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RULE-MAKING ORDER PERMANENT RULE ONLY

CR-103P (December 2017) (Implements RCW 34.05.360)

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WSR 22-23-069

Agency: Office of the Insurance Commissioner

Effective date of rule:

Permanent Rules

☑ 31 days after filing.

Other (specify) (If less than 31 days after filing, a specific finding under RCW 34.05.380(3) is required and should be stated below)

Purpose: To adopt conforming regulations reflecting changes in filing tier II appeals by small pharmacies against pharmacy benefit manager reimbursement settlements.

Insurance Commissioner Matter R 2022-07

Citation of rules affected by this order:

New: Repealed:

Amended: WAC 284-18-515, 284-180-520, 284-180-530 and 284-180-540

Suspended:

Statutory authority for adoption: RCW 48.02.060; RCW 48.200.280 (6); RCW 34.05.485(1)(c); RCW 48.02.100 Other authority:

PERMANENT RULE (Including Expedited Rule Making)

Adopted under notice filed as <u>WSR 22-18--082</u> on <u>September 06, 2022</u> (date). Describe any changes other than editing from proposed to adopted version: There are no differences between the proposed version and the adopted version.

If a preliminary cost-benefit analysis was prepared under RCW 34.05.328, a final cost-benefit analysis is available by contacting:

Name: Simon Casson Address: PO Box 40260, Olympia WA 98504 Phone: 360-725-7038 Fax: 360-586-3109 TTY: Email: Simon.Casson@OIC.wa.gov4 Web site: Other:

Note: If any category is left blank, it will be calculated as zero. No descriptive text.	
Count by whole WAC sections only, from the WAC number through the history note. A section may be counted in more than one category.	
The number of sections adopted in order to comply with	::
Federal statute: Ne	w Amended Repealed
Federal rules or standards: Ne	w Amended Repealed
Recently enacted state statutes: Ne	w Amended Repealed
The number of sections adopted at the request of a nongovernmental entity:	
Ne	w Amended Repealed
The number of sections adopted on the agency's own initiative:	
Ne	w Amended <u>4</u> Repealed
The number of sections adopted in order to clarify, streamline, or reform agency procedures:	
Ne	w Amended <u>4</u> Repealed
The number of sections adopted using:	
Negotiated rule making: Ne	w Amended Repealed
Pilot rule making: Ne	w Amended Repealed
Other alternative rule making: Ne	w Amended Repealed
Date Adopted: November 10, 2022	Signature:
Name: Mike Kreidler	Mile Kridle
Title: Insurance Commissioner	

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

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

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

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

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

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

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

(b) The network pharmacy must request review of the pharmacy benefit manager's decision by ((filing a written petition for review form. A form for this purpose is available)) submitting a petition at www.insurance.wa.gov according to the filing instructions.

The petition for review must include:

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

(ii) The network pharmacy's ($(\frac{\text{federal identification number, uni-fied business identifier number,})$ business address((,)) and mailing address; and

(iii) <u>Documents supporting the appeal;</u>

(c) Documents supporting the appeal include:

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

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

(((vi))) Any additional information that the commissioner may require((-

(c) The network pharmacy must deliver the petition for review to the commissioner's Tumwater office by mail, hand delivery, or by other methods that the commissioner may make available));

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(a) Persons who are natural persons representing themselves;

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

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

(d) Public officials in their official capacity;

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

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

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

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

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

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

(8) **Presiding officer**.

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

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

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

(d) The presiding officer has all authority granted under chapter 34.05 RCW.

(9) Entry of orders.

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

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

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

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

WAC 284-180-530 Review of initial orders from brief adjudicative proceedings. The following procedure applies to the commissioner's review of a brief adjudicative proceeding conducted pursuant to WAC 284-180-520, unless the matter is converted to a formal proceeding as provided in WAC 284-180-540(4).

(1) **Request for review of initial order.** A party to a brief adjudicative proceeding under WAC 284-180-520 may request review of the initial order by filing a written petition for review with the commissioner within ((twenty-one)) <u>21</u> days after service of the initial order is received or deemed to be received by the party. A form for this purpose is available at www.insurance.wa.gov. The request for review must be ((in writing and delivered to the commissioner's Tumwater office by mail, hand delivery, or by other methods that the commissioner may make available) submitted electronically.

(a) When making a petition for review of the initial order, the petitioner must submit to the reviewing officer any evidence or written material relevant to the matter that the party wishes the reviewing officer to consider.

(b) The commissioner may, on its own motion, conduct an administrative review of the initial order as provided for in RCW 34.05.491. (2) **Reviewing officer.** The commissioner shall appoint a reviewing officer who satisfies the requirements of RCW 34.05.491(2). The reviewing officer shall:

(a) Make such determination as may appear to be just and lawful;

(b) Provide both the network pharmacy and the pharmacy benefit manager an opportunity to explain their positions on the matter; and

(c) Make any inquiries necessary to determine whether the proceeding should be converted to a formal adjudicative proceeding. The review is governed by the brief adjudicative procedures of chapter 34.05 RCW and this rule, or WAC 284-02-070 in the event a brief adjudicative hearing is converted to a formal adjudicative proceeding. The reviewing officer shall have the authority of a presiding officer as provided in WAC 284-180-520.

