

R 2020-04 Health care benefit managers

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Comments due to OIC at <u>rulescoordinator@oic.wa.gov</u> by September 15th, 2020

WAC 284-180: New Title: Pharmacy Health Care Benefit Managers

WAC 284-180-110

Purpose

- (1) The purpose of this chapter is to establish uniform regulatory standards for health care benefit managers These regulations implement chapter 19.340 RCW including, but not limited to, the processes and procedures for registration and regulation of pharmacy health care benefit managers by the office of the insurance commissioner (commissioner).
- (2) This chapter applies to all health care benefit managers except as otherwise expressly provided in this chapter. Health care benefit managers are responsible for compliance with the provisions of this chapter and are responsible for the compliance of any person or organization acting on behalf of or at the direction of the health care benefit manager, or acting pursuant to health care benefit manager standards or requirements. Carriers remain responsible for activities of the health care benefit manager conducted on their behalf. A carrier may not offer as a defense to a violation of any provision of this chapter that the violation arose from the act or omission of a health care benefit manager or other person acting on behalf of or at the direction of the health care benefit manager.

WAC 284-180-120

Applicability and Scope

This chapter applies to <u>pharmacy health care</u> benefit managers as defined in RCW <u>48.200.020¹</u> <u>19.340.010</u>.

- (1) This chapter does not apply to the actions of health care benefit managers providing services to, or acting on behalf of:
 - (a) Self-insured health plans;

¹ Current potential citation provided by the Code Reviser for SSB 5601.

- (b) Union plans; and
- (c) Medicare plans.

WAC 284-180-130

Definitions

Except as defined in other subchapters and unless the context requires otherwise, the following definitions apply throughout this chapter:

- (1) Affiliate" or "affiliated employer" has the same meaning as the definition of affiliate or affiliated employer in RCW 48. XXX.
- (2) "Certification" has the same meaning as the definition of certification in RCW 48.43.005.
- (3) "Corporate umbrella" means an arrangement consisting of, but not limited to, subsidiaries and affiliates operating under common ownership or control.
- (3)(4) "Employee benefits programs" has the same meaning as the definition of employee benefits program in RCW XXX.
- (4)(5) "Generally available for purchase" means available for purchase by multiple pharmacies within the state of Washington from national or regional wholesalers.
- (6) "Health care benefit manager" has the same meaning as the definition of health care benefit manager in RCW 48.200.020.
- (7) "Health care provider" or "provider" has the same meaning as the definition of health care provider in RCW 48.43.005.
- (8) "Health care services" has the same meaning as the definition of health care services in RCW 48.43.005.
- (5)(9) "Health carrier" has the same meaning as the definition of health carrier in RCW 48.43.005.
- (10) "Laboratory benefit manager" has the same meaning as the definition of laboratory benefit manager in RCW 48.43.020.
- (11) "Mental health benefit manager" has the same meaning as the definition of mental health manager in RCW 48.200.020.
- (12) "Net amount" means the invoice price that the pharmacy paid to the supplier for a prescription drug that it dispensed, plus any taxes, fees or other costs, minus the amount of all discounts and other cost reductions attributable to the drug.
- (6)(13) "Network" has the same meaning as the definition of network in RCW 48.200.020.
- (14) "Oversight activities" includes all work done by the commissioner to ensure that the requirements of chapter <u>4819.340</u> RCW are properly followed and in fulfilling its duties as required under chapter <u>4819.340</u> RCW.
- (15) "Person" has the same meaning as the definition of person in RCW 48.200.020.

(7)(16) "Pharmacy benefit manager" has the same meaning as the definition of pharmacy manager in RCW XXX.

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

(9)(18) "Radiology benefit manager" has the same meaning as the definition of radiology manager in RCW 48.200.020.

