

Registration and Regulation of Pharmacy Benefit Managers (Rule 2016-07)

Concise Explanatory Statement;
Responsiveness Summary, Rule Development
Process and Implementation Plan

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Mike Kreidler, *Insurance Commissioner*
www.insurance.wa.gov

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Introduction

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

1. Identify the OIC's reasons for adopting the rule;
2. Describe the differences between the proposed rule and the final rule (other than editing changes) and the reasons for the difference;
3. Summarize and respond to all of the comments that the OIC 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. If the OIC did not incorporate the change that the commenter requested, the response will include an explanation of why the agency did not incorporate the change;
4. Be distributed to all persons who commented on the rule during the official public comment period and to any person who requests it.

Reasons for adopting the rule

The Legislature passed 5ESSB 5857 during the 2016 session. In addition to other requirements, the bill gives the Office of the Insurance Commissioner (OIC) enforcement authority over Pharmacy Benefit Managers (PBMs), requires the OIC to begin registering PBMs starting 1/1/17, and requires the agency to start accepting appeals from small pharmacies with under 15 branches in Washington starting 7/1/17. The OIC wrote the rule to implement the requirements of the bill.

Rule development process

On April 29, 2016, the OIC filed a preproposal statement of inquiry (CR-101) for a rule to register and regulate pharmacy benefit managers. The CR-101 comment period was open until June 17, 2016.

Two stakeholders submitted comments to the OIC regarding the rule during the CR-101 comment period.

On August 8, 2016, the OIC released a stakeholder draft.

On August 23, 2016, the OIC held a stakeholder meeting. Comments on the stakeholder draft were due August 30, 2016, and several stakeholders submitted comments.

On November 2, 2016, the OIC filed a CR-102. The agency held a hearing on December 6, 2016. Comments on the CR-102 were due December 6, 2016, and some stakeholders submitted comments.

The OIC filed the CR-103P to adopt the rule on December 20, 2016 and the rule went into effect on January 1, 2017.

Differences between proposed and final rule

In Section 284-180-420(5), the agency replaced the word "OIC" with the word "commissioner."

Responsiveness summary of comments

The OIC received numerous comments and suggestions regarding this rule. The following information contains a description of the comments, the OIC's assessment of the comments, and information about whether the OIC included or rejected the comments.

The OIC received comments from:

- Alliance for Patient Access
- Coventry / First Script
- Envision Pharmaceutical Services / EnvisionRx
- National Community Pharmacists Association
- OptumRx
- Pharmaceutical Care Management Association
- Premera Blue Cross and LifeWise Health Plan of Washington
- UnitedHealthcare
- Washington State Pharmacy Association

Comments regarding definitions

Definition of corporate umbrella

Comment: Two commenters asked the OIC to amend the definition of corporate umbrella to make it clear that the definition includes all subsidiaries and affiliates that operate under common control or ownership.

Response: In response to these comments, the rule team changed the definition of corporate umbrella to "an arrangement consisting of, but not limited to, subsidiaries and affiliates operating under common ownership and control."

Definition of generally available for purchase

Comment: Several stakeholders commented on the definition of "generally available for purchase" in Section 284-180-130(2). These commenters asked the OIC to revise the definition to make it clear that it applies to wholesalers that serve pharmacies in Washington instead of to wholesalers located within Washington. Two of the commenters also asked the OIC to add language saying that the pharmacies are *"not under common ownership or control."*

Response: In response to these comments, the OIC amended the language to say that the wholesalers must serve pharmacies in Washington.

Definition of net amount

Comment: Several stakeholders commented on Section 284-180-130(3), the definition of net amount:

- Some stakeholders expressed concerns that the rule's definition of "net amount or drug acquisition cost" does not reflect the typical contracting relationships between payers, PBMs, pharmacy services administrative organizations, and pharmacies. Because the rule calls for the inclusion of taxes, fees, or other costs as a part of the "net amount or drug acquisition cost," these commenters said, the language could encompass fees that the payer has no knowledge of, or has not contracted to cover as part of its reimbursements.
- Two commenters asked the OIC to add the phrase "plus any taxes, fees or other costs" to the end of the definition.
- One commenter asked the OIC to amend definition of "net amount" to address situations when a pharmacy or its contracting agent submits an appeal for below-cost reimbursement to a PBM.

Response: The OIC deleted the phrase "or drug acquisition cost" from the definition of net amount.

