws of 2024.

(16) "Mail order pharmacy" has the same meaning as the definition of mail order pharmacy in RCW 48.200.020.

(17) "Mental health benefit manager" has the same meaning as the definition of mental health benefit manager in RCW 48.200.020.

((<del>(12)</del>)) <u>(18) Effective January 1, 2026, "multiple source drug"</u> has the same meaning as the definition of multiple source drug in RCW 48.200.280, as amended by section 5, chapter 242, Laws of 2024.

(19) "Net amount" means the invoice price that the pharmacy paid to the supplier for a prescription drug that it dispensed, plus any taxes, fees or other costs, minus the amount of all discounts and other cost reductions attributable to the drug.

(((13))) (20) "Network" has the same meaning as the definition of network in RCW 48.200.020.

(((14))) (21) "Network pharmacy" has the same meaning as the definition of network pharmacy in RCW 48.200.280.

(22) "Oversight activities" includes all work done by the commissioner to ensure that the requirements of chapter 48.200 RCW are properly followed and in fulfilling its duties as required under chapter 48.200 RCW.

 $((\frac{15}{15}))$  (23) "Person" has the same meaning as the definition of person in RCW 48.200.020.

((<del>(16)</del>)) (24) "Pharmacy benefit manager" has the same meaning as the definition of pharmacy benefit manager in RCW 48.200.020.

(((17))) (25) "Pharmacy network" has the same meaning as the definition of pharmacy network in RCW 48.200.020.

(26) "Predetermined reimbursement cost" means maximum allowable cost, maximum allowable cost list, or any other benchmark price utilized by the pharmacy benefit manager, including the basis of the methodology and sources utilized to determine multisource generic drug reimbursement amounts. However, dispensing fees are not included in the calculation of predetermined reimbursement costs for multisource generic drugs.

((<del>(18)</del>)) <u>(27)</u> "Radiology benefit manager" has the same meaning as the definition of radiology benefit manager in RCW 48.200.020.

((<del>(19)</del>)) <u>(28)</u> "Readily available for purchase" means manufactured supply is held in stock and available for order by more than one pharmacy in Washington state when such pharmacies are not under the same corporate umbrella.

((<del>(20) "Retaliate"</del>)) (29)(a) Through December 31, 2025, "retaliate" means action, or the implied or stated threat of action, to decrease reimbursement or to terminate, suspend, cancel or limit a pharmacy's participation in a pharmacy benefit manager's provider network solely or in part because the pharmacy has filed or intends to file an appeal under RCW 48.200.280.

((<del>(21)</del>)) (b) Effective January 1, 2026, "retaliate" means action, or the implied or stated threat of action, to cancel, restrict, or refuse to renew or offer a contract to a pharmacy, to decrease reimbursement or to terminate, suspend, cancel or limit a pharmacy's participation in a pharmacy benefit manager's provider network solely or in part because the pharmacy has:

(i) Filed or intends to file an appeal under RCW 48.200.280;

(ii) Disclosed information in a court, in an administrative hearing, or legislative hearing, if the pharmacist or pharmacy has a good faith belief that the disclosed information is evidence of a violation of a state or federal law, rule, or regulation; or

(iii) Disclosed information to a government or law enforcement agency, if the pharmacist or pharmacy has a good faith belief that the disclosed information is evidence of a violation of a state or federal law, rule, or regulation.

(30) "Union plan" means an employee welfare benefit plan governed by the provisions of the federal Employee Retirement Income Security Act of 1974 (29 U.S.C. Sec. 1001 et seq.) in which an employee organization participates and that exists for the purpose, in whole or in part, of dealing with employers concerning an employee welfare benefit plan.

(31) "Unsatisfied" means that the network pharmacy did not receive the reimbursement that it requested at the first tier appeal.

 $((\frac{22}{2}))$  <u>(32)</u> "Utilization review" has the same meaning as the definition of utilization review in RCW 48.43.005.

AMENDATORY SECTION (Amending WSR 23-23-141, filed 11/20/23, effective 12/21/23)

WAC 284-180-210 Registration and renewal fees. (1) The commissioner must establish fees for registration and renewal in an amount that ensures the program for the registration, renewal, and oversight activities of the health care benefit managers is self-supporting. Each health care benefit manager must contribute a sufficient amount to the commissioner's regulatory account to pay for the reasonable costs, including overhead, of regulating health care benefit managers.

(2) The initial registration fee is \$200.

(3) For the renewal fee, the commissioner will charge a proportional share of the annual cost of the insurance commissioner's renewal and oversight activities of health care benefit managers. Each health care benefit managers' proportional share of the program annual operating costs will be based on their Washington state annual gross income of their health care benefit manager business for the previous calendar year. The renewal fee is \$500, at a minimum, and may increase based on a proportional share of each health care benefit ((managers)) manager's Washington state annual gross income as reported to the insurance commissioner.

(4) If an unexpended balance of health care benefit manager registration and renewal funds remain in the insurance commissioner's regulatory account at the close of a fiscal year, the commissioner will carry the unexpended funds forward and use them to reduce future renewal fees.

(5) Carriers are exempt from the definition of health care benefit manager under RCW 48.200.020.

(a) An entity that is owned or controlled by a holding company that owns or controls a carrier is not exempt from registration as a health care benefit manager.

(b) Under RCW 48.200.050, when a carrier, i.e., "carrier A," acts as a health care benefit manager for another carrier, i.e., "carrier B," carrier B is responsible for the conduct of carrier A with respect to its action as a health care benefit manager on carrier B's behalf.

AMENDATORY SECTION (Amending WSR 23-23-141, filed 11/20/23, effective 12/21/23)

WAC 284-180-220 Health care benefit manager registration. (1) Beginning January 1, 2022, and thereafter, to conduct business in this state, health care benefit managers must ((register and)) have an approved registration with the commissioner <u>as required in RCW</u> <u>48.200.030 and 48.200.300. The registration application is not complete until the commissioner receives the complete registration form, any supporting documentation required by the commissioner, and the <u>\$200 registration fee</u>.</u>

(2) Health care benefit managers must apply for registration using the commissioner's electronic system, which is available at www.insurance.wa.gov.

(3) The registration period is valid from the date of approval of registration through June 30th of the same fiscal year.

(((4) The registration application is not complete until the commissioner receives the complete registration form, any supporting documentation if required by the commissioner, and paid the \$200 registration fee.

(5) A health care benefit manager may conduct business in this state after receiving notice of approval of the registration application from the commissioner.))

