



PROPOSED RULE MAKING

CR-102 (October 2017)
(Implements RCW 34.05.320)
Do **NOT** use for expedited rule making

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STATE OF WASHINGTON
FILED

DATE: December 06, 2017

TIME: 10:51 AM

WSR 17-24-127

Agency: Office of the Insurance Commissioner

Original Notice

Supplemental Notice to WSR _____

Continuance of WSR _____

Preproposal Statement of Inquiry was filed as WSR 17-17-180 ; or

Expedited Rule Making--Proposed notice was filed as WSR _____ ; or

Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1); or

Proposal is exempt under RCW _____.

Title of rule and other identifying information: (describe subject) Update to pharmacy benefit manager rules

Insurance Commissioner Matter No. R 2017-12

Hearing location(s):

Date:	Time:	Location: (be specific)	Comment:
January 11, 2018	11: 00 AM	Office of the Insurance Commissioner, Training Room, TR 120, 5000 Capitol Blvd. SE, Tumwater, WA 98504	

Date of intended adoption: January 12, 2018 (Note: This is **NOT** the effective date)

Submit written comments to:

Name: Candice Myrum

Address: PO Box 40258 Olympia WA 98504

Email: rulescoordinator@oic.wa.gov

Fax: 360-586-3109

Other:

By (date) January 11,2018

Assistance for persons with disabilities:

Contact Lorie Villafores

Phone: 360-725-7000

Fax: 360-582-3109

TTY: 360-586-0241 or 360-725-7087

Email:

Other:

By (date) January 10, 2018

Purpose of the proposal and its anticipated effects, including any changes in existing rules: The rule revises existing language and adds new language, as applicable, in WAC 284-180 to:

- Require PBMs to provide the name of a person who will serve as the PBM's single point of contact with the OIC for appeals;
- Require small pharmacies and PBMs to follow the OIC's filing instructions when uploading documents;
- Require PBMs to respond to the OIC using the OIC's electronic appeal system; and
- Require PBMs, in their responses to appeals under WAC 284-180-400, to provide enough details so that the OIC can identify the exact PBM entity that issued the response.

Reasons supporting proposal: To clarify responsibilities and procedures for requesting appeals and make it easy to identify responsible parties

Statutory authority for adoption: 48.02.060, 48.02.220

Statute being implemented: Chapter 19.340 RCW

Is rule necessary because of a:

Federal Law? Yes No
Federal Court Decision? Yes No
State Court Decision? Yes No

If yes, CITATION:

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters:

Name of proponent: (person or organization) Office of the Insurance Commissioner Private
 Public
 Governmental

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting:	Candice Myrum	PO Box 40258, Olympia, WA 98504	(360) 725-7042
Implementation:	Molly Nollette	PO Box 40255, Olympia, WA 98504	(360) 725-7117
Enforcement:	Toni Hood	PO Box 40255, Olympia, WA 98504	(360) 725-7264

Is a school district fiscal impact statement required under RCW 28A.305.135? Yes No

If yes, insert statement here:

The public may obtain a copy of the school district fiscal impact statement by contacting:

Name:
Address:
Phone:
Fax:
TTY:
Email:
Other:

Is a cost-benefit analysis required under RCW 34.05.328?

Yes: A preliminary cost-benefit analysis may be obtained by contacting:

Name:
Address:
Phone:
Fax:
TTY:
Email:
Other:

No: Please explain: These proposed rules only specify and clarify procedures for requesting, providing information for and responding to appeal requests made to the Office of the Insurance Commissioner. As such, this rule is not a significant legislative rule but rather a procedural rule under the provisions of RCW 35.05.328 (5)(c)(i).

Regulatory Fairness Act Cost Considerations for a Small Business Economic Impact Statement:

This rule proposal, or portions of the proposal, **may be exempt** from requirements of the Regulatory Fairness Act (see chapter 19.85 RCW). Please check the box for any applicable exemption(s):

This rule proposal, or portions of the proposal, is exempt under RCW 19.85.061 because this rule making is being adopted solely to conform and/or comply with federal statute or regulations. Please cite the specific federal statute or regulation this rule is being adopted to conform or comply with, and describe the consequences to the state if the rule is not adopted.

Citation and description:

This rule proposal, or portions of the proposal, is exempt because the agency has completed the pilot rule process defined by RCW 34.05.313 before filing the notice of this proposed rule.

This rule proposal, or portions of the proposal, is exempt under the provisions of RCW 15.65.570(2) because it was adopted by a referendum.

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

- | | |
|---|---|
| <input type="checkbox"/> RCW 34.05.310 (4)(b)
(Internal government operations) | <input type="checkbox"/> RCW 34.05.310 (4)(e)
(Dictated by statute) |
| <input type="checkbox"/> RCW 34.05.310 (4)(c)
(Incorporation by reference) | <input type="checkbox"/> RCW 34.05.310 (4)(f)
(Set or adjust fees) |
| <input type="checkbox"/> RCW 34.05.310 (4)(d)
(Correct or clarify language) | <input checked="" type="checkbox"/> RCW 34.05.310 (4)(g)
((i) Relating to agency hearings; or (ii) process requirements for applying to an agency for a license or permit) |

This rule proposal, or portions of the proposal, is exempt under RCW _____.

Explanation of exemptions, if necessary: All of the required actions under this proposed rule pertain to the processing of appeals for agency hearings.

