



Mike Kreidler- Insurance Commissioner

As required by

The Washington State Administrative Procedures Act

Chapter 34.05 RCW

Matter No. **R 2024-02**

CONCISE EXPLANATORY STATEMENT; RESPONSIVENESS SUMMARY; RULE
DEVELOPMENT PROCESS; AND IMPLEMENTATION PLAN

Relating to the adoption of

Health Care Benefit Managers

December 18, 2024

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Section 1: Introduction

Revised Code of Washington (RCW) 34.05.325(6) requires the Office of the Insurance Commissioner (OIC) to prepare a “concise explanatory statement” (CES) prior to filing a rule for permanent adoption. The CES shall:

1. Identify the OIC’s reasons for adopting the rule;
2. Describe differences between the proposed rule and the final rule (other than editing changes) and the reasons for the differences; and
3. Summarize and respond to all comments received regarding the proposed rule during the official public comment period, indicating whether or not the comment resulted in a change to the final rule, or the OIC’s reasoning in not incorporating the change requested by the comment; and
4. Be distributed to all persons who commented on the rule during the official public comment period and to any person who requests it.

Section 2: Reasons for Adopting the Rule

Engrossed Second Substitute Senate Bill ([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 OIC’s oversight authority regarding HCBM registration and operations. OIC is adopting this rule to implement E2SSB 5213 and ensure that all affected entities understand their rights and obligations under the new law.

In addition to implementing E2SSB 5213, OIC is adopting this rule to ensure that OIC can effectively oversee HCBMs informed by OIC’s regulatory experience and recent health care industry developments, such as the Change Healthcare cyberattack in early 2024.

Section 3: Rule Development Process

OIC filed the CR-101 for this rulemaking with the Washington State Register on May 21, 2024 (WSR 24-111-1126). The comment period for the CR-101 closed on June 20, 2024. OIC received five comment letters on the CR-101.

OIC released the first prepublication draft on July 12, 2024. The comment period for this draft closed on July 26, 2024. OIC received eight comment letters on this draft.

OIC held a public interested parties meeting regarding the first prepublication draft on July 22, 2024, in which 53 individuals participated.

OIC released a second prepublication draft on September 6, 2024. The comment period for this draft closed September 16, 2024. OIC received five comment letters on this draft.

OIC filed the proposed rule (CR-102) on October 23, 2024 (WSR 24-21-158). The comment period for the CR-102 closed on November 26, 2024. OIC received ten comment letters on the CR-102.

OIC held a public hearing on the proposed rule text on November 26, 2024. The hearing was administered by Nico Janssen, Senior Health Policy Analyst, as a virtual meeting. Testimony was presented by:

- Lori Grassi, Washington State Chiropractic Association
- Peter Fjelstad, Pharmaceutical Care Management Association
- LuGina Mendez-Harper, Prime Therapeutics
- Jenny Arnold, Washington State Pharmacy Association
- Clinton Knight, Whole Health Pharmacy

OIC filed the final rule (CR-103) with the Code Reviser on December 18, 2024, and the rule will become effective on January 18, 2025.

Section 4: Differences Between Proposed and Final Rule

There are no differences between the proposed rule (CR-102) and the final rule (CR-103).

Section 5: Responsiveness Summary

OIC received a total of 30 comments regarding R 2024-02, inclusive of the CR-101, first prepublication draft, second prepublication draft, and CR-102. The following section of this CES summarizes the comments by WAC section and additional general comments. It then provides OIC's responses to the comments and whether changes were made in the rule language at any point in the rulemaking process.

The OIC received comments from:

1. AIDS Healthcare Foundation
2. American Physical Therapy Association
3. Association of Washington Health Plans
4. Cambia Health Solutions
5. Cigna
6. Costco
7. Genworth LTC Policyholder

8. Pacific Health Coalition
9. Pharmaceutical Care Management Association
10. Premera Blue Cross
11. Providence Health Plan
12. Washington Association for Community Health
13. Washington Association of Nurse Anesthetists
14. Washington State Health Care Authority
15. Washington State Pharmacy Association
16. Whole Health Pharmacy

Comment	Response
General comments	
Multiple commentors asserted that OIC does not have statutory authority to adopt various provisions of the rule.	RCW 48.02.060 and RCW 48.200.900 are the statutory authorities for adoption of this rule.
One commentor asserted that OIC lacks jurisdiction because the rule language did not repeat the language of the statute, and/or the underlying statute does not support the language.	RCW 48.02.060(1) states that “The commissioner has the authority expressly conferred upon him or her by or reasonably implied from the provisions of this code.”
Another commentor requested that OIC not advance the CR-102 and instead re-write the rule to adhere to the legislative intent.	RCW 48.200.900 states that “the insurance commissioner may adopt any rules necessary to implement this act.”
Commentors’ concerns about specific provisions are also described under each WAC section below.	The OIC may conduct rulemaking to “fill in the gaps” in legislation if such rulemaking is “necessary to the effectuation of a general statutory scheme.” <i>Hama Hama Co. v. Shorelines Hearings Bd.</i> , 85 Wn.2d 441, 448 (1975). The OIC believes that this final rule best effectuates the Legislature’s intent in the statutory scheme as a whole to bring greater transparency to HCBM activities.
A commentor stated that, with respect to this rulemaking, OIC should consider that we are entering a new era in which federal courts are casting aspersions on government entities going beyond the scope of their authority.	OIC assumes the commentor is referencing the U.S. Supreme Court’s June 2024 ruling in <i>Loper Bright Enterprises et. al. v. Raimondo, Secretary of Commerce, et. al.</i> , overruling <i>Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.</i> OIC notes that the <i>Loper Bright</i> ruling relates to federal agencies’ rulemaking authority. Through case law, the Washington State Supreme Court has defined its standards for review of state agency statutory authority. It has determined that review of an agency’s statutory interpretation is <i>de novo</i> . However,

	state courts still give substantial weight to an agency's view of the law.
Two commentors thanked OIC for its work on implementing RCW 48.200 and this rulemaking. The commentors noted that OIC has engaged interested parties and considered their feedback in this process.	OIC appreciates these comments.
A commentor raised concerns about long-term care insurance premiums and asked OIC to address the issue in the rulemaking.	The commentor's concern is outside the scope of the rulemaking. OIC did not include the requested change in the final rule.
A commentor voiced general support for the proposed rule, saying that it will provide additional oversight and transparency, a clear appeals process, and tools to prevent discriminatory business practices that limit patient access to prescription medications.	OIC appreciates this comment.
WAC 284-180-120: Applicability and scope	
A commentor asked OIC to clarify that WAC 284-180 <i>does not</i> apply to the actions of health care benefit managers providing services to or acting on behalf of Medicare Advantage health plans. The commentor asked OIC to clarify that the chapter <i>does</i> apply to standalone dental and vision plans.	<p>OIC added language in the proposed rule, which was retained in the final rule, to clarify that the chapter does not apply to the actions of HCBMs providing services to, or acting on behalf of, Medicare supplement or Medicare Advantage plans (WAC 284-180-120(3) of the final rule).</p> <p>OIC did not include language related to standalone dental or vision plans in the final rule. RCW 48.200 addresses health care benefit management services provided to or on behalf of carriers defined under RCW 48.43.005. See RCW 48.200.020. RCW 48.43.005 defines carriers, which includes carriers offering standalone vision or dental plans. The statutory definitions provide sufficient clarity.</p>
A commentor asked OIC to explain language in the second prepublication draft and CR-102 regarding which entities WAC 284-180 applies to, specifically HCBMs providing services to or acting on	OIC made the revisions referenced in this comment to align with statutory changes and provide clarity to interested parties regarding the entities that are subject to the chapter.

<p>behalf of “Medicare supplement or Medicare Advantage plans,” “self-insured health plans,” “Medicare plans,” “Medicaid plans,” and “union plans.”</p> <p>The commentor also asked whether OIC intends to include managed care Medicaid plans.</p>	<p>Regarding statutory changes, Sec. 9(2) of E2SSB 5213 (RCW 48.200.330(2)) provides that self-funded group health plans governed by the provisions of the federal Employee Retirement Income Security Act of 1974 (29 U.S.C. Sec. 1001 et seq., hereafter, ERISA), may elect to participate in sections 5, 7, and 9 of E2SSB 5213 (RCW 48.200.280, 48.200.310, and 48.200.320, respectively). OIC added WAC 284-180-120(2) of the proposed rule to align with this statutory provision.</p> <p>WAC 284-180-120(1) and (2) define which entities are subject to WAC 284-180. WAC 284-180-120(3) currently lists activities that the chapter <i>does not</i> apply to. OIC determined that it would be clearer if this section described the entities that the chapter <i>does apply to</i>. For example, as stated elsewhere in this responsiveness summary, pharmacy organizations commented that they often do not know whether a PBM’s reimbursement to a network pharmacy is on behalf of a plan subject to RCW 48.200; and that this uncertainty can make it difficult for a network pharmacy to exercise its appeal rights under RCW 48.200.280. WAC 284-180-120 of the final rule seeks to bring clarity to this issue.</p> <p>Finally, OIC does intend to include Medicaid managed care organizations in WAC 284-180-120(1)(b) of the proposed rule, which is retained in the final rule, because these entities are included in the statutory definition of a PBM. Specifically, RCW 48.200.020(14)(a) defines “pharmacy benefit manager” as “a person that contracts with pharmacies on behalf of a health carrier, employee benefits program, or medicaid managed care program...”</p>
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<p>Several commentors asked that OIC clearly define "directly" and "indirectly" in rulemaking.</p> <p>Commentors noted that the receipt of data, services, or information from a vendor does not necessarily "impact" the determination or utilization of benefits or access to care and are used by carriers to make independent decisions.</p> <p>Commentors noted that without additional guidance, carriers may only ultimately understand the OIC's interpretation through enforcement action. Commentors stated that the lack of clarity could lead to unnecessary reporting with no benefit to covered Washingtonians.</p> <p>For example, commentors stated that one may interpret the first prepublication draft to require a software development corporation to register as an HCBM because a carrier uses its word processing software, through an enterprise contract, to draft contracts with entities that manage enrollees' benefits.</p> <p>Commentors asked that OIC interpret RCW 48.200.010 to focus oversight on HCBMs that "exercise broad discretion" and are "making health care decisions on behalf of carriers." They stated that legislative intent was to regulate entities who explicitly have decision making power that impacts patient care and/or benefits. They asked that OIC include the following revision to WAC 284-180-120(1)(a):</p> <p>"This chapter does not apply to persons or entities providing services to, or acting on behalf of, a health carrier or employee benefits programs without authority to exercise broad discretion to affect the</p>	<p>OIC did not include the requested change in the final rule. RCW 48.200.020(5)(a) defines "Health care benefit manager" as "a person or entity providing services to, or acting on behalf of, a health carrier or employee benefits programs, that directly or indirectly impacts the determination or utilization of benefits for, or patient access to, health care services, drugs, and supplies including, but not limited to:</p> <ul style="list-style-type: none"> (i) Prior authorization or preauthorization of benefits or care; (ii) Certification of benefits or care; (iii) Medical necessity determinations; (iv) Utilization review; (v) Benefit determinations; (vi) Claims processing and repricing for services and procedures; (vii) Outcome management; (viii) Payment or authorization of payment to providers and facilities for services or procedures; (ix) Dispute resolution, grievances, or appeals relating to determinations or utilization of benefits; (x) Provider network management; or (xi) Disease management." <p>Regarding the software example that one commentor raises, the OIC has never seen reason to require general office software developers to be registered as HCBMs merely because a carrier uses their word processing software for all of its general office functions, including typing legible documents to use as contracts, and otherwise keeping legible records. The OIC has assumed in the case of word processing software, it is the carrier, not the software, that is drafting the contract terms.</p> <p>However, in the example provided, the</p>
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<p>determination or utilization of benefits for, or patient access to, health care services, drugs, and supplies or when the health carrier or employee benefit program retains sole decision making authority.”</p>	<p>entities the carrier is contracting with to manage enrollee benefits must be registered as HCBMs.</p> <p>If a software developer creates a program that impacts how benefits are determined or utilized, or impacts patient access to services, and the carrier chooses to use that software to design or administer the benefits contained in the contract, rather than the carrier itself performing those functions, then that software developer would need to be registered as an HCBM.</p> <p>If carriers are uncertain about whether the software they are using directly or indirectly impacts the determination or utilization of benefits for, or patient access to services, carriers should err on the side of ensuring that the contracted entity has registered with OIC as an HCBM and filing their contract with the entity as an HCBM contract. This interpretation promotes transparency and regulation of carriers’ use of intermediaries to administer health plan benefits.</p> <p>Finally, regarding legislative findings that commentors reference, legislative findings do not supersede the definition of terms in substantive law. Moreover, the OIC notes that the language in the legislative findings the commenter cites (RCW 48.200.010(1)) does not limit the Legislature’s concern to health care benefit managers who “exercise broad discretion.”</p>
<p>A commentor noted that the OIC should exercise jurisdiction over PBM actions taken on behalf of self-funded group health plans and that if OIC does not exercise jurisdiction, something needs to be done so pharmacies can identify these plans prior to submitting appeals under RCW 48.200.</p>	<p>Sec. 9(2) of E2SSB 5213 (RCW 48.200.330(2)) provides that self-funded group health plans governed by the provisions of ERISA may elect to participate in sections 5, 7, and 9 of E2SSB 5213 (RCW 48.200.280, 48.200.310, and 48.200.320, respectively). Absent an election by a self-funded group health plan to participate in</p>