AMENDATORY SECTION (Amending WSR 23-23-141, filed 11/20/23, effective 12/21/23)

WAC 284-180-230 Health care benefit manager renewal. (1) Health care benefit managers <u>must</u> annually renew their registration((<del>s</del>)) and pay their renewal fee ((<del>using</del>)) <u>as required by RCW 48.200.030. Registration renewal must be submitted through</u> the commissioner's electronic system, which is available at www.insurance.wa.gov.

(2) Health care benefit managers renewing their registrations must, no later than March 1st of each year, submit an electronic renewal report and supporting documents for approval to include:

(a) 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; and

(b) Any additional information, including supporting documents, as required by the commissioner.

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

(4) On or before June 1st of each year, the commissioner will calculate and set the renewal fees for the next July 1st through June 30th fiscal year. Invoices for the renewal fees and electronic payments will be available through the insurance commissioner's electronic filing and payment center. Renewal fee payments are due by July 15th of each year.

(5) The renewal application is not complete until the commissioner receives the complete renewal report, supporting documentation if required by the commissioner, and the payment of the invoiced renewal fee.

(6) Upon successful completion, the health care benefit manager will receive notice of approval of the renewal application from the commissioner.

(7) Failure to timely submit a completed renewal report and fee may result in a delayed renewal or nonrenewal in addition to potential violations if a health care benefit manager provides services without being registered.

(8) Each renewed registration is valid for one fiscal year from July 1st through June 30th fiscal year.

AMENDATORY SECTION (Amending WSR 23-23-141, filed 11/20/23, effective 12/21/23)

WAC 284-180-240 Providing and updating registration information. (1) When registering, a health care benefit manager must ((apply with)) submit with its application an affidavit affirming ((its)) the application's accuracy. An application for registering as a health care benefit manager must ((provide for)) include:

(a) The legal name as well as any additional names that it uses to conduct business;

(b) The names of persons and entities with any ownership or controlling interests, including stockholders, officers and directors, or limited liability company members, managers and officers in the health care benefit manager, and the identity of any entity for which the health care benefit manager has a controlling interest;

(c) A list of tax identification numbers and business licenses and registrations that are active;

(d) Identifying any areas of specialty, such as a pharmacy benefit management, radiology benefit management, laboratory benefit management, mental health care benefit management, or any other areas of specialty identified in the application;

(e) <u>A copy of the health care benefit manager's certificate of</u> registration with the Washington state secretary of state; (f) Contact information for communications regarding registration, renewal and oversight activities, to include name of the contact person, address, phone number, and valid email address;

((<del>(f)</del>)) (g) Name and contact information for the person the health care benefit manager has designated as responsible for compliance with state and federal laws to include name of the contact person, address, phone number, and valid email address;

 $((\frac{g}))$  (h) Identify if the health care benefit manager has committed any violations in this or any state or been the subject of an order from ((a)) any federal or state agency or court; and

((<del>(h)</del>)) <u>(i)</u> Any additional information requested by the commissioner.

(2) Registered health care benefit managers must provide any material change in the information filed with the commissioner.

(a) This information includes, but is not limited to:

(i) Any additional names that the health care benefit manager uses to conduct business; and

(ii) The contact's name and email address for official communications between the commissioner and the health care benefit manager as required in subsection (1)(f) of this section.

(b) Any change in the information provided to obtain, renew, nonrenew, or surrender a registration as a health care benefit manager is a material change and must be reported to the commissioner within 30 days of the change.

(c) Any amendments to its annual renewal reports including the reported annual gross income must be reported to the commissioner no later than May 31st. Amended annual renewal reports may be accepted after review by the commissioner.

AMENDATORY SECTION (Amending WSR 21-02-034, filed 12/29/20, effective 1/1/22)

WAC 284-180-325 Required notices. (1) Carriers must post on their website information that identifies each health care benefit manager contracted with the carrier, either directly or indirectly through subcontracting with a health care benefit manager or other entity, and identify the services provided by ((the)) each health care benefit manager. The information must be ((easy to find)) visually prominent and easily located on the carriers' website with a link from the web page utilized for enrollees. The carrier is required to update the information on their website within ((thirty)) <u>30</u> business days of any change, such as addition or removal of a health care benefit manager or a change in the services provided by a health care benefit manager.

(2) Carriers must notify enrollees in writing and at least annually, including at plan enrollment and renewal, of each health care benefit manager contracted with the carrier to provide any health care benefit management services, either directly or indirectly through subcontracting with a health care benefit manager or other entity. For example, written notices include disclosure in the policy or member handbook. This notice must identify the website address where enrollees can view an updated listing of all health care benefit managers utilized by the carrier. AMENDATORY SECTION (Amending WSR 21-02-034, filed 12/29/20, effective 1/1/22)

WAC 284-180-405 Definitions in this subchapter. The definitions in this section apply throughout this subchapter.

(1) "Complete filing" means a package of information containing forms, supporting information, documents and exhibits submitted to the commissioner electronically using the system for electronic rate and form filing (SERFF).

(2) "Date filed" means the date a complete filing has been received and accepted by the commissioner.

(3) "Filer" means:

(a) A person, organization or other entity that files forms or rates with the commissioner for a carrier or health care benefit manager; or

(b) A person employed by a carrier or heath care benefit manager to file under this chapter.

(4) (("Form" means a)) "Health care benefit management contract <u>form</u>" or "contract" ((and)) <u>or "form"</u> means any written agreement describing the rights and responsibilities of the parties, such as carriers, health care benefit managers, providers, pharmacy, pharmacy services administration organization, and employee benefit program conforming to chapter 48.200 RCW and this chapter including:

(a) All forms that are part of the contract; and

(b) All amendments to the contract.

(5) "NAIC" means the National Association of Insurance Commissioners.

(6) "Objection letter" means correspondence created in SERFF and sent by the commissioner to the filer that:

(a) Requests clarification, documentation, or other information; or

(b) Explains errors or omissions in the filing.

(7) "SERFF" means the system for electronic rate and form filing. SERFF is a proprietary NAIC computer-based application that allows insurers and other entities to create and submit rate, rule, and form filings electronically to the commissioner.

(8) "Type of insurance" or "TOI" means a specific type of health care coverage listed in the Uniform Life, Accident and Health, Annuity and Credit Coding Matrix published by the NAIC and available at www.naic.org.

AMENDATORY SECTION (Amending WSR 21-02-034, filed 12/29/20, effective 1/1/22)

WAC 284-180-411 Purpose of this subchapter. The purpose of this subchapter is to:

(1) Adopt processes and procedures for filers to use when submitting electronic forms and rates to the commissioner by way of SERFF.