- (10)(19) "Readily available for purchase" means manufactured supply is held in stock and available for order by more than one pharmacy in Washington state when such pharmacies are not under the same corporate umbrella.
- (11)(20) "Retaliate" means action, or the implied or stated threat of action, to decrease reimbursement or to terminate, suspend, cancel or limit a pharmacy's participation in a pharmacy benefit manager's provider network solely or in part because the pharmacy has filed or intends to file an appeal under RCW 19.340.100.
- (21) "Unsatisfied" means that the network pharmacy did not receive the reimbursement that it requested at the first tier appeal
- (12)(22) <u>"Utilization review" has the same meaning as the definition of utilization review in RCW 48.43.005.</u>

WAC 284-180-140

Severability

If any provision of this chapter or its application to any person or circumstances is held invalid, the remainder of the chapter or its application of the provision to other persons or circumstances is not affected.

WAC 284-180-210

Registration and renewal fees

(1) The registration, renewal and oversight activities for <u>pharmacy</u> <u>health care</u> benefit managers must be self-supporting. Each <u>pharmacy health care</u> benefit manager must contribute a sufficient amount to the commissioner's regulatory account to pay the reasonable costs, including overhead, of regulating <u>pharmacy health care</u> benefit managers.

(2) The registration fee is <u>\$200</u> dollars.

(3) For the renewal fee, the commissioner will charge a proportional share of the annual cost of renewal and oversight activities to all <u>pharmacy health care</u> benefit managers. The <u>pharmacy health care</u> benefit managers' proportional share shall be based on their Washington state annual gross <u>pharmacy health care</u> benefit manager business income for the previous calendar year. The minimum renewal fee is five hundred dollars.

(4) No later than March 1st of each year, pharmacy benefit managers must report their Washington state annual gross pharmacy benefit manager business income for the previous calendar year on a form prescribed by the commissioner.

(5) On or before June 1st of each year, the commissioner will calculate and set the renewal fees for the ensuing fiscal year of July 1st through June 30th.

(<u>4</u>6) If an unexpended balance of <u>pharmacy health care</u> benefit manager registration and renewal funds remain in the insurance commissioner's regulatory account at the close of a fiscal year, the commissioner will carry the unexpended funds forward and use them to reduce future renewal fees.

WAC 284-180-220

Pharmacy-Health Care Benefit Manager Registration

(1) Beginning January 1, 202217, and thereafter, to conduct business in this state, pharmacy-health care benefit managers must register with the commissioner and must annually renew the registration.

(2) <u>Pharmacy bBHealth care benefit managers must apply for registrationer using the commissioner's</u> electronic system, which is available at www.insurance.wa.gov.

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

(4) The registration <u>application</u> is not complete until the commissioner receives <u>both</u> the complete registration form<u>, any supporting documentation if required by the commissioner</u>, -and the correct registration fee.

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

(6) Previously registered pharmacy benefit managers must submit an application and registration fee to register as a health care benefit manager.

WAC 284-180-230

Pharmacy-Health Care Benefit Manager Renewal

(1) <u>Health care Pharmacy</u> benefit managers must annually renew their registrations <u>andby</u> paying the <u>health care benefit manager's</u> renewal fee <u>using</u>. <u>Pharmacy benefit managers must</u> access invoices through the commissioner's electronic system, which is available at <u>www.insurance.wa.gov</u>.

(2) The renewal is valid for one fiscal year, from July 1st through June 30th.

(3) The renewal fee is due and payable no later than July 15th of each year. Failure to timely pay the renewal fee may subject a pharmacy benefit manager to a civil penalty under RCW 19.340.110(2).

 (2) Health care benefit managers must renew their registrations by:
<u>a. No later than March of each year, submitting a complete renewal form for</u> approval to include:

- i. The health care benefit manager's Washington state annual gross health care benefit manager business income for the previous calendar year; and
 ii. Any additional information as required by the commissioner;
- b. No later than July 15th of each year, pay the renewal fee as invoiced by the commissioner.
 - i. On or before June 1st of each year, the commissioner will calculate and set the renewal fees for the upcoming fiscal year for July 1st through June 30th,

<u>(34)</u>-The renewal <u>application</u> is not complete until the commissioner receives the complete renewal form, and supporting documentation of required by the commissioner and the correct renewal fee.