	<p>the laws noted above, OIC does not have jurisdiction with respect to PBM claims administered on behalf of self-funded group health plans.</p> <p>OIC addresses how pharmacies can identify self-funded group health plans before filing an appeal under WAC 284-180-507(2) of the final rule, which states that, upon request by a pharmacy, a PBM must provide 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 to participate.</p>
WAC 284-180-130: Definitions	
<p>A commentor asked OIC to explain what a "union plan" means through rulemaking. They noted that union plans typically mean Taft-Hartley plans, the benefits of which may be collectively bargained, and that a Taft-Hartley plan may be organized under federal ERISA law.</p>	<p>In response to this comment, OIC added the following language to the proposed rule, which was retained in the final rule, at WAC 284-180-130(30):</p> <p>""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."</p>
<p>A commentor asked OIC to define or remove the reference to "or otherwise" in the definition of "control" in WAC 284-180-130(4). They stated that "otherwise" is not a legal or policy term of art and does not have a clear meaning.</p>	<p>In response to this comment, the OIC removed "or otherwise" from this definition in the proposed rule, which was retained in the final rule.</p> <p>The OIC also added the phrase "such as through" to give examples of specific forms of control. This definition does not preclude additional forms of control. WAC 284-180-130(4) of the final rule provides that:</p>

	<p>“‘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.”</p>
<p>With respect to the definition of “credentialing” in the prepublication drafts and CR-102, a commentor stated that credentialing is not mentioned anywhere in the underlying statute (E2SSB 5213), nor was credentialing ever part of the public debate during the legislative process for E2SSB 5213. They requested that WAC 284-180-130(7) be removed.</p>	<p>OIC did not include the requested change in the final rule.</p> <p>“Credentialing” is specifically referenced in the underlying statute at RCW 48.200.020(5)(c)(xiii) and (xvii)</p> <p>“Credentialing” is also a term used in RCW 48.200.020(14)(a)(v) and RCW 48.200.280(2)(i).</p> <p>Defining this statutory term is within OIC’s regulatory authority to define undefined terms to implement the discussed provisions and effectuate the statutory scheme.</p>
<p>A commentor asked OIC to define “contract price,” saying that there are multiple rates in pharmacy pricing. The commentor stated that a common, explicit definition is needed to ensure all parties have a clear understanding of their obligations.</p>	<p>OIC did not include the requested change in the final rule. The term “contract price” appears in RCW 48.200.310(1)(a), which is effective January 1, 2026. OIC will consider whether this term needs to be defined in rule prior to this effective date.</p>
<p>A commentor noted that the second prepublication draft’s definition of “retaliate” in WAC 284-180-130(29) only includes protections for a pharmacy that has filed an appeal. The commentor asked that the definition include terminology to offer pharmacies the same protections if they submit complaints as well.</p>	<p>The broader scope of retaliation requested by the commentor is reflected in Sec. 8(4) of E2SSB 5213 (RCW 48.200.320(4)). This section of law is not effective until January 1, 2026. The definition in WAC 284-180-130(29) is bifurcated. The current law definition remains in effect until December 31, 2025, and the expanded definition in WAC 284-180-130(29)(b) goes into effect on January 1, 2026. The expanded definition reflects the broader scope of RCW 48.200.320(4) once it goes into effect in 2026. The provision states:</p> <p>“Retaliatory actions against a pharmacy or pharmacist include cancellation of,</p>

	<p>restriction of, or refusal to renew or offer a contract to a pharmacy solely because the pharmacy or pharmacist has:</p> <p>(a) Made disclosures of information that the pharmacist or pharmacy believes is evidence of a violation of a state or federal law, rule, or regulation;</p> <p>(b) Filed complaints with the plan or pharmacy benefit manager; or</p> <p>(c) Filed complaints against the plan or pharmacy benefit manager with the commissioner."</p> <p>The final rule's definition of "retaliate" is consistent with the statute:</p> <p>"(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:</p> <p>(i) Filed or intends to file an appeal under RCW 48.200.280;</p> <p>(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</p> <p>(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."</p>
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<p>A commentor noted that the definition in the second prepublication for the term “retaliate” is troublesome, and that some of these items are actions that may occur in the normal course of business.</p> <p>The commentor stated that in the context of a pharmacy’s inclusion in a network, the language would prohibit a PBM from using certain criteria “solely” or “in part” when deciding for pharmacy network inclusion. The commentor noted that the term, “in part,” does not appear anywhere in the underlying statute, nor was it included in the public debate during the legislative process. As is, the term “in part” may lead to a pharmacy claiming retaliation as it is defined in the second prepublication draft when it declines to accept the terms and conditions for inclusion in the pharmacy network.</p> <p>The commentor stated that the issue was discussed during the 2024 Legislative Session, and that it was always the legislative intent to include restrictions on such actions to exclude a pharmacy from a network <i>only when</i> such actions were done in a manner inconsistent with normal business practices.</p> <p>The commentor requested that OIC add RCW 48.200.320(3) to the final rule. RCW 48.200.320(3) states: “(3) A pharmacist or pharmacy shall make reasonable efforts to limit the disclosure of confidential and proprietary information.”</p>	<p>OIC did not include the requested changes in the final rule.</p> <p>The part of the “retaliate” definition referenced by the commentor is current law at WAC 284-180-130(20) and is not amended in the proposed rule. The current law definition remains in effect until December 31, 2025, and the expanded definition in WAC 284-180-130(29)(b) goes into effect on January 1, 2026. The expanded definition reflects the broader scope of RCW 48.200.320(4) once it goes into effect in 2026.</p> <p>OIC’s retention of the term “solely or in part” within the expanded definition of “retaliate” is part of a reasonable definition of a term the Legislature has not expressly defined in Chapter 48.200 RCW. The term “solely or in part” protects pharmacies – especially independent pharmacies – from PBM retaliation that could stem from multiple factors rather than “solely” for one of the reasons included in WAC 284-180-130(29)(b)(i) through (iii) of the rule.</p> <p>This definition reflects interested party comments and real-world evidence suggesting that PBMs exert significant leverage over pharmacies, and that pharmacies fear PBM retaliation, creating a need for pharmacies to have protections against retaliation.</p> <p>For example, regarding PBMs’ leverage over pharmacies, the Federal Trade Commission’s 2024 interim report found at page 3:</p> <p>“Evidence suggests that increased concentration may give the leading PBMs the leverage to enter into complex and opaque contractual relationships that may</p>
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	<p>disadvantage smaller, unaffiliated pharmacies and the patients they serve. Independent pharmacies generally lack the leverage to negotiate terms and rates when enrolling in PBMs' pharmacy networks, and subsequently may face effectively unilateral changes in contract terms without meaningful choice and alternatives."</p> <p>Regarding the commentor's statement that "...some of these items are actions that may occur in the normal course of business," OIC notes that nothing in the statutory section on retaliation (RCW 48.200.320) exempts a PBM action that happens "in the normal course of business" from being a retaliatory action. On the contrary, the statute clearly lists "cancellation of, restriction of, or refusal to offer a contract to the pharmacy" as examples of PBM actions that could constitute "retaliatory actions," provided the full requirements of RCW 48.200.320(4) are met.</p> <p>The commentor's characterization of legislative intent is not consistent with the clear language of the statute. Regarding the commentor's request for OIC to include language from RCW 48.200.320(3) in the final rule, this provision is already in the statute; it was not necessary to include it in the final rule.</p>
<p>A commentor requested that OIC strike the term "generic" in WAC 284-180-130(15) and (26) of the second prepublication draft due to the risk that a PBM would try to use the terminology of the rule to circumvent the intent of the law.</p>	<p>OIC did not include the requested change in the final rule.</p> <p>OIC cannot amend a statutory definition in rule.</p> <p>E2SSB 5213 expands pharmacy appeals to apply to drugs rather than only multisource generic drugs, effective January 1, 2026. Within the final rule, OIC has referred to</p>

	<p>"multisource generic" drugs for sections that go into effect January 1, 2025. OIC has referred to "drugs" in sections that go into effect January 1, 2026 (see WAC 284-180-507 and WAC 284-180-522 of the final rule).</p>
<p>WAC 284-180-210: Registration and renewal fees</p>	
<p>The commentor states that the definition of HCBM under RCW 48.200.020 includes an exception for insurers. The commentor states that there has been confusion about whether an insurer performing HCBM functions for another entity must also register as an HCBM. A commentor recommended that the rule clarify that insurers are not required to register as an HCBM if they are a Washington state licensed insurance company, even if performing HCBM functions for another insurance entity in the regulation for the future. The commentor noted that this clarification is important because the OIC already has regulatory oversight over licensed insurers.</p>	<p>In response to this comment, the final rule clarifies that "Carriers are exempt from the definition of health care benefit manager under RCW 48.200.020." See WAC 284-180-210(5).</p> <p>RCW 48.200.020 excludes carriers from the definition of an HCBM.</p>
<p>A commentor quoted WAC 284-180-210(1) of the first prepublication draft and asked that OIC define "reasonable costs." The commentor noted that in WAC 284-180-505(9) of the first prepublication draft, the term "reasonable adjustments" is used and in WAC 284-180-520(3) the term "fair and equitable" is used. The commentor stated that, to date, the OIC/OAH hearings officers have only awarded pharmacies break even reimbursements up to their invoice cost when pharmacies win appeals. The commentor stated that this level of reimbursement is not reasonable or fair and equitable, and asked OIC to define what "reasonable" is.</p>	<p>The language cited refers to OIC's reasonable cost of operating the HCBM regulatory program.</p> <p>However, the definition of "reasonable adjustment" and "fair and equitable" in the context of pharmacy appeals is a separate issue. In the CR-103, OIC has defined what a "reasonable adjustment" must include (see WAC 284-180-505 and -507).</p>