(2) Designate SERFF as the method by which filers, including ((health care service contractors, health maintenance organizations, insurers as defined in RCW 48.01.050,)) carriers and health care benefit managers, must submit all health care benefit management contract forms to the commissioner. AMENDATORY SECTION (Amending WSR 21-02-034, filed 12/29/20, effective 1/1/22)

WAC 284-180-455 Carrier filings related to health care benefit managers. (1)(a) A carrier must file all contracts and contract amendments ((with)) between a health care benefit manager and a carrier within ((thirty)) 30 days following the effective date of the contract or contract amendment.

(b) To meet its obligations under RCW 48.200.050(5), a carrier must, for any health care benefit manager that provides services to or acts on behalf of the carrier and is not directly contracted with the carrier:

(i) File all contracts to provide health care benefit management services to or 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; or

(ii) Identify all contracts to provide health care benefit management services to or on behalf of the carrier, ensure that contracted health care benefit managers have filed all required contracts with the commissioner, whether the health care benefit manager is directly or indirectly contracted with the carrier, as required in RCW 48.200.040 and WAC 284-180-460, and submit to the commissioner, as required by the "Washington State SERFF Carrier Provider Agreement and HCBM Contract Filing General Instructions," as a supporting document to the carrier's filings, a list of all health care benefit manager contracts. The list must include the SERFF tracker identifier for each contract.

(2) If a carrier negotiates, amends, or modifies a contract or a compensation agreement that deviates from a previously filed contract, then the carrier must file that negotiated, amended, or modified contract or agreement with the commissioner within ((thirty)) 30 days following the effective date. The commissioner must receive the filings electronically in accordance with this subchapter.

((-2)) (3) Carriers must maintain health care benefit manager contracts at its principal place of business in the state, or the carrier must have access to all contracts and provide copies to facilitate regulatory review upon ((twenty)) 20 days prior written notice from the commissioner.

((3)) <u>(4)</u> Nothing in this section relieves the carrier of the responsibility detailed in WAC 284-170-280 (3)(b) to ensure that all contracts are current and signed if the carrier utilizes a health care benefit manager's providers and those providers are listed in the network filed for approval with the commissioner.

(((4))) (5) If a carrier enters into a reimbursement agreement that is tied to health outcomes, utilization of specific services, patient volume within a specific period of time, or other performance standards, the carrier must file the reimbursement agreement with the commissioner within ((thirty)) 30 days following the effective date of the reimbursement agreement, and identify the number of enrollees in the service area in which the reimbursement agreement applies. Such reimbursement agreements must not cause or be determined by the commissioner to result in discrimination against or rationing of medically necessary services for enrollees with a specific covered condition or disease. If the commissioner fails to notify the carrier that the agreement is disapproved within ((thirty)) 30 days of receipt, the agreement is deemed approved. The commissioner may subsequently withdraw such approval for cause.

(((5))) (6) Health care benefit manager contracts and compensation agreements must clearly set forth the carrier provider networks and applicable compensation agreements associated with those networks so that the provider or facility can understand their participation as an in-network provider and the reimbursement to be paid. The format of such contracts and agreements may include a list or other format acceptable to the commissioner so that a reasonable person will understand and be able to identify their participation and the reimbursement to be paid as a contracted provider in each provider network.

AMENDATORY SECTION (Amending WSR 23-24-034, filed 11/30/23, effective 1/1/24)

Health care benefit manager filings. WAC 284-180-460 (1) A health care benefit manager must file all contracts and contract amendments between the health care benefit manager and a health carrier, provider, pharmacy, pharmacy services administration organization, or other health care benefit manager entered into directly or indirectly in support of a contract with a carrier or employee benefits program within 30 days following the effective date of the contract or contract amendment. Contracts that must be filed by a health care benefit manager shall include all contracts to provide health care benefit management services to or on behalf of the carrier, whether the health care benefit manager is directly or 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.

(2) If a health care benefit manager negotiates, amends, or modifies a contract or a compensation agreement that deviates from a filed agreement, then the health care benefit manager must file that negotiated, amended, or modified contract or agreement with the commissioner within 30 days following the effective date. The commissioner must receive the filings electronically in accordance with this chapter.

(((2))) <u>(3)</u> Contracts or contract amendments that were executed prior to July 23, 2023, and remain in force, must be filed with the commissioner no later than 60 days following July 23, 2023.

(((3))) (4) A health care benefit manager((s)) must maintain health care benefit management contracts at its principal place of business in the state, or the health care benefit manager must have access to all contracts and provide copies to facilitate regulatory review upon 20 days prior written notice from the commissioner.

(((4))) (5) Health care benefit manager contracts and compensation agreements must clearly set forth provider network names and applicable compensation agreements associated with those networks so that the provider or facility can understand their participation as an in-network provider and the reimbursement to be paid. The format of such contracts and agreements may include a list or other format acceptable to the commissioner so that a reasonable person will understand and be able to identify their participation and the reimbursement to be paid as a contracted provider in each provider network. WAC 284-180-465 Self-funded group health plan opt-in. (1)(a) A self-funded group health plan governed by the provisions of the federal Employee Retirement Income Security Act of 1974 (29 U.S.C. Sec. 1001 et seq.) that elects under RCW 48.200.330 to participate in RCW 48.200.280, 48.200.310, and 48.200.320 shall provide notice to the commissioner of their election decision on a form prescribed by the commissioner. Election decisions are effective beginning January 1, 2026. The completed form must include an attestation that the selffunded group health plan has elected to participate in and be bound by RCW 48.200.280, 48.200.310, and 48.200.320 and rules adopted to implement those sections of law. If the form is completed by the self-funded group health plan, the plan must inform any entity that administers the plan of their election to participate. The form will be posted on the commissioner's public website for use by self-funded group health plans.

(b) A pharmacy benefit manager may not, by contract or otherwise, prohibit a self-funded group health plan from electing to participate under RCW 48.200.330.

(2) A self-funded group health plan election to participate is for a full year. The plan may elect to initiate its participation on January 1st of any year or in any year on the first day of the selffunded group health plan's plan year.

(3) A self-funded group health plan's election occurs on an annual basis. On its election form, the plan must indicate whether it chooses to affirmatively renew its election on an annual basis or whether it should be presumed to have renewed on an annual basis until the commissioner receives advance notice from the plan that it is terminating its election as of either December 31st of a calendar year or the last day of its plan year. Notices under this subsection must be submitted to the commissioner at least 15 days in advance of the effective date of the election to initiate participation and the effective date of the termination of participation.