(4). Failure to timely submit a completed renewal form and fees may result in delayed renewal or nonrenewal in additional to potential violations if the health care benefit managers provides services without being registered.

(5). The health care benefit manager will receive notice of approval of the renewal application from the commissioner.

(6). The renewal is valid for one fiscal year from July 1st through June 30th.

WAC 284-180-240

Providing and updating registration information.

(1) At the time of registration, a pharmacy benefit manager submit an application with an affidavit affirming its accuracy. In the application, health care benefit managers must provide:

(a) <u>The lits legal</u> name as well as any and all additional names that it uses to conduct business:-

(b) The names of all persons and entities with any ownership or controlling interest, including officers and directors, in the health care benefit manager, along with completed NAIC Form 11 biographical affidavits and, if requested, an NAIC Approved Third-Party Vendor Background Report;

(c) Tax identification numbers;

(d) Other business licenses that the benefit manager has held and those that are active; (e) Identifying any areas of specialty, such as a pharmacy benefit manager, radiology

benefit manager, laboratory benefit manager, mental health care benefit manager, or any other areas of specialty identified in the application; and

(f) Contact information for communications regarding registration, renewal and oversight activities, including address, phone number, name of the contact person for the health care benefit manager, and valid email address.

(g) Name and contact information for the person the health care benefit manager has designated as responsible for compliance with state and federal laws.

(h) Identify if the health care benefit manager has committed any violations in this or any state or been the subject of an order from a department of insurance or other state agency. (2) Registered pharmacy benefit managers must provide the commissioner with a valid email address, which <u>T</u>

(h)Any additional contact information requested by the commissioner the commissioner will use as the official contact address for communications regarding registrations, renewals and oversight activities.

(3) In addition to providing a valid email address, rRegistered 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 include address, phone number, name of the contact person, and valid email address. Ffill out the form that the commissioner makes available for this purpose at www.insurance.wa.gov.

(4<u>3</u>) Registered <u>health care pharmacy</u> 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 <u>health care pharmacy</u> benefit managers use to conduct business;

(ii) The email address for official communications between the commissioner and the <u>health care pharmacy</u> 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) <u>Any material change in the information provided to the obtain nor renew a</u> registration must be filed wWithin thirty days of the any change by, pharmacy benefit managers must report changes to the commissioner using the commissioner's electronic system.

WAC 284-180-310

Health care Pharmacy benefit manager records.

(1) <u>Health care Pharmacy</u> benefit managers must maintain records <u>for a period of seven years</u> <u>from the date of creation</u> and make them available to the commissioner upon request. Records include, but are not limited to:

(a) <u>All records of for each transaction completed;</u>

(b) Registration and renewal materials that pharmacy benefit managers submit to the commissioner to request registration and renewal; and

(cb) <u>Health care benefit managers that engage in pharmacy benefit management must</u> <u>also retain i</u>Information about appeals under chapter <u>48.200</u> **19.340** RCW.

(2) These materials are subject to review by the commissioner's representatives.

(3) The commissioner may require <u>health care pharmacy</u> benefit managers to provide copies of records.

(4) When the commissioner requests copies of records for inspection, <u>health care</u> <u>benefit managers pharmacy benefit managers</u> must transmit these documents <u>as directed by</u> <u>the commissioner</u> to the commissioner electronically.

WAC 284-180-320

Deadline to provide copies of records.

(1) If the commissioner requests records for inspection for a purpose other than to resolve an appeal under RCW <u>48.200</u>. <u>19.340.100(6)</u>, a <u>health carepharmacy</u> benefit manager must make the records available to the commissioner within fifteen days from the date on the request. If the commissioner grants a written extension, then the records are due by the date indicated on the extension.

(2) Upon receipt of any inquiry from the commissioner concerning a complaint, every health care benefit manager must furnish the commissioner with an adequate response to the inquiry within fifteen working days after receipt of the commissioner's inquiry using the commissioner's electronic company complaint system.

WAC 284-180-330

Actions that may result in a fine.