Definition of reasonable adjustment

Comment: The OIC received several comments regarding the definition of "reasonable adjustment." These comments included:

- Asking the OIC to clarify the language and to add additional standards that require PBMs to meet a minimum benchmark when approving a price adjustment
- Asking the OIC to revise definition of "reasonable adjustment" and add additional requirements for how PBMs must update the price, including retroactively adjusting the reimbursement "for the appealing pharmacy and for all other contracted pharmacies in the network of that PBM that filled a prescription for patients covered under the same health benefit plan to the initial date of service the appealed drug was dispensed"
- Asking the OIC to change the definition of "reasonable adjustment" to reflect more of a reasonable / fair and equitable standard
- Asking the OIC to provide clearer wording regarding appeals and adjustments to reimbursement in WAC 284-180-130, 284-180-400 and -420, because the commenter

said that the language did not seem to take into account how pharmacy costs are calculated or how pharmacies receive discounts and rebates

Response: The OIC deleted the definition of “reasonable adjustment.” Regarding the issue of retroactive applicability, the agency read these comments as suggesting that the OIC require PBMs to – if a small pharmacy wins an appeal – make the amount retroactively available to all pharmacies. These commenters appeared to be asking for the retroactive adjustment to apply to all contracted pharmacies; not just the appealing pharmacy, and not just other small pharmacies.

The OIC was unable to identify language in the bill that provided support for the agency to implement such a requirement, so the agency declined to change the rule language.

However, under the legal theory of collateral estoppel, the PBM should provide the appealing pharmacy with a retroactive reimbursement for the successive months of refills for that specific prescription.

Definition of readily available for purchase

Comment: Two commenters asked the OIC to amend the definition of “readily available for purchase” by adding the phrase “by more than one pharmacy, not in common control or ownership in Washington state” at the end of the definition.

Response: In response to these requests, the OIC amended the language to say “Manufactured supply is held in stock and available for order by more than one pharmacy in Washington state when such pharmacies are not under the same corporate umbrella.”

Definition of retaliate

Comment: Two commenters asked the OIC to expand definition of “retaliate” to include a situation when a PBM violates pharmacy fair audit requirements under RCW 19.340 by targeting a particular pharmacy with audits in retaliation for filing appeals.

Response: The OIC declined to add this language to the rule, determining that the existing definition of “retaliate” is broad enough to encompass the activity these commenters described.

Definition of unsatisfied

Comment: One commenter asked the OIC to change or delete the definition of “unsatisfied” in 284-180-130(8).

Response: In response to this suggestion, the OIC amended the definition to say: ““Unsatisfied” means that the network pharmacy did not receive the reimbursement that it requested at the first-tier appeal.”

Comments regarding PBM registration and renewal fees

Comment: Several stakeholders commented on the registration and renewal fees that PBMs will pay to the OIC. One commenter asked the OIC to charge PBMs a proportionate fee, while other commenters asked the OIC to charge an equal share.

Response: The rule will require PBMs to pay a proportionate share based on market share.

According to information in the PBM study conducted under 5ESSB 5857, the top six PBMs serve 98% of consumers who are enrolled in fully insured health plans in Washington. In addition, the study found that nearly 50% of the appeals that small pharmacies submitted since 2014 went to one PBM, which is one of the top six PBMs. These factors, as well as others, played a role in the agency's decision to charge PBMs a proportionate fee.

Comment: One commenter asked the OIC to limit the fee to no more than \$1000 per PBM.

Response: The rule does not set a cap on the fee. Sections 1 and 5 of the bill specifically require the OIC to set the registration and renewal fees at a level that allows the OIC's PBM activities to be self-supporting. According to information from the Department of Revenue, fewer than 40 PBMs are currently registered to conduct business in Washington, so the PBM pool is relatively small.

With fewer than 40 PBMs currently conducting business in Washington, if the OIC imposed a fee cap of \$1000 per PBM, there would be less than \$40,000 available to fund all of the new PBM-related activities that the bill requires of the OIC.

The fiscal note shows the expenses that the OIC anticipated at the time the Legislature was considering the bill. At that time, the agency estimated that it might receive 1,350 appeals in the first six months of FY2018, 700 in the second six months of FY2018, and 700 for subsequent years. For the OIC to handle PBM-related activities, including this amount of appeals, the OIC estimated a cost of \$847,183 for FY 2017-19 and \$746,348 for FY 2019-21.