(4) A self-funded plan operated by an out-of-state employer that has at least one employee who resides in Washington state may elect to participate in pharmacy benefit manager regulation as provided in RCW 48.200.330 on behalf of their Washington state resident employees and dependents. If a self-funded group health plan established by a Washington state employer has elected under RCW 48.200.330 to participate in RCW 48.200.280, 48.200.310, and 48.200.320 and has employees that reside in other states, those employees are protected by RCW 48.200.330 in RCW 48.200.280, 48.200.310, and 48.200.320 when filling a prescription ordered by a provider in Washington state or at a pharmacy located in Washington state.

AMENDATORY SECTION (Amending WSR 21-02-034, filed 12/29/20, effective 1/1/22)

WAC 284-180-500 Applicability and scope. This subchapter applies to ((health care benefit managers providing pharmacy benefit management services, referred to as)) pharmacy benefit managers ((in this subchapter)) as defined in RCW 48.200.020.

(1) Specifically, this subchapter applies to the actions of pharmacy benefit managers regarding contracts with pharmacies on behalf of ((an insurer, a third-party payor, or the prescription drug purchasing consortium established under RCW 70.14.060)) a carrier, employee benefits program, or medicaid managed care program in regard to:

(a) Fully insured health plans; and

(b) Medicaid <u>managed care</u> plans. However, the appeal requirements of RCW ((19.340.100)) <u>48.200.280</u> do not apply to medicaid <u>managed care</u> plans.

(2) This subchapter does not apply to:

(a) The actions of pharmacy benefit managers ((acting as)) contracting with third-party administrators ((regarding contracts with pharmacies on behalf of an insurer, a third-party payor, or the prescription drug purchasing consortium established under RCW 70.14.060 in regard to:

(a) Self-insured)) to administer prescription drug benefits for self-funded group health plans or union plans, unless a self-funded group health plan or union plan governed by the provisions of the federal Employee Retirement Income Security Act of 1974 (29 U.S.C. Sec. 1001 et seq.) has elected to participate in RCW 48.200.280, 48.200.310, and 48.200.320 under WAC 284-180-465; and

(b) The actions of pharmacy benefit managers contracting to administer prescription drug benefits for medicare plans.

NEW SECTION

WAC 284-180-501 Pharmacy reimbursement. A pharmacy benefit manager may not reimburse a pharmacy in the 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.

AMENDATORY SECTION (Amending WSR 21-02-034, filed 12/29/20, effective 1/1/22)

WAC 284-180-505 Appeals by network pharmacies to health care benefit managers who provide pharmacy benefit management services. A network pharmacy may appeal a reimbursement to a health care benefit manager providing pharmacy benefit management services (first tier appeal) if the reimbursement for the drug is less than the net amount the network pharmacy paid to the supplier of the drug <u>and the claim</u> was adjudicated by the pharmacy benefit manager within the past 90 <u>days</u>. "Network pharmacy" has the meaning set forth in RCW ((19.340.100 (1)(d))) <u>48.200.280</u>. "Pharmacy benefit manager" is a health care benefit manager that offers pharmacy benefit management services and has the meaning set forth in RCW 48.200.020. A pharmacy benefit manager must process the network pharmacy's appeal as follows:

(1) A pharmacy benefit manager must include language in the pharmacy provider contract and on the pharmacy benefit manager's website fully describing the right to appeal under RCW 48.200.280. If the health care benefit manager provides other health care benefit management services in addition to pharmacy benefit management services, then this information must be under an easily located page that is specific to pharmacy services. The description must include, but is not limited to:

(a) Contact information, including:

(i) A telephone number by which the pharmacy may contact the pharmacy benefit manager ((during normal business hours)) between 9 a.m. and 5 p.m. Pacific Time Zone Monday through Friday, except national holidays, and speak with an individual responsible for processing appeals;

(ii) ((A summary of the specific times when the pharmacy benefit manager will answer calls from network pharmacies at that telephone number;

(iii))) A fax number that a network pharmacy can use to submit information regarding an appeal; and

(((iv))) (iii) An email address or a link to a secure online portal that a network pharmacy can use to submit information regarding an appeal. If the pharmacy benefit manager chooses to use a link to a secure online portal to satisfy the requirement of this subsection, the contract must include explicit and clear instructions as to how a pharmacy can gain access to the portal. Submission by a pharmacy of an appeal that includes the claim adjudication date or dates consistent with this subsection and documentation or information described in subsection (2) of this section, or of a request for or information regarding an appeal, to the email address or secure online portal included in the contract under this subsection must be accepted by the pharmacy benefit manager as a valid submission.

(b) A detailed description of the actions that a network pharmacy must take to file an appeal; and

(c) A detailed summary of each step in the pharmacy benefit manager's appeals process.

(2) The pharmacy benefit manager must reconsider the reimbursement. A pharmacy benefit manager's review process must provide the network pharmacy or its representatives with the opportunity to submit information to the pharmacy benefit manager including, but not limited to, documents or written comments. <u>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:</u>

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

(b) Other documentation showing the net amount paid by the network pharmacy; or

(c) An attestation by the network pharmacy that:

(i) 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; and

(ii) Describes the due diligence the network pharmacy undertook to procure the drug at the most favorable amount for the pharmacy, taking into consideration whether the pharmacy has fewer than 15 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. The pharmacy benefit manager must review and investigate the reimbursement and consider all information submitted by the network pharmacy or its representatives prior to issuing a decision.

(3) The pharmacy benefit manager must complete the appeal within ((thirty)) <u>30</u> calendar days from the time the network pharmacy submits the appeal. If the network pharmacy does not receive the pharmacy benefit manager's decision within that time frame, then the appeal is deemed denied.

(4) The pharmacy benefit manager must uphold the appeal of a network pharmacy with fewer than ((fifteen)) 15 retail outlets within the state of Washington, under its corporate umbrella, if the pharmacy demonstrates that they are unable to purchase therapeutically equivalent interchangeable product from a supplier doing business in the state of Washington at the pharmacy benefit manager's list price. "Therapeutically equivalent" is defined in RCW 69.41.110(7).

(5) (a) 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 and price 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 and the name of at least one 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)) has the same meaning as the definition of "multisource generic drug" in RCW 48.200.280.

(b) If the pharmacy benefit manager bases its denial on the fact that one or more of the claims that are the subject of the appeal are not subject to RCW 48.200.280 and this chapter, it must provide documentation clearly indicating that the plan to which the claim relates is a self-funded group health plan that has not opted in under RCW 48.200.330, is a medicare plan or is otherwise not subject to RCW 48.200.280 and this chapter.