(3) Record review.

(a) Review of an initial order is limited to:

(i) The evidence that the presiding officer considered;

(ii) The initial order;

(iii) The recording of the initial proceeding; and

(iv) Any records and written evidence that the parties submitted to the reviewing officer.

(b) However, the record that the presiding officer made does not need to constitute the exclusive basis for the reviewing officer's decision.

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

(d) If the reviewing officer determines that oral testimony is needed, the officer may schedule a time for both parties to present oral testimony. Oral statements before the reviewing officer shall be by telephone, unless specifically scheduled by the reviewing officer to be in person.

(e) Each party will have an opportunity to respond to the other party's request for review and may also submit any other relevant evidence and written material to the reviewing officer.

(i) The other party must:

(A) Submit material within seven days of service of the material submitted by the party requesting review of the initial order; and

(B) Serve a copy of all evidence and written material provided to the reviewing officer to the party requesting review according to WAC 284-180-540(2).

(ii) Proof of service is required under WAC 284-180-540 (2)(g) when a party submits material to the other party under this subsection.

(4) Failure to participate. If a party requesting review of an initial order under subsection (1) of this section fails to participate in the proceeding or fails to provide documentation to the reviewing officer upon request, the reviewing officer may uphold the initial order based upon the record.

(5) Final orders.

(a) The reviewing officer's final order must include the decision of the reviewing officer and a brief statement of the basis and legal authority for the decision.

(b) Unless there are continuances, the reviewing officer will issue the final order within ((twenty)) 20 days of the petition for review.

(6) **Reconsideration.** Unless otherwise provided in the reviewing officer's order, the reviewing officer's order represents the final position of the commissioner. A petitioner may only seek a reconsideration of the reviewing officer's order if the final order contains a right to a reconsideration.

(7) **Judicial review**. Judicial review of the final order of the commissioner is available under Part V, chapter 34.05 RCW. However, as required by RCW 34.05.534, judicial review may be available only if the petitioner has requested a review of the initial order under this subsection and has exhausted all other administrative remedies.

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

WAC 284-180-540 General procedures governing brief adjudicative proceedings before the commissioner. (1) Rules of evidence - Record of the proceeding.

(a) Evidence is admissible if in the judgment of the presiding or reviewing officer it is the kind of evidence on which reasonably prudent persons are accustomed to relying on in conducting their affairs. The presiding and reviewing officer should apply RCW 34.05.452 when ruling on evidentiary issues in the proceeding.

(b) All oral testimony must be recorded manually, electronically, or by another type of recording device. The agency record must consist of the documents regarding the matters that were considered or prepared by the presiding officer, or by the reviewing officer in any review, and the recording of the hearing. These records must be maintained by the commissioner as its official record.

(2) **Service**. All notices and other pleadings or papers filed with the presiding or reviewing officer must be served on the network pharmacy and the pharmacy benefit manager.

(((a) Service is made by one of the following methods:

(i) In person;

(ii) By first-class, registered, or certified mail;

(iii) By fax and same-day mailing of copies;

(iv) By commercial parcel delivery company; or

(v)) By electronic delivery as allowed by the presiding officer.

(((b) Service by mail is regarded as completed upon deposit in the United States mail properly stamped and addressed.

(c) Service by electronic fax is regarded as completed upon the production by the fax machine of confirmation of transmission.

(d) Service by commercial parcel delivery is regarded as completed upon delivery to the parcel delivery company, properly addressed with charges prepaid.

(e)) Service by electronic delivery is regarded as completed on the date that any party electronically sends the information to other parties or electronically notifies other parties that the information is available for them to access.

(((f) For matters before the reviewing officer, service to the reviewing officer must be sent to:

Office of the Insurance Commissioner P.O. Box 40255 Olympia, Washington 98504-0255

(g) Where proof of service is required, the proof of service must include:

(i) An acknowledgment of service;

(ii) A certification, signed by the person who served the document, stating the date of service; that the person served the document upon all or one or more of the parties of record in the proceeding by delivering a copy in person to the recipient; and that the service was accomplished by a method of service as provided in this subsection.))

(3) Conversion of a brief adjudicative proceeding to a formal proceeding. The presiding or reviewing officer may at any time, on motion of either party or on the officer's own motion, convert the brief adjudicative proceeding to a formal proceeding. The presiding or reviewing officer may convert the proceeding if the officer finds that:

(a) Use of the brief adjudicative proceeding violates any provision of law;

(b) The protection of the public interest requires the agency to give notice to and an opportunity to participate to persons other than the parties; or

(c) The issues and interests involved warrant the use of procedures governed by RCW 34.05.413 through 34.05.476 or 34.05.479.