However, the actual number of appeals is likely to end up being higher than the amount that the OIC estimated in the fiscal note. Specifically, the PBM study says that if current PBM and small pharmacy business practices continue, then the OIC will receive 13,500 to 15,500 appeals annually. If this proves to be accurate, the agency's costs will rise accordingly.

Comment: One commenter asked the OIC to avoid basing PBM registration and renewal fees on PBM income that is not related to PBM business in Washington state. This commenter also asked the OIC to move the due date for PBMs to submit financial information to the OIC from March 1 to May 1.

Response: In requesting fee information, the OIC will request PBM income on PBM business that occurs in Washington state. Receiving this information by March 1 will make it possible to

line up the renewal period with the fiscal year, which begins on July 1, so the agency has declined to change the date when PBMs must submit financial information to the OIC.

Comment: One commenter asked the OIC to add language to the rule that specifies that the fees will be limited to an amount that is reasonable and necessary to fund the registration, renewal and appeals activities.

Response: The OIC declined to make changes to the rule in response to this request. It's worth mentioning that Sections 2 and 5 of the bill give the OIC enforcement authority over PBMs, so in addition to covering the activities that the commenter mentioned (registration, renewal and appeals), the fees must also cover the costs of conducting enforcement activities.

The OIC will do everything possible to keep the costs that are within its control as low as possible, but has declined to make changes to the rule language.

Comments regarding public disclosure of PBM information

Comment: Some stakeholders asked the OIC to not release PBM appeals information in response to public records requests. Specifically, one stakeholder said: "Because appeals of reimbursement relate to confidential pricing and contract terms, all information submitted to the OIC under this should remain confidential and not subject to public disclosure."

Response: The OIC has declined to make changes to the rule language in response to these requests. The agency asked the Attorney General's Office to review whether existing state law provides a public disclosure exemption that the agency could use as a basis for withholding records regarding PBM appeals in response to public disclosure requests.

In response, the Attorney General's Office said that current state public records law does not provide protection for withholding these records in response to public disclosure requests. As a result, if the OIC receives a records request regarding PDR information, the agency will follow its normal public disclosure procedures.

However, if the Legislature changes state law to create an exemption for these records, then the OIC will follow the new requirements.

Comment: One commenter provided suggested language for the OIC to add to the rule. The language said that, if the OIC receives a public records request regarding information that a PBM submits to the OIC, the agency will notify the PBM within 24 hours of the request and will hold off on releasing the information to give the PBM an opportunity to obtain a court order to block the release of information.

Response: The OIC has declined to make changes to the rule language in response to this request. If the OIC receives a public records request regarding PBM information, the agency

will follow its usual public disclosure process in compliance with state law.

Comments suggesting that the OIC is acting beyond its scope of authority

Comment: In regard to Sections 284-180-310 and 320, some comments referred to the process of the OIC asking PBMs to provide additional information and said that the OIC should only ask PBMs to submit information related to OIC-level appeals and registration.

Response: Sections 2 and 5 of the bill expressly grant the OIC enforcement authority over PBMs, and asking PBMs to supply this information is part of the OIC's exercise of enforcement authority.

When a state department of insurance (DOI) has a strong reason to believe that a regulated entity has committed a specific violation, the DOI does not automatically declare the entity to be in violation. Instead, the DOI investigates the matter further to determine whether a violation has actually occurred.

When the DOI performs a step-by-step investigation, conducts research, and collects facts, the regulated entity has an opportunity to provide supporting documentation to prove that it is in compliance.

OIC Sections 2 and 5 of the bill expressly grant the OIC enforcement authority over PBMs and include all aspects of RCW 19.340, not just issues related to OIC-level appeals and registration:

Section 2. *A new section is added to chapter 19.340 RCW to read as follows: (1) The commissioner shall have enforcement authority over this chapter [...]*

Section 5. *A new section is added to chapter 48.02 RCW to read as follows:*

(2) The commissioner shall have enforcement authority over chapter 19.340 RCW consistent with requirements established in section 2 of this act.

As an example of a situation where the OIC might need to ask a PBM for information related to a subject other than appeals, registration or renewal: The bill gives the OIC authority over RCW 19.340, which includes limitations on PBMS auditing pharmacy claims (RCW 19.340.040). It is possible that the OIC may hear that a PBM is not complying with this law.