(6) If the pharmacy benefit manager upholds the network pharmacy's appeal, the pharmacy benefit manager 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. The commissioner will presume 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 chapter 48.200 RCW under RCW 48.200.290. If a therapeutically equivalent interchangeable product becomes available during the period that a reasonable adjustment is in effect, the adjustment may reflect the cost of that product from the date it becomes available to the end of the prospective reasonable adjustment period. If the request for an adjustment is from a critical access pharmacy, as defined by the state health care authority by rule for purpose related to the prescription drug purchasing consortium established under RCW 70.14.060, any such adjustment shall apply only to such pharmacies.

(7) If otherwise qualified, the following may file an appeal with a pharmacy benefit manager:

(a) Persons who are natural persons representing themselves;

(b) Attorneys at law duly qualified and entitled to practice in the courts of the state of Washington;

(c) Attorneys at law entitled to practice before the highest court of record of any other state, if attorneys licensed in Washing-

ton are permitted to appear before the courts of such other state in a
representative capacity, and if not otherwise prohibited by state law;
 (d) Public officials in their official capacity;

(e) A duly authorized director, officer, or full-time employee of an individual firm, association, partnership, or corporation who appears for such firm, association, partnership, or corporation;

(f) Partners, joint venturers or trustees representing their respective partnerships, joint ventures, or trusts; and

(g) Other persons designated by a person to whom the proceedings apply.

(8) A pharmacy benefit manager's response to an appeal submitted by a Washington small pharmacy that is denied, partially reimbursed, or untimely must include written documentation or notice to identify the exact corporate entity that received and processed the appeal. Such information must include, but is not limited to, the corporate entity's full and complete name, taxpayer identification number, and number assigned by the office of the insurance commissioner.

(9) Health care benefit managers providing pharmacy benefit management services benefit managers must identify a pharmacy benefit manager employee who is the single point of contact for appeals, and must include the address, phone number, name of the contact person, and valid email address. This includes completing and submitting the form that the commissioner makes available for this purpose at www.insurance.wa.gov.

(10) This section expires December 31, 2025.

#### NEW SECTION

WAC 284-180-507 Appeals by network pharmacies to health care benefit managers who provide pharmacy benefit management services. (1) (a) 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.

(b) If a pharmacy is represented by a pharmacy services administrative organization, or other entity, the contract between the pharmacy benefit manager and the pharmacy must allow the pharmacy services administrative organization or other entity to use the appeal process included in the contract between the pharmacy benefit manager and the pharmacy. The pharmacy benefit manager must meet all statutory, regulatory, and contractual requirements when reviewing an appeal submitted by a representative on behalf of a pharmacy.

(c) A pharmacy services administrative organization may submit an appeal to a pharmacy benefit manager on behalf of multiple pharmacies if:

(i) The claims that are the subject of the appeal are for the same prescription drug; and

(ii) The pharmacies on whose behalf the claims are submitted are members of the pharmacy services administrative organization; and

(iii) The pharmacy benefit manager has contracts with the pharmacies on whose behalf the pharmacy services administrative organization is submitting the claims.

(2) Before a pharmacy files an appeal pursuant to this section, upon request by a pharmacy or pharmacist, a pharmacy benefit manager must provide, within four business days of receiving the request, a current and accurate list of bank identification numbers, processor control numbers, and pharmacy group identifiers for health plans and self-funded group health plans that have elected under for RCW 48.200.330 participate in RCW 48.200.280, 48.200.310, to and 48.200.320 with which the pharmacy benefit manager either has a current contract or had a contract that has been terminated within the past 12 months to provide pharmacy benefit management services.

(3) A pharmacy benefit manager must process the network pharmacy's appeal as follows:

A pharmacy benefit manager must include language in the pharmacy provider contract and on the pharmacy benefit manager's website fully describing the right to appeal under RCW 48.200.280. If the health care benefit manager provides other health care benefit management services in addition to pharmacy benefit management services, this information must be under an easily located page that is specific to pharmacy services. The description must include, but is not limited to:

(a) Contact information, including:

(i) A telephone number by which the pharmacy may contact the pharmacy benefit manager between 9 a.m. and 5 p.m. Pacific Time Zone Monday through Friday, except national holidays, and speak with an individual responsible for processing appeals;

(ii) A fax number that a network pharmacy can use to submit information regarding an appeal; and

(iii) An email address or a link to a secure online portal that a network pharmacy can use to submit information regarding an appeal. If the pharmacy benefit manager chooses to use a link to a secure online portal to satisfy the requirement of this subsection, the contract must include explicit and clear instructions as to how a pharmacy can gain access to the portal. Submission by a pharmacy of an appeal that includes the claim adjudication date or dates consistent with subsection (1) of this section and documentation or information described in subsection (4) of this section, or of a request for information regarding an appeal, to the email address or secure online portal included in the contract under this subsection must be accepted by the pharmacy benefit manager as a valid submission.

(b) A detailed description of the actions that a network pharmacy must take to file an appeal; and

(c) A detailed summary of each step in the pharmacy benefit manager's appeals process.

(4) The pharmacy benefit manager must reconsider the reimbursement amount. A pharmacy benefit manager's review process must provide the network pharmacy or its representatives with an opportunity to submit information to the pharmacy benefit manager including, but not limited to, documents or written comments. Documents or information that may be submitted by a network pharmacy or their representative 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; or

(c) An attestation by the network pharmacy that:

(i) 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; and

(ii) Describes the due diligence the network pharmacy undertook to procure the drug at the most favorable amount for the pharmacy, taking into consideration whether the pharmacy has fewer than 15 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.

(5) The pharmacy benefit manager must review and investigate the reimbursement and consider all information submitted by the network pharmacy or its representatives prior to issuing a decision.

(6) The pharmacy benefit manager must complete the appeal within 30 calendar days from the time the network pharmacy submits the appeal. If the network pharmacy does not receive the pharmacy benefit manager's decision within that time frame, then the appeal is deemed denied.

(7) The pharmacy benefit manager must uphold the appeal of a network pharmacy with fewer than 15 retail outlets within the state of Washington, under its corporate umbrella, if the pharmacy demonstrates that they are unable to purchase therapeutically equivalent interchangeable product from a supplier doing business in the state of Washington at the pharmacy benefit manager's list price. "Therapeutically equivalent" is defined in RCW 69.41.110.

(8) (a) 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, the national drug code, and price 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 reimbursement cost for the drug and the name of at least one 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.