<p>A commentor noted that WAC 284-180-210(5)(b) of the second prepublication draft and CR-102 establishes a requirement that when one carrier acts as an HCBM on behalf of another carrier, the client carrier is responsible for the conduct of the other carrier that is operating as an HCBM on its behalf. The commentor notes that this language does not appear in the statute.</p>	<p>OIC did not include the requested change in the final rule.</p> <p>OIC is interpreting the statutory definition of an HCBM, consistent with the Legislature's apparent intent of bringing greater transparency to the activities and agreements between carriers and healthcare benefit managers.</p> <p>As OIC explains on page 5 of this CES, OIC has regulatory authority to adopt rule language to clarify statutory terms in order to implement Chapter 48.200 RCW and effectuate the statutory scheme.</p>
<p>A commentor noted that RCW 48.200.030(2)(b) states that "The fees for each registration must be set by the commissioner in an amount that ensures the registration, renewal, and oversight activities are self-supporting."</p> <p>The commentor requested that OIC increase the registration and renewal fees to the PBMs and hire more staff to manage PBM oversight and enforcement. They suggested that OIC hire pharmacists who have run an independent pharmacy and note that other state's insurance commissions have pharmacists on staff. They stated that the OIC should be charging the PBMs high enough registration fees that they can hire sufficient staff and data analysis experts to work with pharmacies to gather claims information and ensure pharmacies are being paid fairly.</p>	<p>OIC did not include the requested change in the final rule.</p> <p>OIC decided not to amend registration or renewal fees in the final rule. OIC will consider the resources needed for HCBM oversight and whether fee amendment is needed in the next budget biennium. For the 2023-2025 budget biennium, the Legislature has appropriated \$175,000 to OIC for implementation of E2SSB 5213.</p>
<p>WAC 284-180-220: Health care benefit manager registration</p>	
<p>A commentor noted that WAC 284-180-220 (6) of the CR-101 and first prepublication draft requires HCBMs to receive notice of approval of their registration prior to conducting business in</p>	<p>OIC did not include the requested change in the final rule.</p> <p>OIC acknowledges that it encountered delays in the initial implementation of the</p>

<p>Washington state. They pointed to delays in processing HCBM registrations when the HCBM law first went into effect in 2022. They noted that much of this was likely attributed to standing up the OIC's oversight program initially and interested parties experiencing a steep learning curve with the new requirements. The commentor expressed appreciation that in January 2022, during the initial implementation of the requirements, the OIC granted a safe harbor to HCBMs to continue to conduct business in the state while first-time registrations were processed by OIC. They requested that permanent protection be included in these rules to avoid disruption in HCBM services to enrollees.</p> <p>The commentor noted instances where objections/rejections arose on a HCBM contract filing, and the OIC notified the carrier they must cease doing business with that HCBM. They recommended that the OIC provide conditional approval for the HCBM to continue operating while the carrier and/or HCBM works to resolve objections/concerns or for the carriers to find a new vendor to fulfill the services.</p> <p>They also requested that the OIC set a timeframe for review of a HCBM registration to provide the industry with a level of certainty.</p> <p>The commentor provided potential draft language below for this section:</p> <p>WAC 284-180-220(6)(a) "The commissioner may allow a health care benefit manager to continue operating in the state while the health care benefit manager and/or carrier addresses issues identified by the commissioner in the health care benefit</p>	<p>HCBM registration process. The COVID-19 pandemic contributed to these delays and created a backlog of registrations.</p> <p>However, OIC has now addressed this backlog and simplified the registration process. The commentor's request is not needed.</p> <p>OIC also notes that the commentor's suggested language would be inconsistent with the statute (RCW 48.200.030(1)), which states: "To conduct business in this state, a health care benefit manager must register with the commissioner and annually renew the registration."</p>
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<p>manager's registration, renewal application and/or contract filings."</p> <p>WAC 284-180-220(7) "If the commissioner takes no action within thirty calendar days after submission, the health care benefit manager registration application is deemed approved, except that the commissioner may extend the approval period an additional thirty calendar days upon giving notice before the expiration of the initial thirty-day period. Approval may be subsequently withdrawn for cause."</p>	
<p>WAC 284-180-230: Health care benefit manager renewal</p>	
<p>A commentor raised concerns regarding language in WAC 284-180-230(2)(a) of the prepublication drafts and CR-102, related to HCBM's calculation of gross income for registration renewal.</p> <p>The commentor noted that the language is not supported by the underlying statute, does not appear in the underlying statute, and is outside OIC's regulatory authority. They also noted that the information is unnecessary and outside the scope of both initial registration, as well as renewals.</p> <p>The commentor requested that this language be removed or be limited only to health plans/carriers based in Washington, with prescription[s] filled in Washington.</p>	<p>OIC did not include the first commentor's requested change in the final rule.</p> <p>The relevant language the commentor cites, as finalized in the rule, provides that:</p> <p>"(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:</p> <p>(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;"</p> <p>OIC adopted this language, including the requirement to itemize gross income received from each contracted entity, because several HCBMs have amended reported income to show zero income or</p>

	<p>have initially reported having zero income as part of their renewal application, despite indications that these HCBMs are doing business in Washington state. Further, the statute requires that OIC set registration fees “in an amount that ensures the registration, renewal, and oversight activities are self-supporting.” See RCW 48.200.030(2(b)). Requiring gross income to be broken down by each contracted entity allows OIC to receive accurate and prompt information about the amount of business HCBMs are conducting in Washington state.</p> <p>Finally, OIC has the authority expressly conferred or reasonably implied from the provisions of the insurance code. See RCW 48.02.060(1). OIC explains its statutory authority to adopt this language further in the “general comments” subsection of this responsiveness summary on page 5.</p>
<p>A commentor noted the potential that gross income data would include out-of-state health plans covering Washington residents, because of the language stating: “each entity with which the HCBM has contracted.” They asked whether HCBMs would have to include any amounts when an individual who is not a resident of Washington travels to the state and has a prescription filled.</p>	<p>Out of state plans operating in Washington state – and the HCBMs they contract with – are required to comply with Washington state law. See RCW 48.01.020: “All insurance and insurance transactions in this state, or affecting subjects located wholly or in part or to be performed within this state, and all persons having to do therewith are governed by this code.”</p>
<p>A commentor supported the gross income reporting requirement in WAC 284-180-230(2)(a) of the CR-102. They stated that carriers commonly use HCBMs to make critical decisions about health benefits, and that HCBMs are typically out-of-state. The commentor stated that, since passage of SB 5601 in 2020, HCBMs have increased the entities they contract with to include not only carriers but other HCBMs. The commentor stated that it is important that all HCBM gross income is disclosed,</p>	<p>OIC appreciates this comment.</p>

<p>including income received by the HCBM from each contracted entity that has made payments to the HCBM. The commentor stated that this language provides transparency regarding the relationship between HCBMs and the entities they contract with.</p>	
<p>A commentor noted that WAC 284-180-230(3) in the first prepublication draft and CR-102 draft shortens the timeframe OIC allows for HCBMs to amend annual gross income reports for the previous year from May 31 to April 1 and that the second prepublication draft extends this deadline by two weeks (to April 15). The commentor stated that this language is unsupported by E2SSB 5213 and requested that OIC grant HCBMs greater time to cure any errors via amended reports. The commentor requested that OIC work with affected entities to find a realistic timeframe.</p>	<p>In response to the comment on the first prepublication draft, OIC amended the language in the second prepublication draft to extend the deadline to April 15. This extended deadline aligns with the federal tax filing deadline for the previous tax year.</p> <p>April 15 is a reasonable deadline for HCBMs to meet. OIC notes that this deadline is for entities to fix errors from the previous year. HCBMs who file correct information would not need to fix errors from the previous year.</p> <p>In response to the comment on the second prepublication draft, OIC retained the April 15 deadline in the final rule. OIC kept this date so that the agency has sufficient time to review amendments to HCBM filings, readjust calculations, and issue accurate invoices to HCBMs before the June 30th deadline. Allowing sufficient time to perform these functions also ensures that OIC complies with the statutory requirement that registration fees be set "in an amount that ensures the registration, renewal, and oversight activities are self-supporting." See RCW 48.200.030(2(b)). The existing deadline of May 31 in WAC 284-180-230 (which this rule amends) did not allow OIC enough time to perform these functions in a timely manner, especially in cases where the HCBM amended its gross income reports on May 31.</p>

	Regarding OIC's authority, OIC has addressed this issue in the "general comments" section of this responsiveness summary on page 5.
A commentor voiced strong support for the language basing HCBM registration and renewal fees on Washington state gross income within the second prepublication draft, saying it is equitable.	OIC appreciates this comment.
WAC 284-180-325: Required notices	
<p>Multiple commentors noted that WAC 284-180-325(1) in the second prepublication draft requires carriers to post information that identifies each HCBM on their website and that the information be "...easy to find on the carriers' website with a link from the web page utilized for enrollees."</p> <p>A commentor asked for the rulemaking to further define "prominently displayed" so that carriers can understand OIC's expectation and intent regarding this requirement. Another commentor asked for this language to be removed, stating that the language is unsupported by the statute.</p> <p>The commentors also note that WAC 284-180-325 in the prepublication drafts and CR-102 draft applies HCBM requirements to HCBMs contracted with a carrier "either directly or indirectly or indirectly through subcontracting with a HCBM or other entity." One commentor asked OIC to define "indirectly" and "other entity" and/or give examples of arrangements that fall under these terms to ensure carriers' understanding and compliance. Another commentor requested the language be removed and noted that the language is not supported in statute.</p>	<p>In response to the comment requesting that OIC further define "prominently displayed," OIC added language to the Second Prepublication Draft, and retained in the final rule specifying that this information must be "visually prominent and easily located."</p> <p>This language sets a clearer expectation for how carriers must display information identifying HCBM contracts and aligns with similar requirements for carriers, such as in WAC 284-170-285(2), related to mental health and substance use disorder web pages.</p> <p>HCBMs make decisions on behalf of carriers that directly impact enrollees' access to care, such as development and administration of prescription drug formularies and prior authorization processes. If carriers choose to contract out these critical services to HCBMs, then their enrollees should know which entity is managing that service as an HCBM. While carriers are fully responsible for the conduct of their contracted (both directly and indirectly) HCBMs, consumers are often communicating directly with HCBMs and should have a clear understanding of the role of that HCBM in the administration of their health plan.</p>

	<p>Regarding the comments about the phrase "either directly or indirectly through subcontracting," WAC 284-180-460(1) provides examples of arrangements. This provision states in part:</p> <p>"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."</p> <p>Regarding OIC's authority to adopt this language, OIC has implied authority to regulate carriers and the HCBMs the carriers are using. See RCW 48.200.050(5)(a).</p> <p>OIC addresses the issue of regulatory authority more fully in the "general comments" subsection of this responsiveness section on page 5.</p>
<p>WAC 284-180-455: Carrier filings related to health care benefit managers</p>	
<p>A commentor notes that under current regulations governing provider contract filings, OIC must respond to a filing submission within 30 days (WAC 284-170-480(3)). The commentor asked for the rulemaking to include a similar provision applicable to carrier and HCBM contract filings to give the industry a predictable schedule to create business processes and plan operations.</p>	<p>OIC did not include the requested change in the final rule.</p> <p>Provider contracts submitted per RCW 48.43.730 and WAC 284-170-480 must be filed with the OIC thirty calendar days <i>prior to use</i>. A provider contract not affirmatively disapproved by OIC is deemed approved, except that the OIC may extend this period by an additional 15-day period. The OIC is not required to respond to a provider contract filing submission within 30 days.</p>