If that happens, to comply with the enforcement authority granted in Sections 2 and 5 of the bill, the OIC would need to take steps to determine whether a problem actually existed. If the OIC's investigation determines that the PBM is not complying with the law, then the OIC will need to take additional steps to ensure that the PBM begins complying with the law, and continues to comply in the future.

In including this language in the rule, the OIC is not intending to expand its authority beyond the authority that the Legislature granted in the bill. Instead, the agency is seeking to ensure that it will be able to carry out the duties that the bill requires the agency to perform.

Comment: Some commenters asked the OIC to delete the language in WAC 284-180-320 that says that the records the OIC may request “are not limited to [...]”, saying that this language is an impermissible expansion of the OIC’s statutory authority. One commenter asked the OIC to add language that says the agency will only ask for records that are necessary for PBM registrations, renewals or appeals.

Response: As mentioned in the above response, Sections 2 and 5 of the bill expressly grant the OIC enforcement authority over PBMs and include all aspects of RCW 19.340, not just issues related to OIC-level appeals and registration.

In including this language in the rule, the OIC is not intending to expand its authority beyond the authority that the Legislature granted in the bill. Instead, the agency is seeking to ensure that it will be able to carry out the duties that the bill requires the agency to perform.

Comment: Some commenters asked the OIC to provide clearer wording regarding the agency’s access to PBM records in sections such as WAC 284-180-310 and -420. The commenters said that the records that the OIC received from PBMs under these sections might include proprietary and competitive business information, so it would be helpful for the OIC to provide more clarity up front regarding the types of records it might request.

Response: The OIC did not change the rule language in response to these comments.

As discussed above, Sections 2 and 5 of the bill give the OIC enforcement authority over PBMs (specifically, over RCW 19.340). In including this language in the rule, the OIC is not intending to expand its authority beyond the authority that the Legislature granted in the bill. Instead, the agency is seeking to ensure that it will be able to carry out the duties that the bill requires the agency to perform.

Comments asking the OIC to take actions beyond its scope of authority

To summarize generally, numerous commenters asked the OIC to conduct activities that are beyond the scope of what the bill gives the OIC the authority to do.

Under the Washington Administrative Procedures Act (APA), when a Washington state agency writes a rule to implement a bill, the rule cannot change, delete or contradict the language of the bill. In addition, the subject matter of the issues in the rule cannot be outside the scope of the subject matter of the bill. For these reasons, the OIC did not make the changes that these commenters had requested.

Comment: Two commenters asked the OIC to remove the sentence in the rule that says that if the PBM doesn't respond regarding first-tier (PBM-level appeal) within required timeframe, the appeal is deemed denied.

Response: This requirement comes directly from the bill (Section 4(3)), so the OIC does not have the authority to change it in the rule. Because this requirement comes directly from the bill, it would apply regardless of whether the OIC included it in the rule.

However, the agency understands the frustration that these commenters are expressing regarding the lack of an explicit cutoff date.

In using this language, it's possible that the bill drafters were using the format that provider contracts normally use. Instead of using a specific cutoff date, provider contracts normally say that an appeal is deemed denied if there's no response within a certain period of time. However, regardless of whether this was the bill drafter's intent in using this language, the OIC does not have the authority to negate this requirement through the rule.

Comment: Two commenters asked the OIC to add additional requirements regarding the timeframes PBMs must follow after pharmacies submit appeals to them. The commenters' suggested additions were aimed at addressing situations where PBMs either did not respond at all, or did not respond in a timely manner.

Response: Section 4(3) of the bill requires PBMs – not the OIC – to establish their own processes for handling appeals. Because the bill requires PBMs to establish their own processes, the OIC felt that it would be acting beyond the scope of its authority if it created this process instead of allowing PBMs to develop their own processes.

However, the fact that the OIC has not developed this process does not mean that the OIC will not take any action if a PBM fails to comply with the timeframes from Section 4 of the bill. Sections 2 and 5 of the bill explicitly give the OIC enforcement authority over RCW 19.340, and the agency will exercise this enforcement authority as necessary and appropriate if it becomes aware of a problem.

Comment: Some commenters asked the OIC to change the language in RCW 19.340.100(4)(b), which requires PBMs to provide at the time of denial "the reason for the denial and 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."