The commissioner may issue a fine against any person, corporation, third-party administrator of prescription drug benefits, pharmacy benefit manager, or business entity for failing to comply with any statute or rule pertaining to pharmacy benefit managers as specified in chapter **19.340** RCW and Title 284 WAC. [Statutory Authority: RCW **48.02.060**, **19.340.010**, **19.340.030**, **19.340.100**, **19.340.110**, and 2016 a 210 SS 1 and 2 through 7, WSD 17, 01, 120 (Matter No. D, 2016, 07), S 284, 180, 220

2016 c 210 §§ 1 and 2 through 7. WSR 17-01-139 (Matter No. R 2016-07), § 284-180-330, filed 12/20/16, effective 1/1/17.]

WAC 284-180-340

When a violation is knowing and willful.

(1) A violation is knowing and willful for the purpose of chapter **19.340** RCW when the actor as defined in WAC **284-180-330** who committed the violation was aware or should have been aware of each act, failure to act, or other facts or circumstances that led to the violation. A violation is knowing and willful regardless of whether the person who committed the violation had a malicious motive, intended to violate the law, or knew that the law was being violated.

(2) A person should have been aware of an act, failure to act, or other facts or circumstances when the person had information that would lead a reasonable person in the same situation to be aware of the act, failure to act, or other facts or circumstances. A person is presumed to have intended the natural and probable consequences of their voluntary acts.

[Statutory Authority: RCW **48.02.060**, **19.340.010**, **19.340.030**, **19.340.100**, **19.340.110**, and 2016 c 210 §§ 1 and 2 through 7. WSR 17-01-139 (Matter No. R 2016-07), § 284-180-340, filed 12/20/16, effective 1/1/17.]

WAC 284-180-330

Required Notices.

(1) Carriers must post on their website information that identifies each health care benefit manager contracted with the carrier and identify the services provided by the benefit manager. The information must be easy to find on the carriers website with a link from the webpage utilized for enrollees. The carrier is required to update the information on their website within three business days of any change, such as addition or removal of a benefit manager or a change in the services provided by a benefit manager.

(2) Carriers must notify enrollees in writing and at least annually, including at plan enrollment and renewal, of each health care benefit manager contracted with the carrier to provide any benefit management services. For example, written notices include disclosure in the policy or member handbook. This notice must identify the website address where enrollees can view an updated listing of all benefit managers utilized by the carrier.

SUBCHAPTER XXX: Contract Filings

WAC 284-180-405

Definitions in this Subchapter

The definitions in this section apply throughout this subchapter.

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

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

(3) "Filer" means:

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

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

(4) "Form" means a:

(a) "Health Care Benefit Management Contract" or "Contract" as defined in means any written agreement describing the rights and responsibilities of the parties, such as carriers, health care benefit managers, providers, pharmacy, pharmacy services administration organization, and employee benefit program conforming to the Chapter of RCW 48.200 and this chapter including

(i) All forms that are part of the contract and

(ii) All amendments to the contract.

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

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

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

(b) Explains errors or omissions in the filing;

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

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

WAC 284-180-410

Purpose of this subchapter

The purpose of this chapter is to:

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

(2) Designate SERFF as the method by which filers, including Disability, HCSCs, HMOs and health care benefit managers must submit all health care benefit management contract forms to the commissioner

WAC 284-180-415

Scope of this subchapter

This chapter applies to all carriers and health care benefit managers that must file forms under RCW XXX.

WAC 284-180-420

Filing Instructions that are incorporated into this subchapter

SERFF is a dynamic application that the NAIC will revise and enhance over time. To be consistent with NAIC filing standards and provide timely instructions to filers, the commissioner will incorporate documents posted on the SERFF website into this chapter. By reference, the commissioner incorporates these documents into this chapter:

(1) The SERFF Industry Manual available within the SERFF application; and

(2) The Washington State SERFF Health Care Benefit Management General Filing Instructions posted on the commissioner's website (www.insurance.wa.gov)

General health care benefit management form filing rules

(1) Each health care benefit management contract form and contract amendment form filing must be submitted to the commissioner electronically using SERFF.

(a) Every form filed in SERFF must:

(i) Be attached to the form schedule; and

(ii) Have a unique identifying number and a way to distinguish it from other versions of the same form.