	<p>The submission of carrier HCBM contracts is subject to RCW 48.43.731 and WAC 284-180-455, which require HCBM contracts and contract amendments to be filed within thirty days following the effective date of the contract or contract amendment.</p> <p>The OIC did not amend the rule language in response to this concern because the statutes provide different filing requirements and review standards for each type of contract. The process for carrier filing of HCBM contracts, as finalized in this rule, is clear and predictable.</p>
<p>A commentor noted that they are required to file each HCBM agreement multiple times for each corresponding Washington carrier, even though they are the same contract document, and the System for Electronic Rate and Form Filing (SERFF) allows a filing to list more than one company. The commentor asked for a new provision in this section allowing a single HCBM contract filing if the HCBM agreement is at the parent/holding company level and applicable to more than one Washington licensed carrier.</p>	<p>OIC did not include the requested change in the final rule.</p> <p>HCBM filing submissions are made in the Life, Disability, and Health (LDH) SERFF Instance. They are a subset of many filing types that are filed in this Instance (i.e. Medicare supplement plans, annuities, life policies, medical plans, dental plans, vision plans, student health plans, disability income, etc.). At the LDH Instance level there are several state specific configuration requirements, including the ability to file "multiple company filings." Washington state's configuration must consider all requirements for the vast types of submissions made in the LDH Instance.</p> <p>Washington state has made the decision to not permit "multiple company filings" in the LDH Instance. As a subset filing type, HCBM filings cannot be configured differently from the higher-level configuration.</p>

<p>The following comments all pertain to WAC 284-180-455(1) of the final rule. These comments were made in response to the prepublication drafts and the CR-102 draft.</p> <p>Multiple commentors voiced concern with the prepublication drafts' requirement for a carrier to file with the OIC all agreements to directly or indirectly provide HCBM services, even if the carrier is not a party to that agreement. The commentors stated that this requirement is unsupported in statute, and that the Legislature created a bifurcated filing process that does not contemplate overlapping filings by carriers and HCBMs for agreements held between two HCBMs. Further, the commentors stated that a carrier is not a party to the contract the HCBM has with its subcontractors, and that the contract would be confidential and proprietary to the HCBM and its subcontractor. The commentors voiced concerns that the language would subject carriers to enforcement action by OIC and that proprietary information and trade secrets within these contracts could potentially be disclosed. The commentors suggested that the OIC remove and/or revise this language.</p> <p>A commentor suggested that providing a summary of subcontracting arrangements or requiring only HCBMs to disclose their subcontracting relationships as part of its HCBM registration, could meet the regulation's goals and reduce administrative burden. Another commentor stated that OIC could alternatively address transparency in downstream contracts by revisions to carrier websites.</p>	<p>To address commentors' concerns about administrative burden and disclosing "downstream" contracts that carriers are not parties to, the OIC amended language in the second prepublication draft and retained this language in the final rule. Specifically, OIC created an alternative option for carriers to meet their obligations under RCW 48.200.050(5). Health carriers will have two pathways for identifying all contracts to provide HCBM services to or on behalf of the carrier. These two pathways ensure that contracted HCBMs have filed all required contracts with OIC, whether the HCBM is directly or indirectly contracted with the carrier. Pathway one allows the carrier to file contracts and contract amendments. (see WAC 284-180-455(1)(b)(i) of the rule) Pathway two allows the carrier to submit to the OIC a list of all HCBM contracts and contract amendments that should be filed with the OIC, but still requires carriers. (See WAC 284-180-455(1)(b) of the final rule.)</p> <p>Regarding the commentor's concern about filing propriety information, OIC has instructed carriers that filings are confidential, consistent with the statute. See RCW 48.200.731(3) and RCW 48.200.040(3).</p> <p>Carriers are responsible for their contracted HCBMs' compliance with all applicable laws. See RCW 48.200.050(5)(a). This obligation includes carriers' duty to ensure that their contracted HCBMs have filed their contracts with "downstream" HCBMs, as required in RCW 48.200.040.</p> <p>More broadly, the rule language is informed by OIC's recent experience overseeing HCBMs and promotes OIC's effective oversight of HCBMs and their</p>
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	<p>relationships with carriers.</p> <p>For example, in February 2024, Change Healthcare, a firm that performs claims processing and other functions in Washington state and nationally, suffered a cyberattack. Following the cyberattack, the Washington State Hospital Association characterized the event as creating “significant operational and financial consequences for hospitals, other providers, and the communities they serve.” Similarly, in a March 2024 letter to Congress, the American Hospital Association called Change Healthcare “the predominant source of more than 100 critical functions that keep the [U.S.] health care system operating.” The U.S. House Energy and Commerce Committee learned that an estimated one-third of Americans had sensitive health information leaked as a result of the cyberattack. By its own estimate, Change Healthcare processes 15 billion transactions annually, equivalent to \$1.5 trillion in annual claims, as of 2021.</p> <p>In the aftermath of the Change Healthcare incident, OIC determined that no carrier had filed an HCBM contract with OIC. Yet OIC had heard directly from providers in Washington state that were greatly impacted by the Change Healthcare cyberattack.</p> <p>That led the OIC to release a Technical Assistance Advisory to health carriers regarding HCBM obligations in April 2024. As stated in the Technical Assistance Advisory, OIC determined that entities such as Change Healthcare are “intricately involved in the claims processing and utilization review of several [Washington state] health carriers.”</p>
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	<p>These events indicate that, while HCBM services directly affect consumers' access to necessary health services, not all HCBMs are appropriately registering or informing their health carrier partners of their obligations to file contracts with OIC. It was clear to OIC that if a carrier is not a party to a contract between one HCBM and another HCBM providing services to that carrier, the carrier did not know of the relationship and therefore OIC was not receiving the contract filing from either the carrier or HCBM putting the health carrier at risk for enforcement.</p> <p>The rule language is therefore intended to promote effective HCBM oversight and enforcement by ensuring that HCBM contracts are filed and identified.</p>
Multiple commentors thanked OIC for adding an alternative option for carriers to file all indirect HCBM contracts in WAC 284-180-455(1)(b). The commentors said that this is more realistic for carriers while achieving the goal of transparency. Two commentors encouraged OIC to extend "this same simplification/flexibility" to HCBM filings.	OIC appreciates these comments. OIC did not include the request to change HCBM filing requirements to match the carrier filing requirements, given the statutory requirement at RCW 48.200.040 .
WAC 284-180-460: Health care benefit manager filings	
A commentor raised concerns with WAC 284-180-460(1) of the first prepublication and second prepublication drafts, which requires HCBMs to file with the OIC "all contracts to directly or indirectly provide health care benefit management services on behalf of a carrier, such as but not limited to health care benefit management services contracts that result from a carrier contracting with a health care benefit manager who then contracts or subcontracts with another health care benefit manager." The commentor requested that OIC remove this language, stating that it is redundant and	<p>OIC did not include the commentor's requested changes in the final rule.</p> <p>The language that the first commentor is asking OIC to remove is supported by statute. RCW 48.200.040(2) states: "A health care benefit manager must file with the commissioner 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</p>

unsupported by the statute.	<p>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.”</p> <p>More broadly, OIC has adopted this language to promote effective HCBM oversight and enforcement by ensuring that HCBM contracts are filed. OIC discusses the rationale for this language more broadly in the subsection on WAC 284-180-455 (carrier filings) on page 22 of this responsiveness summary.</p>
A second commentor strongly encouraged “protective language in WAC 284-180-460 that ensures there is disclosure of all contracting together.”	OIC appreciates this comment.
A commentor stated that they did not question OIC’s authority to expand WAC 284-180-460 to require HCBMs to file all HCBM agreements that directly or indirectly provide HCBM services, as RCW 48.200.900 grants OIC the authority to establish “any rules necessary to implement this act.”	OIC appreciates this comment.
A commentor expressed support for this section of the CR-102, specifically the requirement for HCBMs to file all contracts.	OIC appreciates this comment.
WAC 284-180-465: Self-funded group health plan opt-in	
<p>A commentor asked OIC to establish a process to educate employers about opting into the protections of this bill, including an application process.</p> <p>In addition, the commentor asked OIC to restrict a PBM from including as a condition of coverage that employers may not be able to opt out of the protections of this law. The commentor voiced concern that PBMs could limit the impact of this law by refusing to contract with employers that opt into the protections of this chapter.</p>	<p>In advance of the January 1, 2026 effective date of this law, OIC will implement a process to allow private self-funded group health plans subject to ERISA to opt into the relevant provisions of Chapter 48.200 RCW. OIC has implemented an analogous system for self-funded group health plans to participate in the Washington state Balance Billing Protection Act. As part of this process, OIC plans to offer webinars and website materials to educate private self-funded plans about the opt-in provision.</p>

	<p>OIC added WAC 284-180-465(1)(b) in the proposed rule, which is retained in the final rule. This provision establishes that “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.”</p> <p>This language seeks to ensure that self-funded group health plans may exercise their legal right to participate in the statute’s protections, as the Legislature enacted.</p> <p>In developing the rule language, OIC reviewed evidence suggesting that some employers have little visibility into how PBMs are managing their self-funded plan’s prescription drug benefit. For example, an October 2024 article in KFF Health News summarizing KFF’s 2024 Employer Survey found: “Most employers have little idea what the [PBMs] they hire do with the money they exchange for the medications used by their employees...” The article quoted Gary Claxton, senior vice president at KFF, as saying: “Employers are generally frustrated by the lack of transparency into all the prices out there...”</p> <p>These findings are consistent with the FTC’s report referenced previously, finding that “...PBM business practices and their effects remain extraordinarily opaque.”</p> <p>The Legislature enacted E2SSB 5213 in part to increase transparency regarding PBM business practices (statement of Senator Patty Kuderer, prime sponsor of E2SSB 5213). Hence, OIC notes that self-funded plans and employers who may lack information or oversight into their PBM may seek increased transparency through</p>
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	the opt-in provision.
<p>A commentor stated that the “opt-in” for self-funded group health plans may be misguided and have unintended consequences because self-funded groups could face hurdles if they opt-in and later want to opt out. The commentor also raised a concern that the first and second prepublication drafts make no clarification between self-funded group health plans organized under ERISA and those that are not, saying that not all self-funded groups are organized under ERISA. The commentor requested that OIC clarify the opt-in language, stating that this important distinction is in the statute.</p> <p>A second commentor asked OIC to clarify whether self-funded group health plans organized under ERISA who do <u>not</u> opt into the law can continue to administer their prescription drug benefits pursuant to their existing PBM contracts. The commentor cited E2SSB 5213’s final bill report, specifically the section on self-funded group health plans. The commentor asked OIC to clearly define the reach of the rule as it applies to these plans.</p>	<p>Regarding the first comment, the option to participate in E2SSB 5213 is modeled on the option to participate in the Washington state Balance Billing Protection Act (BBPA). This system allows self-funded group health plans to opt out. OIC has not received ERISA preemption challenges regarding this opt-in process. To date, more than 450 self-funded group health plans have elected to participate in the BBPA.</p> <p>In response to the issue of self-funded plans not organized under ERISA, WAC 284-180-465(1)(a) of the proposed rule, retained in the final rule, refers only to self-funded group health plans governed by ERISA. Relatedly, OIC amended the definition of “union plan” in the final rule.</p> <p>In response to the second commentor, the final rule does not apply to HCBMs providing services to or acting on behalf of a self-funded group health plan organized under ERISA, with the exception of plans that opt in under WAC 284-180-465 of the final rule. This is consistent with RCW 48.200.330.</p>
WAC 284-180-501: Pharmacy reimbursement	
<p>An organization asked OIC to define the phrase “same pharmacy services” within RCW 48.200.280(2)(k). This provision provides that “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 providing the same pharmacy services.”</p> <p>The commentor was uncertain whether this phrase referred to each individual drug or</p>	<p>In response to this comment, WAC 284-180-501 of the final rule clarifies the statute’s meaning. This section states: “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.”</p>