Response: This language comes directly from the bill, so the OIC does not have the authority to change it. Because this language comes from the bill, the requirement would still apply even if the OIC didn't include it in the rule.

Comment: One commenter asked the OIC to remove the requirement that only pharmacies with fewer than 15 branches can file appeals with the OIC.

Response: This language comes directly from the bill, so the OIC does not have the authority to change it. Because this language comes from the bill, the requirement would still apply even if the OIC didn't include this language in the rule.

Comment: One commenter asked the OIC to discourage PBMs from conducting non-medical switching, which the commenter defined as dropping coverage of certain medications or pricing patients out of their drugs, and asked the OIC to require PBMs to provide updated formularies to enrollees.

Response: In writing this rule to implement 5ESSB 5857, the OIC's authority is limited to implementing the requirements of the bill. Those requirements include registering and regulating PBMs, first-tier (PBM-level) appeals, and higher-level (OIC-level) appeals.

Non-medical switching and providing formularies to enrollees are not within the subject matter of the bill, so the OIC would be acting outside of the scope of its statutory authority if it addressed these topics in the rule.

Comment: One commenter asked the OIC to amend the language in WAC 284-180-400 regarding when pharmacies can appeal to PBMs (first-tier appeals). The language currently says that a pharmacy can appeal "if the reimbursement for the drug is less than the net amount that the network pharmacy paid to the supplier of the drug," and the commenter asked the OIC to change that language.

Response: This language comes directly from Section 4(3) of the bill, so if the OIC changed the language, it would be acting outside of the scope of its authority.

Comment: Two commenters asked the OIC to require PBMs to submit additional information for registration or renewal, such as financial records, the amount of patients and contracted pharmacies the PBM has in Washington, and any current or pending legal or enforcement actions against the PBM in any state.

Response: The OIC did not add language to the rule requiring this additional information. Although this type of in-depth information is within the scope of what state agencies would normally request as part of the licensing process, it is beyond the scope of what state agencies would normally request prior to registration or renewal process.

Specifically, licensing normally involves an in-depth review, while registration and renewal are relatively perfunctory, consisting mostly of ensuring that the entity properly completes the form and submits the necessary payment.

When the Legislature spelled out the OIC's authority over PBMs, it specifically said that the OIC will register PBMs and annually renew the registration. The bill did not say that the OIC will license them.

For this reason, the agency did not add the requirement that these stakeholders had suggested, because adding such a requirement would be beyond the scope of the agency's authority under the bill.

However, it's possible that an issue may arise at some point in the future after a PBM registers or renews with the OIC. Sections 2 and 5 of the bill explicitly give the OIC enforcement authority over RCW 19.340, and the agency will exercise this enforcement authority as necessary and appropriate if it becomes aware of a specific problem.

Comment: A commenter asked the OIC to assess penalties against pharmacies for filing frivolous appeals or for filing appeals in bad faith. As an alternative to this request, the commenter also asked the OIC to put a cap on the number of appeals that a pharmacy can file each month. As an example of frivolous or bad faith appeals, the commenter mentioned that pharmacies submitted a high volume of complaints regarding Medicare Part D plans to the Oregon Department of Insurance regarding Part D claims, even though the Oregon PBM law does not cover these plans.

Response: Sections 1 and 5 of the bill expressly requires the OIC to set the PBM registration and renewal fee at a level so that that OIC's PBM-related activities are self-supporting.

As a result, the bill requires PBMs – not pharmacies – to bear the cost of the appeals. Assessing penalties against pharmacies for filing appeals for any reason would contradict this requirement.

In addition, the OIC declined to set a cap on the number of appeals that a pharmacy can file each month. However, WAC 284-180-420(1)(b)(iii) requires small pharmacies to submit the documents from the first-tier appeal when they forward the appeal to the OIC.

This information that small pharmacies will submit to the OIC to request an appeal will include the form that the pharmacy filled out to request the PBM-level appeal (the PBM appeal form). The OIC has seen several PBM appeal forms, and most of them appear to require pharmacies to fill out a separate form for each appeal. Although this does not set an actual cap on the number of appeals that a pharmacy can file each month, it will in effect set some limitation, because a pharmacy will need to submit a copy of the PBM appeal form for each appeal that it forwards to the OIC.

Comments – Miscellaneous

Comment: One commenter said that she will be tracking this regulation on behalf of her employer, a health insurance company, because this rule could affect the relationship between PBMs and insurance companies. This commenter also said that she hopes the OIC will hold a stakeholder discussion regarding the rule.