(b) If the pharmacy benefit manager bases its denial on the fact that one or more of the claims that are the subject of the appeal is not subject to RCW 48.200.280 and this chapter, it must provide documentation clearly indicating that the plan to which the claim relates is a self-funded group health plan that has not opted in under RCW 48.200.330, is a medicare plan, or is otherwise not subject to RCW 48.200.280 and this chapter.

(9) If the pharmacy benefit manager upholds the network pharmacy's appeal, the pharmacy benefit manager must make a reasonable adjustment no later than one day after the date of the determination. The commissioner will presume 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 chapter 48.200 RCW under RCW 48.200.290. If a therapeutically equivalent interchangeable product becomes available during the period that a reasonable adjustment is in effect, the adjustment may reflect the cost of that product from the date it becomes available to the end of the prospective reasonable adjustment period. If the request for an adjustment is from a critical access pharmacy, as defined by the state health care authority by rule for purpose related to the prescription drug purchasing consortium established under RCW 70.14.060, any such adjustment shall apply only to such pharmacies. (10) If otherwise qualified, the following may file an appeal with a pharmacy benefit manager:

(a) Persons who are natural persons representing themselves;

(b) Attorneys at law duly qualified and entitled to practice in the courts of the state of Washington;

(c) Attorneys at law entitled to practice before the highest court of record of any other state, if attorneys licensed in Washington are permitted to appear before the courts of such other state in a representative capacity, and if not otherwise prohibited by state law;

(d) Public officials in their official capacity;

(e) A duly authorized director, officer, or full-time employee of an individual firm, association, partnership, or corporation who appears for such firm, association, partnership, or corporation;

(f) Partners, joint venturers or trustees representing their respective partnerships, joint ventures, or trusts; and

(g) Other persons designated by a person to whom the proceedings apply.

(11) A pharmacy benefit manager's response to an appeal submitted by a Washington small pharmacy that is denied, partially reimbursed, or untimely must include written documentation or notice to identify the exact corporate entity that received and processed the appeal. Such information must include, but is not limited to, the corporate entity's full and complete name, taxpayer identification number, and number assigned by the office of the insurance commissioner.

(12) Health care benefit managers providing pharmacy benefit management services must identify a pharmacy benefit manager employee who is the single point of contact for appeals, and must include the address, phone number, name of the contact person, and valid email address. This includes completing and submitting the form that the commissioner makes available for this purpose at www.insurance.wa.gov.

(13) This section is effective January 1, 2026.

AMENDATORY SECTION (Amending WSR 22-23-069, filed 11/10/22, effective 12/11/22)

WAC 284-180-515 Use of brief adjudicative proceedings for appeals by network pharmacies to the commissioner. (1) The commissioner has adopted the procedure for brief adjudicative proceedings provided in RCW 34.05.482 through 34.05.494 for actions involving a network pharmacy's appeal of a pharmacy benefit manager's reimbursement for a drug subject to predetermined reimbursement costs for multisource generic drugs (reimbursement). WAC 284-180-500 through 284-180-540 describe the procedures for how the commissioner processes a network pharmacy's appeal (second tier appeal) of the pharmacy benefit manager's decision in the first tier appeal through a brief adjudicative proceeding.

This rule does not apply to adjudicative proceedings under WAC 284-02-070, including converted brief adjudicative proceedings.

(2) This section expires December 31, 2025.

WAC 284-180-517 Use of brief adjudicative proceedings for appeals by network pharmacies to the commissioner. (1) The commissioner has adopted the procedure for brief adjudicative proceedings provided in RCW 34.05.482 through 34.05.494 for actions involving a network pharmacy's appeal of a pharmacy benefit manager's reimbursement for a drug subject to predetermined reimbursement costs for multisource generic drugs (reimbursement). WAC 284-180-500 through 284-180-540 describe the procedures for how the commissioner processes a network pharmacy's appeal (second tier appeal) of the pharmacy benefit manager's decision in the first tier appeal through a brief adjudicative proceeding.

This rule does not apply to adjudicative proceedings under WAC 284-02-070, including converted brief adjudicative proceedings.

(2) This section is effective January 1, 2026.

AMENDATORY SECTION (Amending WSR 22-23-069, filed 11/10/22, effective 12/11/22)

WAC 284-180-520 Appeals by network pharmacies to the commissioner. The following procedure applies to brief adjudicative proceedings before the commissioner for actions involving a network pharmacy's appeal of a pharmacy benefit manager's decision in a first tier appeal regarding reimbursement for a drug subject to predetermined reimbursement costs for multisource generic drugs, unless the matter is converted to a formal proceeding as provided in WAC 284-180-540(3).

(1) **Grounds for appeal.** A network pharmacy or its representative may appeal a pharmacy benefit manager's decision to the commissioner if it meets all the following requirements:

(a) The pharmacy benefit manager's decision must have denied the network pharmacy's appeal, or the network pharmacy must be unsatisfied with the outcome of its appeal to the pharmacy benefit manager;

(b) The network pharmacy must request review of the pharmacy benefit manager's decision by submitting a petition at www.insurance.wa.gov according to the filing instructions.

The petition for review must include:

(i) The network pharmacy's basis for appealing the pharmacy benefit manager's decision in the first tier appeal;

(ii) The network pharmacy's business address and mailing address; and

(iii) Documents supporting the appeal;

(c) Documents supporting the appeal include:

(i) The documents from the first tier review, including the documents that the pharmacy submitted to the pharmacy benefit manager as well as the documents that the pharmacy benefit manager provided to the pharmacy in response to the first tier review, if any (if the pharmacy benefit manager has not issued a decision on the first tier appeal in a timely manner, a signed attestation to that fact must be submitted by the appealing pharmacy);

(ii) Documentation evidencing the net amount paid for the drug by the small pharmacy;

(iii) If the first-tier appeal was denied by the pharmacy benefit manager because a therapeutically equivalent drug was available in the state of Washington at a price less than or equal to the predetermined reimbursement cost for the multisource generic drug and documentation provided by the pharmacy benefit manager evidencing the national drug code of the therapeutically equivalent drug; and

(iv) Any additional information that the commissioner may require;

(d) The network pharmacy must file the petition for review with the commissioner within 30 days of receipt of the pharmacy benefit manager's decision or within 30 days after the deadline for the pharmacy benefit manager's deadline for responding to the first tier appeal;

(e) The network pharmacy making the appeal must have less than 15 retail outlets within the state of Washington under its corporate umbrella. The petition for review that the network pharmacy submits to the commissioner must include a signed attestation that this requirement is satisfied; and

(f) Electronic signatures and electronic records may be used to facilitate electronic transactions consistent with the Uniform Electronic Transactions Act chapter 1.80 RCW.