pharmacy services in the aggregate. The commentor cited examples of other states that have clarified the meaning of "pharmacy services."	
A commentor voiced support for WAC 284-180-501 of the CR-102 draft. The commentor stated that community health centers have reported receiving lower reimbursement rates compared to affiliate pharmacies for the dispensing the same drug. The commentor said they appreciate what they see as the language's intent to ensure fair reimbursement on a per unit basis.	OIC appreciates this comment.
A commentor asserted that WAC 284-180-501 of the CR-102 is not supported by the statute. The commentor requested that OIC remove this section.	OIC discusses its statutory authority to adopt the CR-103 language on page 5 of this responsiveness summary.
WAC 284-180-505 and 507: Appeals by network pharmacies to health care benefit managers who provide pharmacy benefit management services	
<p>The following comments all pertain to the definition of "reasonable adjustment" in WAC 284-180-505(6) and WAC 284-180-507(9) of the prepublication drafts and CR-102.</p> <p>A commentor stated that the cost of drugs changes daily and, therefore, requiring a PBM to continue to reimburse at a higher rate for any period of time when prices fluctuate so much results in overpayments. The commentor appreciated OIC's changes to this provision in the second prepublication draft and CR-102, however, they stated that they are still concerned with the language. They requested that OIC remove or change this language and suggested alternative language. They stated that the language is not supported by the statute.</p> <p>A commentor requested that OIC establish what an adequate adjustment for a</p>	<p>OIC did not include the requested changes in the final rule.</p> <p>WAC 284-180-505(6) and -507(9) of the CR-102, retained in the final rule, address the obligation of the PBM when a pharmacy's appeal is upheld. PBMs must make a "reasonable adjustment" to the pharmacy that includes "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."</p> <p>The Legislature established a mechanism for pharmacies to appeal PBM payments when a pharmacy is reimbursed less for a drug than the net amount they paid for the drug. This statutory process aligns with the law's intent to "protect and promote the health, safety, and welfare of Washington residents by establishing standards for regulatory oversight of health care benefit managers" who exercise "broad discretion</p>

<p>medication should be. The commentor stated that when PBMs adjust a price, they only pay the cost of the medication, not the dispensing fees. The commentor suggested setting the reasonable adjustment as the Actual Acquisition Cost plus the Washington state Health Care Authority state plan amendment dispensing fee as a benchmark. The commentor also suggested adjusting reimbursement for an approved claim and the list price for the medication for all pharmacies, all claims and all patients paid from that list for a period of nine months or longer and requiring PBMs to cover attorney fees in the tier 2 appeals process if the appeal request is upheld. Finally, the commentor asked OIC to ensure that pharmacies receive reasonable adjustments from PBMs when an appeal is upheld; the commentor stated that, in some cases, PBMs have required a patient to pay a higher co-insurance rate to the pharmacy rather than making a reasonable adjustment directly to the pharmacy.</p> <p>A commentor asked OIC to explain what a reasonable adjustment is under RCW 48.200.280(5)(a). The commentor asked OIC to order the PBM to make an adjustment to include the drug invoice price, the cost to dispense, and the dispensing fee, and apply the reasonable adjustment for all pharmacies in the state in the network. Responding to the CR-102, the commentor noted that pharmacies have employees and massive overhead; and if pharmacies are paid at "net zero" as the CR-102 establishes in its definition of "reasonable adjustment," there will be no pharmacies left.</p> <p>Additionally, the commentor raised concerns with the first prepublication</p>	<p>to affect health care services."</p> <p>OIC reviewed evidence suggesting that PBM underpayments to pharmacies are jeopardizing consumer access to pharmacy services and leading to pharmacy closures, particularly among independent, retail, and rural pharmacies.</p> <p>The Washington State Pharmacy Association has reported that 83 Washington State pharmacies have closed in the year and a half ending in June 2024. A Seattle Times analysis of data from the Washington State Department of Health found that about 60 pharmacies in Washington state closed in 2023 – twice as many as recorded in 2022.</p> <p>There is evidence that ties pharmacy closures to PBM underpayments for prescription drugs. A 2024 New York Times investigation found that PBMs "have been systematically underpaying small pharmacies, helping to drive hundreds out of business." The Washington Health Alliance has stated that "pharmacies are receiving lower reimbursements for the same prescriptions that employers are paying higher prices for, leading to closures of pharmacies while PBMs pocket the difference for profit."</p> <p>OIC reviewed information demonstrating that pharmacies provide myriad important services to consumers. For example, a 2020 research article published by the U.S. Centers for Disease Control and Prevention established that "Community retail pharmacies provide prescription services, as well as health promotion and disease management services, such as immunizations, rapid influenza screening, cholesterol testing, blood pressure management, blood glucose monitoring,</p>
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<p>draft's requirement for the pharmacy to provide the PBM with its invoice or wholesale cost during the appeals process, stating that this information is proprietary and pharmacies cannot provide it.</p> <p>A commentor asked OIC to require that any appeal findings that a PBM has reimbursed less than the pharmacy's cost apply to all similarly situated pharmacies. The commentor noted that it is expensive and time consuming for some pharmacies to appeal. Additionally, the pharmacy asked OIC to confirm that the appeal process applies to both generics and brand name drugs.</p> <p>A commentor requested that OIC explain its reasoning for including the language in the CR-102 stating "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." The commentor stated that OIC should be able to request proof of a price adjustment if the pharmacy does not see an appropriate adjustment based on an appeal.</p>	<p>and substance use treatment."</p> <p>Washington state has many rural communities, with limited access to physicians. In these communities, a pharmacy may be the only local source of medical care. The pharmacists in those communities may have longstanding relationships with community members, especially seniors, who have complex medication regimens. A research article published in the Journal of the American Medical Association (JAMA) in 2019 found that "Pharmacy closures are associated with persistent, clinically significant declines in adherence to cardiovascular medications among older adults in the United States. Efforts to reduce nonadherence to prescription medications should consider the role of pharmacy closures, especially among patients at highest risk."</p> <p>In light of this evidence, the requirement that pharmacies receive a minimum reasonable adjustment equal to their net cost, affords pharmacies a protection against underpayments which could preserve retail pharmacy access for consumers.</p> <p>This language is also consistent with OIC's review of the Office of Administrative Hearings (OAH)'s decisions on tier two appeals from a PBM's denial of a pharmacy appeal. In the cases OIC reviewed from OIC's publicly available consumer lookup tool, OAH final orders and decisions require the PBM to pay the pharmacy the pharmacy's net cost. The rule language is therefore consistent with this current practice.</p> <p>In response to the concern about</p>
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	<p>fluctuating drug prices and the potential for overpayment if payments are applied prospectively for 90 days, the proposed rule, retained in the final rule, does not require a reasonable adjustment to apply prospectively for a period of 90 days, as contemplated in the second prepublication draft. However, the language provides that "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." This language acknowledges that drug prices can fluctuate when generics are introduced and addresses the concern about PBM "overpayments."</p> <p>The proposed and final rule provide that 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." This provision 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.</p> <p>In response to the assertion that the language is unsupported in statute, OIC notes that "reasonable adjustments" are already required in statute. See RCW 48.200.280. OIC has authority to define what a reasonable adjustment is under certain circumstances. OIC discusses its authority regarding this rule in greater detail in the General comments subsection on page 5 of this responsiveness summary.</p>
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	<p>Multiple commentors requested that OIC require reasonable adjustments to include dispensing fees in addition to “payment of the claim or claims at issue at the net amount paid by the pharmacy to the supplier of the drug.” While OIC appreciates the commentor’s concerns about pharmacy expenses, OIC determined that the statute does not support this requested change. OIC notes that the statute (RCW 48.200.280(3)) refers to the pharmacy appeals process applying to “reimbursement for a drug” without reference to other amounts. Further, RCW 48.200.280(2)(g) states that a PBM “shall ensure that dispensing fees are not included in the calculation of the predetermined reimbursement costs for multisource generic drugs.”</p> <p>Relatedly, multiple commentors requested that reasonable adjustments apply to more than one pharmacy and more than one claim. The commentors suggested applying reasonable adjustments to other “similarly situated” or in-network pharmacies. The commentors also requested that these adjustments apply retrospectively and/or prospectively for established time periods, such as nine months or one year after the original reasonable adjustment is made. OIC determined that the statute and legislative history do not support making these changes. RCW 48.200.280(3) refers to “a network pharmacy” appealing “its reimbursement for a drug.” OIC’s review of the legislative history of this policy indicates that the PBM’s “reasonable adjustment” relates to the specific appeal brought by a pharmacy, with no requirement to apply that adjustment beyond the specific appeal before it. In addition, OIC notes that the current tier</p>
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	<p>two appeals process considers individual claims from individual pharmacies rather than multiple claims from multiple pharmacies.</p> <p>In response to the request for OIC to clarify whether the pharmacy appeal process applies to both generic and brand name drugs, effective January 1, 2026, E2SSB 5213(5)(3) expands the pharmacy appeals process to brand name drugs. Specifically, this provision amends the pharmacy appeals process from applying to a "multisource generic drug" to "a drug." Accordingly, WAC 284-180-505 of the final rule is effective until December 31, 2025 and is limited to multisource generic drugs, while WAC 284-180-507 of the final rule applies to "drugs," and is effective January 1, 2026.</p>
<p>The following comments pertain to WAC 284-180-505 and -507 of the final rule, specifically the timeframe a pharmacy has after claim adjudication to file a first-tier appeal.</p> <p>Regarding the amount of time a pharmacy has to file a first-tier appeal, a commentor asked to allow pharmacies to file an appeal for a claim that is adjudicated "during the last two years." The commentor stated that PBMs can audit pharmacies for claims going back 24 months under RCW 48.200.220, and that pharmacies should have this same time window to review and appeal claims. The commentor stated that some PBMs are limiting the pharmacy appeals to 30 days after the claim was adjudicated, which is not stipulated by law and is too restrictive, especially given the glitches in PBM appeal systems. The commentor stated that the 90-day requirement in the CR-102 would not allow pharmacies to audit the final price paid for</p>	<p>The new rule language in WAC 284-180-505 states:</p> <p>"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 and the claim was adjudicated by the pharmacy benefit manager within the past 90 days."</p> <p>The primary issue commentors raise is the effective "lookback period" that pharmacies may use to file an appeal with a PBM; in other words, the time between adjudication of a claim and the pharmacy's filing of an appeal.</p> <p>OIC's first prepublication draft defined that period as "during the term of the current or immediate past contract between the network pharmacy and the pharmacy</p>