Response: The OIC appreciates this input.

Comment: One commenter asked the OIC to remove the language from the stakeholder draft that would require PBMs to post specific info on their websites regarding their response times for responding to appeal-related phone calls. The commenter asked the OIC to only require PBMs to post information on their websites regarding days and times that PBMs accept calls.

Response: In response to this request, the OIC has removed this requirement from the rule.

Comment: Two commenters asked the OIC to add language to the rule to emphasize that the requirements of WAC 204-180 apply even if a pharmacy services administrative organization is acting on behalf of a pharmacy.

Response: In response to this request, the OIC added language to WAC 284-180-400(7) and 284-180-420(5) that allows small pharmacies to have other entities, such as an attorney or a pharmacy services administrative organization, act on their behalf.

Comment: One commenter asked the OIC to expand the rule to apply to PBMs in their role as administrators of self-funded health plans. To support this request, the commenter said a federal court has allowed the Iowa PBM law to apply to PBMs in their role as administrators of self-funded health plans.

Response: To determine the scope of the OIC's authority regarding PBMs, the agency obtained a legal opinion from the Attorney General's Office. After conducting in-depth legal analysis of applicable Washington laws and cases, the Attorney General's Office concluded that the OIC's scope of authority over PBMs does not extend to PBMs in their role as administrators of self-funded health plans.

Again, this analysis was based specifically on laws that apply in the jurisdiction where the Washington Office of the Insurance Commissioner is located. It's possible that an analysis of the laws in another state might reach a different conclusion, which would explain why the legal decision regarding the Iowa PBM law was different than the outcome in Washington: the decisions were based on applicable laws in those jurisdictions, and those jurisdictions have different laws. Because Washington law does not give the OIC authority over self-funded health plans, the agency declined to make this change.

Comment: Two commenters said that, at the time PBMs register, the OIC should require them to provide the name of a specific staffer who will be responsible for registration and compliance.

Response: Although the OIC appreciates these comments, the agency has declined to add this requirement to the rule. However, the agency might add this requirement to the PBM registration and renewal forms.

Comment: Two commenters asked the OIC to add the following underlined language to 284-180-340: "a violation is knowing and willful for the purposes of chapter 19.340 RCW when the person, corporation, third-party administrator of prescription drug benefits, pharmacy benefit manager, or business entity who committed..."

Response: In response to these comments, the OIC amended the language in this section. Specifically, the agency added the phrase "actor as defined in 284-180-330."

Comment: One commenter asked the OIC to review each PBM's description of the steps pharmacies need to take to file PBM-level appeals and to invite pharmacy representatives to participate in this review process.

Response: The OIC already reviews this information as part of its normal business process when it reviews provider contracts, so the agency declined to make changes to the rule in response to this request.

Comment: In regard to WAC 284-180-400(5), two commenters asked the OIC to require PBMS to mention the specific Washington-licensed wholesaler from whom small pharmacies can purchase the drug at a price that is at or below the maximum allowable cost.

Response: The OIC did not add this requirement to the rule. The agency did not find language in the bill that would support adding such a requirement.

Comment: One commenter expressed appreciation for the fact that the rule requires pharmacies to go through a PBM-level ("first-tier") appeal before filing an appeal with the OIC.

Response: Because this requirement comes from the bill, the Legislature deserves credit for this, not the OIC.

Comment: One commenter asked the OIC to require pharmacies to submit identifying information regarding each claim when they submit second-tier appeals to the OIC.

Response: Although the rule does not expressly require this, small pharmacies will need to submit this information to the OIC.

To file an OIC appeal, the rule requires pharmacies to submit copies of materials from the first-tier appeal. To file a first-tier appeal, most PBMs require pharmacies to fill out appeal request forms.

Because most PBM appeal request forms already require this identifying information, small pharmacies will be submitting identifying information for each claim each time they send a copy of an appeal to the OIC to request an OIC-level appeal.

Comment: One commenter asked the OIC to require pharmacies to file a separate appeal regarding each drug.

Response: To file an OIC appeal, the rule requires pharmacies to submit copies of materials from the first-tier appeal. To file a first-tier appeal, PBMs require pharmacies to fill out appeal request forms.