(b) Filers must send all written correspondence related to a form filing in SERFF.

(2) All filed forms must be legible for both the commissioner's review and retention as a nonpublic record. Filers must submit new or revised forms to the commissioner for review in final form displayed in ten-point or larger type.

(3) Filers must submit complete filings that comply with the SERFF Industry Manual available within the SERFF application and the Washington State SERFF Health Care Benefit Management General Filing Instructions, as revised from time to time and posted on the commissioner's website (www.insurance.wa.gov)

WAC 284-180-430

The commissioner may reject filings

(1) The commissioner may reject and close any filing that does not comply with this subchapter. If the commissioner rejects a filing, the filer has not filed forms with the commissioner.

(2) If the commissioner rejects a filing and the filer resubmits it as a new filing, the date filed will be the date the commissioner receives and accepts the new filing.

WAC 284-180-435

Filing authorization rules.

A carrier or health care benefit manager may authorize a third-party filer to file forms or rates on its behalf. For the purposes of this section, a "third-party filer" means a person or entity in the business of providing regulatory compliance services.

(1) If a carrier or health care benefit manager delegates filing authority to a third-party filer, each filing must include a letter as supporting documentation signed by an officer of the carrier or health care benefit manager authorizing the third-party filer to make filings on behalf of the carrier or health care benefit manager.

(2) The carrier or health care benefit manager may not delegate responsibility for the content of a filing to a third-party filer. The commissioner considers errors and omissions made by the third-party filer to be errors and omissions of the carrier or health care benefit manager.

(3) If a third-party filer has a pattern of making filings that do not comply with this chapter, the commissioner may reject a delegation of filing authority.

WAC 284-180-440

Rules for responding to an objection letter.

An objection letter may ask the filer to revise a noncompliant form or provide clarification or additional information. The objection letter will state the reason(s) for the objection, including relevant case law, statutes and rules. Filers must:

(1) Provide a complete response to an objection letter. A complete response must include:

(a) A separate response to each objection, and if appropriate;

(b) A description of changes proposed to noncompliant forms, and a replacement form attached to the form schedule; or

(c) Revised exhibits and supporting documentation.

(2) Respond to the commissioner in a timely manner designated by the insurance commissioner in the objection letter.

(3) Failure to timely respond to an objection is a violation.

WAC 284-180-445

Rules for revised or replaced forms.

If carrier or health care benefit manager files a revised or replaced form, the filer must provide the supporting documentation described below:

(1) If a form is revised due to an objection(s) from the commissioner, the filer must provide a detailed explanation of all material changes to the replaced form.

(2) If a form is replaced with a new version, the filer must submit an exhibit that marks and identifies each change or revision to the replaced form using one of these methods:

(a) A draft form that strikes through deletions and underlines additions or changes in the form;

(b) A draft form that includes comments in the margins explaining the changes in the form; or

(c) A side-by-side comparison of current and proposed language.

WAC 284-180-450

Effective date rules.

(1) Filers must include a common implementation date for all forms submitted in a filing.

(2) Filers may submit a request to change the implementation date of a filing as a note to reviewer.

WAC 284-180-455 NEW

Carrier filings related to health care benefit managers.

(1) A carrier must file all contracts and contract amendments with a health care benefit manager within thirty days following the effective date of the contract or contract amendment. If a carrier negotiates, amends, or a modifies a contract or a compensation agreement that deviates from a previously filed contract, then the carrier must file that negotiated, amended, or modified contract or agreement with the commissioner within thirty days following the effective date. The commissioner must receive the filings electronically in accordance with this subchapter.

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

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

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

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

WAC 284-180-460 NEW

Health care benefit manager filings.

(1) A health care benefit manager must file all contracts and contract amendments between a provider, pharmacy, pharmacy services administration organization, or other health care benefit manager entered into directly or indirectly in support of a contract with a carrier or employee benefits program within thirty days following the effective date of the contract or contract amendment. If a health care benefit manager negotiates, amends, or modifies a contract or a compensation agreement that deviates from a filed agreement, then the health care benefit manager must file that negotiated, amended or modified contract or agreement with the commissioner within thirty days following the effective date. The commissioner must receive the filings electronically in accordance with this chapter.