COMPLETE THIS SECTION ONLY IF NO EXEMPTION APPLIES

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

- No Briefly summarize the agency's analysis showing how costs were calculated.
- Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses, and a small business economic impact statement is required. Insert statement here:

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

Name:
Address:
Phone:
Fax:
TTY:
Email:
Other:

Date: December 6, 2017

Name: Mike Kreidler

Title: Insurance Commissioner

Signature:



AMENDATORY SECTION (Amending WSR 17-01-139, filed 12/20/16, effective 1/1/17)

WAC 284-180-240 Providing and updating registration information.

(1) At the time of registration, a pharmacy benefit manager must provide its legal name as well as any and all additional names that it uses to conduct business.

(2) Registered pharmacy benefit managers must provide the commissioner with a valid email address, which the commissioner will use as the official contact address for ~~((all))~~ communications regarding registrations, renewals and oversight activities.

(3) In addition to providing a valid email address, registered pharmacy benefit managers must identify a pharmacy benefit manager employee who is the single point of contact for appeals under WAC 284-180-420 and 284-180-430, and must fill out the form that the commissioner makes available for this purpose at www.insurance.wa.gov.

(4) Registered pharmacy benefit managers must ensure that the information that they disclosed when they registered with the commissioner remains current by notifying the commissioner of any changes or additions.

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

(i) Any and all additional names that pharmacy benefit managers use to conduct business; ~~((and))~~

(ii) The email address for official communications between the commissioner and the pharmacy benefit manager; and

(iii) The name, contact information, and any other information that the pharmacy benefit manager submitted on the commissioner's form under subsection (3) of this section regarding the pharmacy benefit manager employee who is the pharmacy benefit manager's single point of contact for appeals under WAC 284-180-420 and 284-180-430.

(b) Within thirty days of any change, pharmacy benefit managers must report changes to the commissioner using the commissioner's electronic system.

AMENDATORY SECTION (Amending WSR 17-01-139, filed 12/20/16, effective 1/1/17)

WAC 284-180-400 Appeals by network pharmacies to pharmacy benefit managers. A network pharmacy may appeal a reimbursement to a pharmacy benefit manager (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. "Network pharmacy" has the meaning set forth in RCW 19.340.100 (1)(d). "Pharmacy benefit manager" has the meaning set forth in RCW 19.340.010 (6)(a). A pharmacy benefit manager must process the network pharmacy's appeal as follows:

(1) A pharmacy benefit manager must include language in the pharmacy provider contract and on the pharmacy benefit manager's web site fully describing the right to appeal under RCW 19.340.100. The description must include, but is not limited to:

(a) Contact information, including:

(i) A telephone number by which the pharmacy may contact the pharmacy benefit manager during normal business hours and speak with an individual responsible for processing appeals;

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

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

(iv) An email address that a network pharmacy can use to submit information regarding an appeal.

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

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

(2) The pharmacy benefit manager must reconsider the reimbursement. A pharmacy benefit manager's review process must provide the network pharmacy or its representatives with the opportunity to submit information to the pharmacy benefit manager including, but not limited to, documents or written comments. The pharmacy benefit manager must review and investigate the reimbursement and consider all information submitted by the network pharmacy or its representatives prior to issuing a decision.

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

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

(5) If the pharmacy benefit manager denies the network pharmacy's appeal, the pharmacy benefit manager must provide the network pharmacy with a reason for the denial and the national drug code of a drug that has been purchased by other network pharmacies located in the state of Washington at a price less than or equal to the predetermined reimbursement cost for the multisource generic drug. "Multisource generic drug" is defined in RCW 19.340.100 (1)(c).

(6) If the pharmacy benefit manager upholds the network pharmacy's appeal, the pharmacy benefit manager must make a reasonable adjustment no later than one day after the date of the determination. If the request for an adjustment is from a critical access pharmacy, as defined by the state health care authority by rule for purpose related to the prescription drug purchasing consortium established under RCW 70.14.060, any such adjustment shall apply only to such pharmacies.

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

(a) Persons who are natural persons representing themselves;

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

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

(8) In the response to the network pharmacy, the pharmacy benefit manager must provide sufficient information to identify the exact corporate entity that received and processed the appeal. Such information must include, but is not limited to, the corporate entity's full and complete name, taxpayer identification number, and number assigned by the office of the insurance commissioner.

AMENDATORY SECTION (Amending WSR 17-01-139, filed 12/20/16, effective 1/1/17)

WAC 284-180-420 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 284-180-440(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 at www.insurance.wa.gov.

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 federal identification number, unified business identifier number, business address, and mailing address;

(iii) 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; and

(iv) 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 days of receipt of the pharmacy benefit manager's decision; and

(e) The network pharmacy making the appeal must have less than fifteen retail outlets within the state of Washington under its corporate umbrella. The petition for review that the network pharmacy sub-

mits to the commissioner must state that this requirement is satisfied, and must be signed and verified by an officer or authorized representative of the network pharmacy.

(2) **Time frames governing appeals to the commissioner.** The commissioner must complete the appeal within thirty calendar days of the receipt of the network pharmacy's appeal. 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 ~~((+7))~~ (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, or may take 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 multi-source 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.

~~((7))~~ (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.

~~((8))~~ (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 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 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 284-180-430(1).

(10) Filing instructions. When a small pharmacy or a pharmacy benefit manager provides information to the commissioner regarding appeals under WAC 284-180-420, the small pharmacy or pharmacy benefit manager must follow the commissioner's filing instructions, which are available at www.insurance.wa.gov.