Most PBM appeal request forms already require a separate appeal for each NDC code, so by forwarding a copy of this information to the OIC to request an appeal, small pharmacies will already be submitting a separate appeal for each NDC code.

For this reason, the rule team has declined to make this change.

Comment: One commenter expressed appreciation for the fact that the rule requires pharmacies to submit appeals within a certain timeframe.

Response: Because this requirement comes from the bill, the Legislature – not the OIC – deserves credit for this.

Comment: Two commenters provided background information about the bill in regard to both state-level efforts and national efforts.

Response: The OIC appreciates this input.

Comment: Two commenters asked the OIC to add language to the rule to make it clear that pharmacy services administrative organizations have the right to bring appeals on behalf of pharmacies.

Response: In response to this request, the OIC has added language to WAC 284-180-400(7) and 284-180-420(5) that says that other entities can act on behalf of small pharmacies.

Comment: One commenter sought clarification on whether the rule's exemption for Medicare includes both Medicare Supplement plans and Medicare Advantage plans.

Response: The Medicare exemption applies to all types of Medicare plans, including Medicare Supplement and Medicare Advantage plans.

Comment: One commenter mentioned that WAC 284-180-420(1) addresses filing second-tier appeals with the OIC, but does not address concurrent service on the PBM and does not address when the appeal timeline starts and ends. In contrast, this commenter observed, WAC 284-180-440(2) does address these issues. This commenter asked the OIC to add clarifying language to WAC 284-180-420(1) similar to the language in 284-180-440(2).

Response: WAC 284-180-440(2)(a) through (e) actually apply to both levels of appeal within the OIC: the appeal before the presiding officer (the “second-tier” appeal) and the appeal before the reviewing officer.

Comment: One commenter pointed out that WAC 284-180-420(5) uses the abbreviation “OIC.” The abbreviation is inconsistent with the rest of the proposed chapter, which uses the term “commissioner.”

Response: The OIC appreciates this observation and has changed the applicable language in the rule.

Comment: In response to the CR-102 draft, one commenter asked the OIC to clarify that the rule does not apply to workers’ compensation health plans.

Response: The OIC is aware that in many states, workers’ compensation is included in the insurance code and is within the jurisdiction of the state department of insurance. However, this is not the case in Washington, where workers’ compensation is under the jurisdiction of the Washington State Department of Labor and Industries.

Because the OIC has no jurisdiction over workers compensation, it is not really necessary to specify this in the rule. For the sake of clarity, though, the OIC might have made this change if it had received this request prior to the CR-102 draft.

The Washington Administrative Procedures Act (APA) limits the types of changes that state agencies can make to the draft rule language between the CR-102 and the CR-103. If the OIC had received this request earlier – specifically, prior when it filed the CR-102 –the agency might have implemented this change.

Comment: One stakeholder pointed to the OIC’s use of the term “provider contract” in 284-180-400(1) and said that this term is not used in the PBM industry because PBMs do not always consider pharmacies to be providers. This commenter asked the OIC to use the term “network agreement” instead.

Response: Under Washington state law, pharmacists are providers. Specifically, RCW Title 18 classifies pharmacists as “providers” and places them under the jurisdiction of the Washington State Department of Health.

When health insurers enter contracts with pharmacists, they must forward those contracts to the OIC, just like they would for any other type of provider. In the health insurance world, these contracts between health insurers and providers – including pharmacists – are called “provider contracts.” Because this is the standard terminology in the health insurance world and is the terminology that the OIC already uses, the agency did not change the rule language in response to this request.

Comment: One stakeholder mentioned 284-180-400(7) and 284-180-420(5), which spell out who can file an appeal or appear at an appeal proceeding on behalf of a pharmacy. The language in these sections allows pharmacies to, for example, hire an attorney or a pharmacy services administrative organization to pursue the appeal on their behalf. This stakeholder said that the only entity that should be able to bring the appeal is the entity that is a party to the contract with the PBM.

Response: The OIC declined to make changes to the rule in response to this request, and emphasizes that pharmacies have the right to arrange for outside representation.

Comment: One commenter discussed the language in WAC 284-180-420(1)(b)(iv) that says that the OIC may request additional information from pharmacists when reviewing an appeal. The commenter asked the OIC to revise the language to say “Any additional information the commissioner may require that is necessary for the review of the appeal.”