<p>a medication, adding that PBMs often retroactively deny claims on a quarterly basis. The commentor requested that if OIC does not set the timeframe at the commentor's desired length of 24 months, then OIC should adopt a compromise of a 180-day minimum to account for the quarterly adjustment period utilized by PBMs.</p> <p>A commentor noted that, as a pharmacist, they have challenged PBMs' time limits within the second-tier hearings process, and that the hearing officer has found in their favor in every case and "affirmed the fact that the intent of the law has no time limit." The commentor asked OIC to leave the timeframe undefined, or if OIC does set a timeframe, to set it at 24 months.</p> <p>A commentor suggested that a pharmacy should have the same period to file a first-tier appeal as a PBM has to process an appeal (30 days). The commentor stated that the language in the prepublication drafts regarding the timeframe for pharmacies to appeal would create a significant administrative burden, and that the language is inconsistent with other state laws. The commentor appreciated OIC's inclusion of the shorter timeframe of 90 days within the CR-102 but said that it is still too long. The commentor asked OIC to remove the language, stating that it is not in the statute. The commentor asked that OIC explain its authority to establish a timeline.</p>	<p>benefits manager."</p> <p>In response to the multiple comments objecting to that language, and one comment requesting a two-year lookback period, OIC removed this language in the second prepublication draft and replaced it with a lookback period of 24 months. This change acknowledged the pharmacy community's concerns about the difficulty of filing appeals and the fact that PBM audits may "look back" twenty-four months (RCW 48.200.220).</p> <p>The proposed and final rule set the lookback period at 90 days (three months). That timeline responds to continued concerns from the PBM community and reflects OIC's finding that a 24-month "lookback period" would make Washington an outlier among the states. This 90-day period also acknowledges the pharmacy community's concern that 30 days is not enough time to file an appeal with complicated and "glitchy" systems. It also aligns more closely with other state laws governing pharmacy appeal periods, such as Oregon and Indiana, which set this period at 60 days. This language also significantly lessens the appeals-related administrative burden on PBMs compared to the second prepublication draft.</p>
<p>A commentor noted that pharmacies have substantial challenges contacting PBMs. The commentor asked OIC to define "normal business hours" and recommended 9 a.m. – 5 p.m. in the time zone in which the network pharmacy is located. The commentor stated that the</p>	<p>In response to the first comment, the OIC wrote in its second prepublication draft the requirement that PBMs have telephone availability between 9AM and 5PM Pacific Standard Time, including weekends and holidays. In addition to acknowledging the commentor's concerns, OIC reviewed the</p>

<p>information needs to be readily available to pharmacies when they have the time to work on them.</p> <p>A commentor raised concerns with WAC 284-180-505 (1)(a)(i) of the second prepublication draft, which requires a PBM to provide a telephone number for the pharmacy to contact the PBM "between 9 a.m. and 5 p.m. Pacific Standard Time every day, including weekends and holidays..." While the commentor appreciated the CR-102's removal of weekends and holidays from the language, the commentor asked OIC to explain why it made this change and stated that OIC has no statutory authority to implement this requirement.</p>	<p>U.S. Bureau of Labor Statistic's Occupational Outlook Handbook on pharmacists, which found "some [pharmacists] work nights, weekends, and holidays."</p> <p>However, OIC revised and retained in the final rule the requirement to remove "weekends and holidays." This change responds directly to the second commentor's concern about having a telephone number be available on weekends and holidays. This language defines "normal business hours" as the first commentor requests but eases the administrative burden on the second commentor.</p>
<p>The following comments pertain to the documents or information a network pharmacy may submit to support its appeal. This issue is addressed in WAC 284-180-505(2) of the final rule, and comments refer to the CR-102 and prepublication drafts.</p> <p>A commentor stated that in reviewing a pharmacy's appeal, PBMs need a copy of the invoice that reflects all post-invoice discounts to achieve the standard of "net price" paid. The commentor stated that an image or screenshot from a wholesale ordering system is inadequate, and that any image must include a date. Additionally, the commentor stated that the use of "may" is permissive, is likely to result in overpayments, and could result in pharmacies not submitting anything to PBMs. The commentor stated that this language is unsupported in statute. The commentor suggested alternative rule language in WAC 284-180-505(2).</p> <p>The commentor noted that this provision goes on to describe that a pharmacy may</p>	<p>The relevant section of WAC 284-180-505(2) in the proposed rule, retained in the final rule, states:</p> <p>"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:</p> <ul style="list-style-type: none"> (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: <ul style="list-style-type: none"> (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

<p>take into consideration whether it has "...fewer than fifteen retail outlets within the state of Washington under its corporate umbrella and whether the network pharmacy's contract with a wholesaler or secondary supplier restricts disclosure of the amount paid to the wholesaler or secondary supplier for the drug." The commentor raised a concern that this language will lead to an appeals process where the network pharmacy does not need to offer any proof. The commentor stated that this language is unsupported in statute.</p> <p>Another commentor stated that the discounts pharmacies receive are low and are rarely linked to medications.</p> <p>Multiple commentors voiced support for language in the second prepublication draft and CR-102 providing that an image from the ordering system is sufficient documentation for the pharmacy's appeal purposes. The commentors stated that this information will prove that a pharmacy could not purchase the medication for less. One of these commentors asked OIC to add "or their representative" after a network pharmacy for document submission.</p> <p>A commentor noted that their pharmacy's invoice costs are a proprietary trade secret, confidential, and subject to non-disclosure agreements, and that these costs cannot be presented in a first-tier appeal.</p> <p>A commentor noted the "net amount" of a prescription drug that a network pharmacy pays to a supplier is the result of contracting between a pharmacy and other entities within the pharmaceutical supply chain. The commentor stated that PBMs</p>	<p>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."</p> <p>The Legislature established a right for pharmacies to appeal PBM payments that are less than the amount the pharmacy has paid for a drug. If the pharmacy cannot, under the terms of its contract with a wholesaler or supplier, disclose the amount that they have paid for a drug, then requiring the submission of this information as part of an appeal would create a complete barrier to a pharmacy's ability to exercise its right under the statute to submit an appeal to a PBM.</p> <p>OIC reviewed evidence indicating that most pharmacies are not achieving resolution through the appeal rights that the Legislature created. According to a report by the Washington State Health Care Authority, as of 2020, a vast majority of Washington State pharmacy appeals to PBMs were denied (96%). This report found that: "Given the high rate of denials and subsequent appeals to OIC, pharmacies may be discouraged from submitting appeals..." and that "...these numbers may actually be suppressed compared to the frequency at which pharmacies are not adequately reimbursed for the prescriptions they dispense." The pharmacy community's comments to this rule, specifically about the fear of retaliation and the difficulty of filing appeals, are consistent with the report's findings.</p> <p>OIC also reviewed evidence suggesting that PBMs commonly reimburse</p>
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<p>are not privy to information shared between pharmacies, Pharmacy Service Administrative Organizations (PSAOs), and wholesalers. The commentor was concerned that this provision specifies “net amount,” but other provisions of the CR-102 allow pharmacies to circumvent providing proof of “net amount” by stating their contracts do not permit them to share pricing data. The commentor stated that this language leaves loopholes for pharmacies to not provide documentation of what the “net amount” is. The commentor asked that OIC both correct and standardize the definition of “net amount.”</p>	<p>independent and retail pharmacies below their net cost. A 2024 New York Times investigation found that “P.B.M.s frequently pay the pharmacies at rates that do not cover the costs of the drugs, according to more than 100 pharmacists around the country and dozens of examples of insurance paperwork and legal documents,” and that “...the P.B.M.s sometimes pay their own pharmacies more than what they pay local drugstores for the same medications.” While OIC does not have access to comprehensive data on the true extent of “underpayments” to pharmacies, the reports indicating that pharmacies are commonly underpaid for prescriptions would also suggest that OIC must take action to effectuate the Legislature’s intent that pharmacies have an effective means to appeal claims payment by PBMs.</p> <p>Further, in developing this language, OIC reviewed exhibits provided by pharmacies as part of the OAH Administrative Law Judge (ALJ) decisions in the second-tier appeals process. These exhibits show that, in practice, ALJs are accepting attestation and similar information that OIC includes in this rule language. OIC notes that proof of “net amount” is a question of fact for ALJs in these cases.</p> <p>Regarding the PBM community’s request that the sole means for a pharmacy to show “net price” is by showing a copy of the invoice, OIC did not adopt this change. In comments to this rule, the pharmacy community has expressed that the pharmacy’s invoice in the first tier is proprietary and “the PBM could use that information to set their list prices and undermine our state laws.”</p>
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	Regarding the definition of "net amount," OIC notes that existing WAC 284-180-130(12) defines "net amount." OIC is not amending this definition in the final rule. OIC determined it was not necessary to define the term further in the final rule.
In WAC 284-180-507(1)(b) of the second prepublication draft, a commentor suggested that the language should reference a contract between a PBM and a PSAO, rather than a contract between a PBM and a pharmacy. The commentor stated that if a PSAO represents a pharmacy, then the pharmacy does not have a contract with a PBM.	OIC did not include the requested change in the final rule. The language of WAC 284-180-507 addresses how and when a PSAO can file an appeal on behalf of a pharmacy.
Regarding WAC 284-180-507(1)(c) of the second prepublication draft, a commentor asked OIC to clarify whether this language allows a PSAO to submit an appeal for multiple pharmacies on the same appeal. The commentor suggested that OIC allow a pharmacy to appeal multiple claims on a single appeal, if the provision's other requirements are met. The commentor noted that, currently, PBMs require an appeal for each claim. Another commentor requested that WAC 284-180-507(1)(c)(iii) of the provision be removed because reimbursement amounts vary by contract, and pharmacies in the same network are reimbursed different amounts for the same drugs.	OIC did not include the requested changes in the final rule. WAC 284-180-507(1)(c) of the final rule allows submission of multiple claims in an appeal initiated by a PSAO if certain conditions are met: "(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; (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."
A commentor noted that the provisions in WAC 284-180-505(7) to (9) of the second prepublication draft and CR-102 allow for individuals and/or entities, irrespective of their relevance to the appeals process, to be involved in it. The commentor stated	OIC did not include the requested change in the final rule. RCW 48.200.280(3), as amended by E2SSB 5213, requires that "A pharmacy benefit manager must establish a process by which

<p>that only a pharmacy or its contracted PSAO are the relevant entities for PBM claims and appeals. The commentor stated that these provisions would require PBMs to maintain and submit information such as taxpayer identification numbers or numbers assigned to entities submitting appeals, for which PBMs have no information.</p> <p>Regarding this provision's requirement that a PBM have a single-point of contact for appeals, the commentor asked what would happen if that single-point of contact leaves the position.</p> <p>Finally, the commentor noted that these provisions, along with the rest of the section, expire on December 31, 2025. The commentor asked OIC to explain its reasoning for varying expiration dates with overlapping rule language.</p> <p>The commentor asked that OIC strike all the language referenced in its comment from the rule.</p>	<p>a network pharmacy, or its representative, may appeal its reimbursement for a drug." Hence, the statute allows a pharmacy's representative to be involved in the appeals process.</p> <p>Regarding the requirement for PBMs to "maintain and submit information related to individuals or entities submitting appeals for which they have no information," OIC notes that this language is current law; OIC is not amending this language in this rulemaking .</p> <p>With respect to the comment related to the single point of contact for appeals, the PBM is responsible for maintaining that role and updating the information if a particular staff person leaves that position and another staff person takes their place.</p> <p>Several of the provisions of E2SSB 5213 were effective on June 6, 2024. Sections 5 and 7 through 9 of the Act take effect January 1, 2026. To effectuate these multiple effective dates, the proposed and final rule include two sections on similar issues, one of which expires on December 31, 2025 and the other of which is effective January 1, 2026. The rule sections that expire on December 31, 2025 reflect changes in rule impacted by provisions of E2SSB 5213 that were effective on June 6, 2024. The sections that are effective beginning January 1, 2026 reflect changes in rule impacted by both the provisions of E2SSB 5213 that were effective on June 6, 2024 and those that will go into effect on January 1, 2026.</p>
<p>A commentor stated that much of the language in the second prepublication draft is redundant from the first prepublication draft, such as WAC 284-180-505 in the first prepublication draft,</p>	<p>OIC did not include the requested change in the final rule.</p> <p>Several of the provisions of E2SSB 5312 were effective on June 6, 2024. Sections 5</p>