(2) Time frames governing appeals to the commissioner. The commissioner must complete the appeal within 30 calendar days of the receipt of the network pharmacy's complete petition for review. A complete petition for review means that all requirements under <u>subsection</u> (1) of this ((<del>subsection</del>)) <u>section</u> have been satisfied, including the submission of all required documents and documentation. An appeal before the commissioner is deemed complete when a presiding officer issues an initial order on behalf of the commissioner to both the network pharmacy and pharmacy benefit manager under subsection (8) of this section. Within seven calendar days of the resolution of a dispute, the presiding officer shall provide a copy of the initial order to both the network pharmacy and pharmacy benefit manager.

(3) **Relief the commissioner may provide.** The commissioner, by and through a presiding officer or reviewing officer, may enter an order directing the pharmacy benefit manager to make an adjustment to the disputed claim, denying the network pharmacy's appeal, issuing civil penalties pursuant to RCW 48.200.290, or taking other actions deemed fair and equitable.

(4) **Notice.** If the presiding officer under the use of discretion chooses to conduct an oral hearing, the presiding officer will set the time and place of the hearing. Written notice shall be served upon both the network pharmacy and pharmacy benefit manager at least seven days before the date of the hearing. Service is to be made pursuant to WAC 284-180-440(2). The notice must include:

(a) The names and addresses of each party to whom the proceedings apply and, if known, the names and addresses of any representatives of such parties;

(b) The official file or other reference number and name of the proceeding, if applicable;

(c) The name, official title, mailing address, and telephone number of the presiding officer, if known;

(d) A statement of the time, place, and nature of the proceeding;

(e) A statement of the legal authority and jurisdiction under which the hearing is to be held;

(f) A reference to the particular sections of the statutes or rules involved;

(g) A short and plain statement of the matters asserted by the network pharmacy against the pharmacy benefit manager and the potential action to be taken; and

(h) A statement that if either party fails to attend or participate in a hearing, the hearing can proceed and the presiding or reviewing officer may take adverse action against that party.

(5) Appearance and practice at a brief adjudicative proceeding. The right to practice before the commissioner in a brief adjudicative proceeding is limited to:

(a) Persons who are natural persons representing themselves;

(b) Attorneys at law duly qualified and entitled to practice in the courts of the state of Washington;

(c) Attorneys at law entitled to practice before the highest court of record of any other state, if attorneys licensed in Washington are permitted to appear before the courts of such other state in a representative capacity, and if not otherwise prohibited by state law;

(d) Public officials in their official capacity;

(e) A duly authorized director, officer, or full-time employee of an individual firm, association, partnership, or corporation who appears for such firm, association, partnership, or corporation;

(f) Partners, joint venturers or trustees representing their respective partnerships, joint ventures, or trusts; and

(g) Other persons designated by a person to whom the proceedings apply with the approval of the presiding officer.

In the event a proceeding is converted from a brief adjudicative proceeding to a formal proceeding, representation is limited to the provisions of law and RCW 34.05.428.

(6) Method of response. Upon receipt of any inquiry from the commissioner concerning a network pharmacy's appeal of a pharmacy benefit manager's decision in the first tier appeal regarding reimbursement for a drug subject to predetermined reimbursement costs for multisource generic drugs, pharmacy benefit managers must respond to the commissioner using the commissioner's electronic pharmacy appeals system.

(7) **Hearings by telephone.** If the presiding officer chooses to conduct a hearing, then the presiding officer may choose to conduct the hearing telephonically. The conversation will be recorded and will be part of the record of the hearing.

(8) **Presiding officer**.

(a) Per RCW 34.05.485, the presiding officer may be the commissioner, one or more other persons designated by the commissioner per RCW 48.02.100, or one or more other administrative law judges employed by the office of administrative hearings. The commissioner's choice of presiding officer is entirely discretionary and subject to change at any time. However, it must not violate RCW 34.05.425 or 34.05.458.

(b) The presiding officer shall conduct the proceeding in a just and fair manner. Before taking action, the presiding officer shall provide both parties the opportunity to be informed of the presiding officer's position on the pending matter and to explain their views of the matter. During the course of the proceedings before the presiding officer, the parties may present all relevant information.

(c) The presiding officer may request additional evidence from either party at any time during review of the initial order. After the presiding officer requests evidence from a party, the party has seven days after service of the request to supply the evidence to the presiding officer, unless the presiding officer, under the use of discretion, allows additional time to submit the evidence. (d) The presiding officer has all authority granted under chapter 34.05 RCW.

(9) Entry of orders.

(a) When the presiding officer issues a decision, the presiding officer shall briefly state the basis and legal authority for the decision. Within 10 days of issuing the decision, the presiding officer shall serve upon the parties the initial order, as well as information regarding any administrative review that may be available before the commissioner. The presiding officer's issuance of a decision within the 10-day time frame satisfies the seven day requirement in subsection (2) of this section.

(b) The initial order consists of the decision and the brief written statement of the basis and legal authority. The initial order will become a final order if neither party requests a review as provided in WAC 284-180-530(1).

(10) Filing instructions. When a small pharmacy or a pharmacy benefit manager provides information to the commissioner regarding appeals under WAC 284-180-520, the small pharmacy or pharmacy benefit manager must follow the commissioner's filing instructions, which are available at www.insurance.wa.gov.

(11) This section expires December 31, 2025.

NEW SECTION

WAC 284-180-522 Appeals by network pharmacies to the commissioner. The following procedure applies to brief adjudicative proceedings before the commissioner for actions involving a network pharmacy's appeal of a pharmacy benefit manager's decision in a first tier appeal regarding reimbursement for a drug, unless the matter is converted to a formal proceeding as provided in WAC 284-180-540(3).

(1) **Grounds for appeal.** A network pharmacy or its representative may appeal a pharmacy benefit manager's decision to the commissioner if it meets all the following requirements:

(a) The pharmacy benefit manager's decision must have denied the network pharmacy's appeal, or the network pharmacy must be unsatisfied with the outcome of its appeal to the pharmacy benefit manager;

(b) The network pharmacy must request review of the pharmacy benefit manager's decision by submitting a petition at https:// www.insurance.wa.gov according to the filing instructions.