Response: This commenter’s proposed language captures the OIC’s intent in regard to this section of the rule. Specifically, the agency does not intend to ask pharmacies for information that is not necessary to complete the review of the appeal. However, the agency did not make changes to the draft in response to this request, because the agency received this request in response to the CR-102 draft.

The Washington Administrative Procedures Act (APA) limits the types of changes that state agencies can make to the draft rule language between the CR-102 and the CR-103. If the OIC had received this request earlier – specifically, prior when it filed the CR-102 – it is likely that the agency would have implemented this change.

Implementation plan

Implementation and enforcement of the rule

The OIC intends to implement and enforce the rule through the Rates and Forms Division and Market Conduct Oversight Unit, which is part of the Company Supervision Division. Using existing resources, OIC staff will continue to work with carriers, providers, and interested parties in complying with the requirements of the rule.

How the agency will inform and educate affected persons about the rule

After the agency files the permanent rule and adopts it with the Office of the Code Reviser:

- Policy staff will distribute copies of the final rule and the Concise Explanatory Statement (CES) to all interested parties through US mail, post to the OIC's standard rule making listserv and email to stakeholder participants.
- The Rules Coordinator will post the CR-103 documents on the OIC's website
- OIC staff will address questions as follows:

Type of Inquiry	Division
Consumer assistance	Consumer Protection Division
Rule content	Rates and Forms
Authority for rules	Policy and Legislative Affairs
Enforcement of rule	Legal Division
Market Compliance	Company Supervision

How the agency intends to promote and assist voluntary compliance for this rule

The steps listed under implementation will inform and educate affected persons on the changes and help promote voluntary compliance. The OIC's Rates and Forms Division has also added these requirements to its analyst checklists, which health carriers use to ensure that their plans comply with all applicable state and federal laws.

How the agency intends to evaluate whether the rule achieves the purpose for which it was adopted

The OIC will work closely with carriers, providers, and other interested parties to evaluate the effectiveness of the rule as well as to monitor consumer complaints and to monitor plans for non-compliance. The OIC will review health plan filings to ensure that this coverage is provided.

Appendix A – Hearing Summary

Summarizing Memorandum

To: Mike Kreidler, Insurance Commissioner
From: Bianca Stoner, presiding official for rule hearing
Matter: Rule 2016-21
Topic: Exchange special enrollment rule: Expanded Health Benefit Exchange request

This memorandum summarizes the hearing on the above-named rulemaking, which was held on December 6, 2016 at 1:00 p.m. in Olympia. I presided over this hearing in your place.

In attendance but did not testify:

- Diana Carlen – Optum
- Maral Farsi – CVS Health
- Atal Singh Khalsh
- Dedi Little – Washington State Pharmacy Association
- Matt Miller – CVS Health
- Mich'l Needham – Washington State Senate Committee Services
- Sherri Nelson
- Mel Sorenson – Express Scripts and America's Health Insurance Plans
- Carrie Tellefson – CVS Health
- Michael Temple – PCMA
- Andrea Tull – Coordinated Care

The hearing began at 1:05 p.m.

In attendance and testified:

- April Alexander – PCMA
 - Because Ms. Alexander's testimony did not differ from the written comments that the OIC received in the comment letter from PCMA, the applicable

Commissioner's response for the written comments on the subject applies to the comments that she mentioned during the hearing.

- Jenny Arnold - Washington State Pharmacy Association
 - Ms. Arnold expressed gratitude towards the OIC for various aspects of the rule, including but not limited to making the registration and renewal fees proportionate based on each PBM's market share instead of a flat fee.
 - She said that pharmacies might want to revisit this issue in the future to possibly expand the ability to submit appeals to the OIC to pharmacies with 15 or more branches in Washington.
 - In addition, she emphasized an issue regarding retroactive applicability that the National Community Pharmacy Association mentioned in a comment letter to the OIC dated August 30, 2016. Specifically, if a small pharmacy wins an appeal, the PBM would need to notify other in-network pharmacies regarding the adjustment for that medication and would need to permit those pharmacies to resubmit claims to reflect the adjusted maximum allowable cost regarding that medication.
 - She said that it could be necessary to revise the rule in the future.
- Joe Cammach – Jim's Pharmacy
 - Mr. Cammach emphasized the importance of Ms. Arnold's point regarding the retroactive applicability.

The hearing was adjourned.

SIGNED this 6th day of December, 2016

Bianca Stoner, Presiding Official