<p>which substantially overlaps with the language of WAC 284-180-507 in the second prepublication draft.</p>	<p>and 7 through 9 of the Act take effect January 1, 2026. To effectuate these multiple effective dates, the proposed and final rule include two sections on similar issues, one of which expires on December 31, 2025 and the other of which is effective January 1, 2026. The sections that expire on December 31, 2025 reflect changes in rule impacted by provisions of E2SSB 5213 that were effective on June 6, 2024. The sections that are effective beginning January 1, 2026 reflect changes in rule impacted by both the provisions of E2SSB 5213 that were effective on June 6, 2024 and those that will go into effect on January 1, 2026.</p>
<p>The following comments pertain to the requirement in WAC 284-180-505(5)(a) of the final rule, which requires in part that a PBM provide “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” as part of the appeals process.</p> <p>A commentor suggested that OIC add “and price” after “national drug code” and replace “pharmacies” with “small pharmacies.” The commentor stated that the appeals section pertains to small pharmacies.</p> <p>Another commentor stated that PBMs do not contract with a pharmacy’s wholesaler or supplier and therefore do not know the price that a particular pharmacy would pay for a drug at any given time. The commentor stated that this language is inconsistent with how pharmacy-wholesaler contracting actually works, is not supported in the underlying statute, and should be removed.</p>	<p>Under the statute (RCW 48.200.280(3)(b)), a PBM must 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 for the multisource generic drug.”</p> <p>In response to the first comment, OIC’s proposed rule, retained in the final rule, adds the phrase “and price” to WAC 284-180-505(5)(a). However, OIC determined that redefining “pharmacies” as “small pharmacies” would be inconsistent with the statute and did not make this change.</p> <p>In response to the second comment, OIC revised the language of the proposed rule, retained in the final rule, to specify that a PBM must provide the name of “at least one” wholesaler or supplier rather than “the name of” the wholesaler or supplier.</p> <p>The final rule does not require a PBM to know the <i>specific</i> price of the wholesaler or supplier from which the pharmacy purchased the drug. However, the PBM</p>

	<p>would need to identify at least one wholesaler or supplier from which the drug was available for purchase on the date of the claim subject to the appeal.</p> <p>This language promotes greater transparency in how PBMs reimburse for drugs, in keeping with the Legislature's intent of providing greater transparency on drug reimbursements by PBMs.</p> <p>In developing this rule, OIC reviewed evidence suggesting that PBM reimbursement to pharmacies lacks transparency to pharmacies and to the public. For example, the Federal Trade Commission's interim report found that "the proliferation of complex and opaque contract terms and adjustments has increased uncertainty in pharmacy reimbursements...For instance, the rates in PBM contracts with independent pharmacies often do not clearly reflect the amount the pharmacy will ultimately be paid." The report further found that "...PBM business practices remain extraordinarily opaque."</p>
<p>A commentor raised concerns with WAC 284-180-505(5)(b) of the CR-102 draft which provides:</p> <p>"(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."</p> <p>The commentor stated that PBMs do not</p>	<p>OIC did not include the requested change in the final rule.</p> <p>The statute sets out which specific health plans it applies to and establishes a pharmacy appeal process related to claims for such health plans. It is within OIC's authority to require a PBM to provide documentation that a particular appeal is not subject to the Act. OIC has a reasonably implied power to ascertain that the PBM is correct in its determination that a specific appeal is not subject to RCW 48.200.280.</p>

<p>have information on which self-funded group health plans have opted in with OIC. The commentor requested that OIC remove the language.</p>	
<p>A commentor requested that in WAC 284-180-507(2) of the CR-102 draft, OIC ensure the availability and accuracy of the list of included BIN, PCN, and group identifiers covered by the regulation. The commentor stated that PBMs use interchangeable BIN, PCN, and group codes for ERISA, Taft-Hartley, and fully insured individual or group commercial plans, making it impossible for the OIC or pharmacies to understand which claims fall under OIC enforcement and the appeals process. The commentor stated it is not sufficient to require PBMs to report only the opt-in plans. The commentor stated that PBMs have previously evaded accountability by falsely claiming an ERISA exemption, and there must be a consequence if an accurate list is not maintained. The commentor asked that the language require that PBMs maintain and provide an accurate list within one business day of a request, and if a PBM provides a look-up for covered lives, it should indicate whether the individual is covered by this chapter's provisions.</p> <p>A commentor appreciated that, in the first prepublication draft, OIC is trying to make it possible for pharmacies to identify plans to determine if the state laws apply to the claim in question. However, the commentor raised concerns with the wording of this language, stating that it creates a roadblock by requiring the pharmacy to request the information from a PBM, potentially leading to delays in PBM responses.</p> <p>Another commentor raised concerns with</p>	<p>In response to the first comment, OIC included language in the proposed rule, retained in the final rule (WAC 284-180-507(2)), to require a PBM to supply this information for health plans (as set forth in WAC 284-180-500) and for self-funded group health plans that have elected under RCW 48.200.330 to participate in RCW 48.200.280, 48.200.310, and 48.200.320. The PBM must supply this information "within four business days." This timeframe provides a reasonable opportunity for the PBM to assemble the information called for in the rule.</p> <p>WAC 284-180-507(2) applies to pharmacy appeals for claims that are subject to the rule, i.e., fully-insured health plans and self-funded group health plans that have elected to participate in the law.</p> <p>Regarding the second commentor's suggestion, the rule language mirrors the statute in RCW 48.200.280(4), which requires that a pharmacy request the information. OIC did not change the language in response to this comment as the change would be inconsistent with the statute.</p>

<p>WAC 284-180-507(2) in the second prepublication draft, which requires that PBMs provide, within four business days of a pharmacy's request, bank identification numbers, processor control numbers, and pharmacy group identifiers. The commentor stated that this requirement puts an unreasonable and punitive burden on PBMs that does not appear in the underlying statute, and that bank identification numbers are not necessarily something a PBM can provide without permission from a client. The commentor requested that OIC work with stakeholders to negotiate language for a reasonable timeline.</p>	
<p>A commentor asked OIC to create a standardized first-tier appeal form so that OIC can guide the possible outcomes of the first-tier appeal, save time for interested parties, and curb unlawful PBM tactics. The commentor stated that PBMs use non-standardized forms.</p>	<p>OIC did not include the requested change in the final rule. The need for standardized submission formats will be assessed as the rule is implemented.</p>
<p>A commentor requested that OIC require a PBM to complete an appeal within seven days.</p>	<p>OIC did not include the requested change in the final rule.</p> <p>The statute sets the 30-day timeline. OIC does not have statutory authority to shorten the time a PBM has to complete an appeal.</p>
<p>A commentor voiced concerns that the current appeals process is much too onerous and time consuming for busy pharmacists to manage at scale. The commentor stated that in the first five months of 2024, their pharmacy has been underpaid by PBMs on 8,697 claims. The commentor stated that under the current OIC system, they could not submit and track all these claims as appeals. The commentor stated that PBMs purposely make the process convoluted and time consuming and asked that OIC completely strike WAC 284-180-505 from the rule and</p>	<p>OIC appreciates this comment.</p> <p>OIC has developed the final rule with a general goal to improve the appeals process for interested parties, including pharmacies. As discussed elsewhere in this subsection, OIC has adopted language in this final rule regarding pharmacy "lookback period," information a pharmacy may submit to support an appeal, the definition of "reasonable adjustment," the information a PBM must provide after denying an appeal, and other appeal-related issues.</p>

allow pharmacies to appeal directly to the OIC.	Regarding the suggestion to strike WAC 284-180-505, OIC does not have statutory authority to redesign the appeals process as developed by the Legislature in RCW 48.200.280, including the tier-one appeal process in which the pharmacy appeals first to the PBM. OIC did not include the requested change in the final rule.
A commentor asked OIC to explain WAC 284-180-500(1) in the first prepublication draft, which specified the plans that are subject to the PBM requirements. The commentor stated that they do not see limitations on the types of plans subject to the requirements in the statute.	OIC did not include the requested change in the final rule. The statute limits the scope of RCW 48.200.210 to 48.200.901 PBM contracts with carriers, PEBB/SEBB, and Medicaid managed care organizations. OIC does not have statutory authority to apply the PBM provisions of the final rule to additional lines of business.
<p>The following comments all pertain to requirements of current law that one commentor does not believe are being enforced, and/or that PBMs are not following. Broadly speaking, the commenter would like OIC to address these concerns in rule and explain how OIC is enforcing current law, including investigating PBMs and issuing penalties. These provisions include:</p> <p>RCW 48.200.290(2): The commentor requested that OIC outline what constitutes a knowing and willful violation.</p> <p>RCW 48.200.290: The commentor requested that OIC enforce the laws to their full authority for each violation of the chapter, not just underpayment appeals. The commentor stated that there needs to be a process for pharmacists and patients to notify the OIC when PBMs are violating Chapter 48.200 RCW.</p> <p>RCW 48.200.280(2)(k): The commentor</p>	<p>Generally speaking, these comments are not related to the scope of the final rule; hence, OIC did not adopt language in the final rule that speaks to enforcement of these provisions directly.</p> <p>If a pharmacist believes that a PBM is in violation of the provisions in Chapter 48.200 RCW, the pharmacist may file a complaint using OIC's complaint portal: https://www.insurance.wa.gov/file-complaint-or-check-your-complaint-status OIC has modified its complaint portal to provide an option to note issues related specifically to PBMs. Under RCW 48.200.050, OIC is required to respond to and investigate complaints related to the conduct of health care benefit managers.</p> <p>Regarding the knowing and willful comment," OIC notes that the Insurance Code (Title 48 RCW) does not define knowing and willful, but the criminal code does. For example, RCW 9A.08.010(1)(b) defines knowledge (knowing) as being</p>

<p>stated that nationally, there have been major cases in which PBMs have been found to be violating this provision. They noted that OIC has oversight authority in RCW 48.200.050(3) regarding this issue.</p> <p>RCW 48.200.280(2)(h): The commentor stated that patients show them letters in which their PBM tries to steer them away from the commentor's pharmacy to a PBM-owned mail order pharmacy.</p> <p>RCW 48.200.280(2)(i): The commentor states they have proof that their pharmacy has been charged over \$7,000 in transaction fees since this law was enacted. The commentor stated that they are starting a long-term care pharmacy, and Express Scripts is requiring a \$500 setup fee and application fee just to set up contracts with them.</p> <p>RCW 48.43.430(2): The commentor stated that they have examples that this provision is being violated.</p>	<p>"aware of a fact, facts, or circumstances or result described by a statute defining an offense..." and RCW 9A.08.010(4) specifies that the definition for knowingly and willfulness are the same. While this language is not in Title 48, it is instructive as to what the law requires for this particular mental state; especially since many of these statutory definitions are the same as state common law definitions across the country.</p>
<p>A commentor requested that OIC require pharmacies to be awarded lawyer fees during the appeal process in WAC 284-180-505 and -507 if the pharmacy wins the appeal.</p>	<p>OIC did not include the requested change in the final rule.</p> <p>The Legislature did not authorize attorney's fees in the statute, therefore the OIC cannot impose attorney's fees in rule.</p>
<p>A commentor asked why a PBM should have to reconsider a reimbursement amount if the claim at issue is for a health plan outside the scope of the OIC's authority. The commentor also asked why a PBM should have to reconsider if a pharmacy and/or PSAO submit an incomplete and/or inaccurate appeal. The commentor requested that this language be removed.</p>	<p>OIC did not include the requested change in the final rule.</p> <p>OIC notes that the phrase "The pharmacy benefit manager must reconsider the reimbursement" is already in current WAC 284-180-505(2). OIC is not amending this phrase in this rulemaking.</p>