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

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

PBM subchapter (Moved)

WAC 284-180-5400 (originally in 400 moved to 500)

This subchapter applies to health care benefit managers providing pharmacy benefit management services, referred to as pharmacy benefit managers in this subchapter.

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

(a) Fully insured health plans; and

(b) Medicaid plans. However, the appeal requirements of RCW 19.340.100 do not apply to medicaid plans.

(2) This chapter does not apply to the actions of pharmacy benefit managers acting as third-party administrators regarding contracts with pharmacies on behalf of an insurer, a third-party payor, or the prescription drug purchasing consortium established under RCW 70.14.060 in regard to:

- (a) Self-insured health plans; and
- (b) Medicare plans.

WAC 284-180-505 Appeals by network pharmacies to <u>benefit managers who have</u> <u>identified that the health care benefit manager provides</u> pharmacy benefit management <u>services</u>.

A network pharmacy may appeal a reimbursement to a <u>benefit manager providing</u> pharmacy benefit manage<u>ment services</u>r (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" is a benefit manager that offers pharmacy benefit management services and has the meaning set forth in RCW 19.340.010 (6)(a) (NEW citation when codified inserted). 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. If the benefit manager provides other benefit management services in addition to pharmacy benefit management services, then this information must be under an easily located page that is specific to pharmacy services. The description must include, but is not limited to:

(a) Contact information, including:

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

(9) 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 include address, phone number, name of the contact person, and valid email address. Fill out the form that the commissioner makes available for this purpose at www.insurance.wa.gov.

WAC 284-180-510 (relocated)

Computation of Time

In computing any period of time in this chapter, the commissioner:

(1) Will not count the first day;

(2) Will count the last day, unless the last day is a weekend or a state legal holiday; and

(3) Will count the next day that is not a weekend or a state legal holiday as the last day if the last day is a weekend or a state legal holiday.

WAC 284-180-5150

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-<u>5</u>410 through **284-180-<u>5</u>440** describe the procedures for how the commissioner processes a network pharmacy's 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.

WAC 284-180-<u>5</u>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) (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) Documentation evidencing the net amount paid for the drug by the small pharmacy;
- (iii)(v) If the first-tier appeal was denied by the pharmacy benefit manager because a therapeutically equivalent drug was available in the state of Washington at a price less than or equal to the predetermined reimbursement cost for the multisource generic drug and documentation provided by the pharmacy benefit manager evidencing the national drug code of the therapeutically equivalent drug; and

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

(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 submits 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 <u>complete petition for review appeal</u>. A complete petition for review means that all requirements <u>under WAC 284-180-520(1) have been satisfied, including the submission of all required</u> <u>documents and documentation</u>. 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 and pharmacy and pharmacy and pharmacy and pharmacy.

(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 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 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 <u>www.insurance.wa.gov</u>.

WAC 284-180-5430

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 <u>284-180-420</u>, unless the matter is converted to a formal proceeding as provided in WAC <u>284-180-440</u>(4).

(1) **Request for review of initial order.** A party to a brief adjudicative proceeding under WAC <u>284-180-420</u> may request review of the initial order by filing a written petition for review with the commissioner within twenty-one 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.

(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 <u>34.05.491</u>.

(2) **Reviewing officer.** The commissioner shall appoint a reviewing officer who satisfies the requirements of RCW <u>34.05.491</u>(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 <u>34.05</u> RCW and this rule, or WAC <u>284-02-070</u> 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 <u>284-180-420</u>.

(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 <u>284-180-440</u>(2).

(ii) Proof of service is required under WAC $\underline{284-180-440}$ (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 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 <u>34.05</u> RCW. However, as required by RCW <u>34.05.534</u>, 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.

WAC 284-180-5440

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 <u>34.05.452</u> 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 <u>34.05.413</u> through <u>34.05.476</u> or <u>34.05.479</u>.