The petition for review must include:

(i) The network pharmacy's basis for appealing the pharmacy benefit manager's decision in the first tier appeal;

(ii) The network pharmacy's business address and mailing address; and

(iii) Documents supporting the appeal;

(c) Documents supporting the appeal include:

(i) The documents from the first tier review, including the documents that the pharmacy submitted to the pharmacy benefit manager as well as the documents that the pharmacy benefit manager provided to the pharmacy in response to the first tier review, if any (if the pharmacy benefit manager has not issued a decision on the first tier appeal in a timely manner, a signed attestation to that fact must be submitted by the appealing pharmacy); (ii) Documentation evidencing the net amount paid for the drug by the small pharmacy;

(iii) If the first-tier appeal was denied by the pharmacy benefit manager because a therapeutically equivalent drug was available in the state of Washington at a price less than or equal to the reimbursement cost for the drug and documentation provided by the pharmacy benefit manager evidencing the national drug code of the therapeutically equivalent drug; and

(iv) Any additional information that the commissioner may require;

(d) The network pharmacy must file the petition for review with the commissioner within 30 days of receipt of the pharmacy benefit manager's decision or within 30 days after the deadline for the pharmacy benefit manager's deadline for responding to the first tier appeal;

(e) The network pharmacy making the appeal must have less than 15 retail outlets within the state of Washington under its corporate umbrella. The petition for review that the network pharmacy submits to the commissioner must include a signed attestation that this requirement is satisfied; and

(f) Electronic signatures and electronic records may be used to facilitate electronic transactions consistent with the Uniform Electronic Transactions Act chapter 1.80 RCW.

(2) Time frames governing appeals to the commissioner. The commissioner must complete the appeal within 30 calendar days of the receipt of the network pharmacy's complete petition for review. A complete petition for review means that all requirements under subsection (1) of this section have been satisfied, including the submission of all required documents and documentation. An appeal before the commissioner is deemed complete when a presiding officer issues an initial order on behalf of the commissioner to both the network pharmacy and pharmacy benefit manager under subsection (8) of this section. Within seven calendar days of the resolution of a dispute, the presiding officer shall provide a copy of the initial order to both the network pharmacy and pharmacy benefit manager.

(3) **Relief the commissioner may provide.** The commissioner, by and through a presiding officer or reviewing officer, may enter an order directing the pharmacy benefit manager to make an adjustment to the disputed claim, denying the network pharmacy's appeal, issuing civil penalties pursuant to RCW 48.200.290, or taking other actions deemed fair and equitable.

(4) **Notice.** If the presiding officer under the use of discretion chooses to conduct an oral hearing, the presiding officer will set the time and place of the hearing. Written notice shall be served upon both the network pharmacy and pharmacy benefit manager at least seven days before the date of the hearing. Service is to be made pursuant to WAC 284-180-440(2). The notice must include:

(a) The names and addresses of each party to whom the proceedings apply and, if known, the names and addresses of any representatives of such parties;

(b) The official file or other reference number and name of the proceeding, if applicable;

(c) The name, official title, mailing address, and telephone number of the presiding officer, if known;

(d) A statement of the time, place, and nature of the proceeding;

(e) A statement of the legal authority and jurisdiction under which the hearing is to be held;

(f) A reference to the particular sections of the statutes or rules involved;

(g) A short and plain statement of the matters asserted by the network pharmacy against the pharmacy benefit manager and the potential action to be taken; and

(h) A statement that if either party fails to attend or participate in a hearing, the hearing can proceed and the presiding or reviewing officer may take adverse action against that party.

(5) Appearance and practice at a brief adjudicative proceeding. The right to practice before the commissioner in a brief adjudicative proceeding is limited to:

(a) Persons who are natural persons representing themselves;

(b) Attorneys at law duly qualified and entitled to practice in the courts of the state of Washington;

(c) Attorneys at law entitled to practice before the highest court of record of any other state, if attorneys licensed in Washington are permitted to appear before the courts of such other state in a representative capacity, and if not otherwise prohibited by state law;

(d) Public officials in their official capacity;

(e) A duly authorized director, officer, or full-time employee of an individual firm, association, partnership, or corporation who appears for such firm, association, partnership, or corporation;

(f) Partners, joint venturers or trustees representing their respective partnerships, joint ventures, or trusts; and

(g) Other persons designated by a person to whom the proceedings apply with the approval of the presiding officer.

In the event a proceeding is converted from a brief adjudicative proceeding to a formal proceeding, representation is limited to the provisions of law and RCW 34.05.428.

(6) **Method of response.** Upon receipt of any inquiry from the commissioner concerning a network pharmacy's appeal of a pharmacy benefit manager's decision in the first tier appeal regarding reimbursement for a drug, pharmacy benefit managers must respond to the commissioner using the commissioner's electronic pharmacy appeals system.

(7) **Hearings by telephone.** If the presiding officer chooses to conduct a hearing, then the presiding officer may choose to conduct the hearing telephonically. The conversation will be recorded and will be part of the record of the hearing.

(8) **Presiding officer**.

(a) Per RCW 34.05.485, the presiding officer may be the commissioner, one or more other persons designated by the commissioner per RCW 48.02.100, or one or more other administrative law judges employed by the office of administrative hearings. The commissioner's choice of presiding officer is entirely discretionary and subject to change at any time. However, it must not violate RCW 34.05.425 or 34.05.458.

(b) The presiding officer shall conduct the proceeding in a just and fair manner. Before taking action, the presiding officer shall provide both parties the opportunity to be informed of the presiding officer's position on the pending matter and to explain their views of the matter. During the course of the proceedings before the presiding officer, the parties may present all relevant information.

(c) The presiding officer may request additional evidence from either party at any time during review of the initial order. After the presiding officer requests evidence from a party, the party has seven days after service of the request to supply the evidence to the presiding officer, unless the presiding officer, under the use of discretion, allows additional time to submit the evidence. (d) The presiding officer has all authority granted under chapter 34.05 RCW.

#### (9) Entry of orders.

(a) When the presiding officer issues a decision, the presiding officer shall briefly state the basis and legal authority for the decision. Within 10 days of issuing the decision, the presiding officer shall serve upon the parties the initial order, as well as information regarding any administrative review that may be available before the commissioner. The presiding officer's issuance of a decision within the 10-day time frame satisfies the seven day requirement in subsection (2) of this section.

(b) The initial order consists of the decision and the brief written statement of the basis and legal authority. The initial order will become a final order if neither party requests a review as provided in WAC 284-180-530(1).

(10) Filing instructions. When a small pharmacy or a pharmacy benefit manager provides information to the commissioner regarding appeals under WAC 284-180-520, the small pharmacy or pharmacy benefit manager must follow the commissioner's filing instructions, which are available at www.insurance.wa.gov.

(11) This section is effective January 1, 2026.