<p>A commentor voiced support for WAC 284-180-507(8)(a) in the CR-102 draft. This provision relates to the information a PBM must provide to a network pharmacy if the PBM denies the network pharmacy's appeal.</p>	<p>OIC appreciates this comment.</p>
<p>Regarding WAC 284-180-505(1)(a)(iii) of the CR-102 draft, a commentor voiced appreciation that OIC included secure online portals as one way to conduct appeals. The commentor also voiced appreciation for this provision's language surrounding a PBM's acceptance of "a valid submission," saying that the provision will add integrity to the process. However, the commentor remained concerned that if a pharmacy submits an appeal with incomplete or inaccurate information, the provision may still put the burden on the PBM to accept the appeal with no accountability for the pharmacy.</p>	<p>OIC appreciates these comments. OIC did not include the requested change in the final rule.</p> <p>This provision of the final rule requires pharmacies using secure online portals for appeals to include "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..."</p>
<p>Regarding WAC 284-180-507(12) of the CR-102 draft, a commentor stated that PBMs do not provide a single point of contact for pharmacies to use to file appeals, as required in statute. The commentor asked OIC whether it will make this single point of contact available to pharmacies.</p>	<p>OIC did not include the requested change in the final rule.</p> <p>The final rule language the commentor cites reads:</p> <p>"(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."</p> <p>Under the final rule, PBMs are required to provide contact information, through the pharmacy provider contract and on the PBM's website, that includes contact information for appeals (see WAC 284-</p>

	180-505(a) and 507(3)(a)). The OIC does not plan to provide the single point of contact directly to pharmacies in the first-tier appeals process.
WAC 284-180-515 Use of brief adjudicative proceedings for appeals by network pharmacies to the commissioner	
A commentor stated that its organizations' members would like to learn why brief adjudicative proceedings are used by OIC. The commentor suggested a call with OIC.	The statute establishes the brief adjudicative proceedings process. OIC would be happy to discuss this process directly with the organization.
WAC 284-180-517 Use of brief adjudicative proceedings for appeals by network pharmacies to the commissioner	
A commentor noted that the second prepublication draft establishes a procedure for OIC to conduct adjudicative proceeding regarding a network pharmacy's appeal of a PBM's decision and states that the language does not apply to adjudicative proceedings under WAC 284-02-070, including "converted brief adjudicative proceedings." The commentor asked OIC to explain its intent for inserting a caveat to the OIC's adjudicative proceedings.	The adjudicative proceeding described by WAC 284-02-070 is for adjudicative hearings brought by the OIC against entities it regulates. These proceedings are governed by Chapter 48.04 RCW and RCW 34.05.410 through 34.05.476. The appeals process mandated in RCW 48.200.280(6) does not fit either of the proceedings outlined in WAC 284-02-070. This provision merely clarifies that the brief adjudicative hearing process adopted by the OIC in this rule is governed by RCW 48.200.280 and RCW 34.05.482 through 34.05.494.
WAC 284-180-522 Appeals by network pharmacies to the commissioner	
A commentor asked OIC to explain why this section does not have an effective date of January 1, 2026, when it establishes multiple areas of new administrative procedure law.	In proposed and final rule, WAC 284-180-522 includes the following language: (11) This section is effective January 1, 2026.
The following comments relate to sections of E2SSB 5213 that interested parties would like addressed in the rule, and which are otherwise not addressed by OIC in this summary. These comments were to the CR-101. Sec. 7(1)(a)-(c): A commentor encouraged OIC to have an audit process to verify compliance with this section, stating that it	The OIC did not specifically address these issues in the final rule. These issues were generally outside the scope of the final rule, either because: (a) they are already addressed in statute; (b) OIC lacks authority to address them; or (c) they relate to enforcement of statute or regulation rather than the language of the rule itself. In response to the comment on Sec. 7(2)

<p>would be difficult to identify non-compliance through a complaint process.</p> <p>Sec. 7(2) and 7(3): A commentor stated that noncompliance with this section will largely be complaint based and encouraged OIC to educate consumers about their rights under these sections.</p> <p>Sec. 5(2)(b) and 5(2)(c): A commentor recommended that, in enforcement of the appeals language under Sec. 5(3) through (7), OIC should hold PBMs accountable for including unavailable or obsolete drugs on their pricing lists. The commentor stated that PBM medication list prices are routinely set based on obsolete or unavailable products, leading to increasingly inaccurate drug lists.</p> <p>Sec. 5(2)(i): A commentor requested that OIC make it clear that fees should not be charged for pharmacy network enrollment. Additionally, the commentor noted that carriers have been forcing pharmacy claims to be processed through a discount card instead of by a PBM. The commentor stated that the discount cards charge fees of \$4-10 per claim to a pharmacy. The commentor stated that carriers should be accountable for the fees charged by their partners to pharmacies.</p> <p>Sec. 5(2)(k): A commentor noted that this provision of law prohibits PBMs from paying owned or affiliated pharmacies a different price for medications. The commentor referenced a study they commissioned by 3 Axis Advisors showing that PBMs pay their owned pharmacies (chain and mail order pharmacies) increased prices for medications. The commentor attached a copy of this study to their comments. The commentor stated</p>	<p>and 7(3) of E2SSB 5213, the OIC will update or create webpages with information regarding new protections.</p>
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that enforcement of this section should be a top priority for patients, employers, and pharmacies in Washington state.	
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Section 6: Implementation Plan

A. Implementation and enforcement of the rule.

As described below, implementation of the rule will occur through numerous activities at OIC. The Legal Division's investigations unit will rely on this rule when determining whether to initiate an investigation of an HCBM and during any such investigation. The Legal Division will rely upon the rule in determining whether enforcement action is appropriate. The Rates, Forms, and Provider Networks Division will rely on this rule in the carrier filing process. The Company Supervision Division will rely on the rule in the HCBM registration and renewal process. The Consumer Protection Division will continue to respond to consumer complaints related to HCBMs. Through these activities, OIC will monitor the impact of rule implementation.

B. How the Agency intends to inform and educate affected persons about the rule.

OIC Policy staff will distribute the final rule and this Concise Explanatory Statement (CES) to all interested parties by posting and sharing the documents through the OIC's standard rulemaking listserv and emailing the documents to interested parties. The OIC Policy Division will post the CR-103 documents on the OIC's website.

Type of Inquiry	Division
Consumer assistance	Consumer Advocacy Program
Rule content	Policy Division
Authority for rules	Legal Division
Enforcement of rule	Legal Division

C. How the Agency intends to promote and assist voluntary compliance for this rule.

OIC will respond to inquiries from entities that plan to act or are acting as HCBMs in Washington state. The OIC will provide these entities with an opportunity to fully understand and comply with these rules. OIC also stands ready to meet with organizations representing carriers, HCBMs, PBMs, pharmacies, consumer groups and others to respond to questions and share perspectives on implementation of the rule. Additionally, OIC plans to produce educational materials, such as

webinars, for self-funded group health plans regarding the opt-in language in the rule, as well as information on the OIC website regarding the rule in general.

D. How the Agency intends to evaluate whether the rule achieves the purpose for which it was adopted.

The goal of the laws implemented through this rulemaking is to “protect and promote the health, safety, and welfare of Washington residents by establishing standards for regulatory oversight of health care benefit managers.” See [RCW 48.200.010\(3\)](#). OIC will monitor HCBM registrations, renewals, and filings, as well as carrier filings and consumer complaints. OIC will review the outcome of HCBM-related investigations undertaken pursuant to this rule.

Appendix A

CR-102 Public Hearing Summary

Summarizing Memorandum

To: Mike Kreidler
Insurance Commissioner
From: Nicolaus "Nico" Janssen
Presiding Official, Hearing on Rulemaking

Matter No. R 2024-02

Topic of Rulemaking: Health Care Benefit Managers

This memorandum summarizes the hearing on the above-named rulemaking, held on November 26, 2024, at 11:00 am Pacific Time on Zoom, over which I presided in your stead.

The following agency personnel were present:

- Jane Beyer
- Joyce Brake
- Jennifer Kreidler
- Ron Pastuch
- Deanne Fritschy
- Joanne Najdzin
- Colby Robinson
- Mary Tedders-Young
- Simon Casson
- Dory Nicpon
- Donna Lewis

In attendance and testifying:

Testified:

- Lori Grassi, Washington State Chiropractic Association
- Peter Fjelstad, Pharmaceutical Care Management Association
- LuGina Mendez-Harper, Prime Therapeutics
- Jenny Arnold, Washington State Pharmacy Association
- Clinton Knight, Whole Health Pharmacy

Attended:

- Tamara Rancore
- Donna Lewis
- Heather Ebert
- Dedi Little
- Jeff Gingold
- Beau Reitz
- Melissa Saiz
- Kurt Swanson
- Courtney Taylor
- Edwin Chen
- Jennifer Davis
- Thalia Cronin
- Joel Kurzman

Contents of the presentations made at hearing:

- Lori Grassi (Washington State Chiropractic Association) testified in support of the CR-102 draft's requirement for HCBMs to file all contracts.
- Peter Fjelstad (Pharmaceutical Care Management Association) testified with concerns about the CR-102 draft. He stated that many of the rule provisions are not supported by the underlying statute and asked OIC to change the rule language to address the organization's concerns. He stated that:
 - PBMs do not have access to the net amount and discounts attributed to a drug.
 - The CR-102 draft allows pharmacies to play by less stringent rules compared to other entities in the prescription drug supply chain.
 - The CR-102 draft contains duplicative and redundant language.
 - The Supreme Court's *Loper Bright* decision may curtail state agency rulemaking authority.
 - The CR-102 draft applies to HCBMs for whom the OIC does not have regulatory authority.
- LuGina Mendez-Harper (Prime Therapeutics) voiced concerns with the CR-102. She requested that the rule not be advanced and instead be re-written to adhere to the intent of the underlying statute and achieve maximum compliance. She stated that:

- The CR-102 draft undermines the clear legislative intent behind E2SSB 5213 to provide transparency and accountability on both sides of pharmacy reimbursement.
- PBMs have no visibility into pharmacy reimbursement contracts, but the CR-102 draft requires PBMs to provide unknowable information to pharmacies in the appeal process.
- The underlying legislation defines net amount as applying to all discounts and cost reductions, but the CR-102 draft provides loopholes to pharmacies to not meet this requirement, including the ability for pharmacies to submit a screenshot from an ordering system and an attestation regarding the net amount paid and the pharmacy's due diligence.
- Jenny Arnold (Washington State Pharmacy Association) testified with appreciation for the CR-102 language and the OIC's attention to detail in developing it. She stated that:
 - When pharmacies appeal a reimbursement to a PBM, the PBM provides outdated or inaccurate information to the pharmacy regarding the availability of a drug at a lower price.
 - Discounts that pharmacies receive are rarely linked to medications and constitute low amounts.
- Clinton Knight (Whole Health Pharmacy) testified with appreciation for the OIC's work on implementing RCW 48.200 since 2017 and with concerns regarding several aspects of the CR-102 draft. He commented that:
 - The statute does not set a time limit or "lookback period" for pharmacies to appeal a reimbursement after the claim's adjudication. Setting a 90-day limit, as the CR-102 draft includes, puts an undue burden on small pharmacies. If the OIC does create a time limit, it should be two years. The statute was intended to protect pharmacies and the people of our state, not to make the process less burdensome on PBMs.
 - He appreciates the CR-102 draft's provisions that establish how a pharmacy may prove it cannot purchase a medication at a lower rate.
 - Pharmacies have employees and massive overhead; if pharmacies are paid at net zero as the CR-102 draft establishes in its definition of "reasonable

adjustment,” there will be no pharmacies left. The reasonable adjustment should include the cost to dispense a drug, and OIC should work with pharmacy groups to determine a fair payment.

- The CR-102 draft’s language regarding a PBM’s single point of contact for appeal is appreciated, but the PBMs do not provide this information, and this requirement is already in law. OIC should explain whether the agency will provide this single point of contact to pharmacies.
- OIC should require a standardized form for the first-tier appeal. The existing process, in which PBMs establish the information required from pharmacies, puts too much of a burden on the pharmacies.

The hearing was adjourned.

SIGNED this 26th day of November, 2024

Nicolaus H. Janssen
Presiding Official