

**WSR 21-02-034
PERMANENT RULES
OFFICE OF THE**

INSURANCE COMMISSIONER

[Filed December 29, 2020, 8:54 a.m., effective January 1, 2022]

Effective Date of Rule: January 1, 2022.

Purpose: The commissioner is adopting rules regarding health care benefit managers to ensure implementation of registration, associated filings, and regulation as provided for in 2SSB 5601 (chapter 240, Laws of 2020), which has been codified in chapter 48.200 RCW. In addition to adding new sections, the commissioner is amending existing WAC and repealing older WAC.

Citation of Rules Affected by this Order: New WAC 284-180-325, 284-180-405, 284-180-411, 284-180-415, 284-180-421, 284-180-425, 284-180-431, 284-180-435, 284-180-441, 284-180-445, 284-180-450, 284-180-455, 284-180-460 and 284-180-500; repealing WAC 284-180-330 and 284-180-340; and amending WAC 284-180-110, 284-180-120, 284-180-130, 284-180-210, 284-180-220, 284-180-230, 284-180-240, 284-180-310, 284-180-320, 284-180-400, 284-180-410, 284-180-420, and 284-180-430.

Statutory Authority for Adoption: RCW 48.02.060 and 48.200.900. Adopted under notice filed as WSR 20-22-081 on November 3, 2020.

Changes Other than Editing from Proposed to Adopted Version: A technical change was made in WAC 284-180-230 to add "(c)" to correct a sentence that did not have a subsection identifier with it. Another technical change was made to WAC 284-180-120 to align with existing law, which identifies that this chapter does not apply to the actions of health care benefit managers providing services to or on behalf of medicaid.

A final cost-benefit analysis is available by contacting Tabba Alam, P.O. Box 40260, Olympia, WA 98504-0260, phone 360-725-7170, email TabbaA@oic.wa.gov, website www.insurance.wa.gov.

Number of Sections Adopted in Order to Comply with Federal Statute: New 0, Amended 0, Repealed 0; Federal Rules or Standards: New 0, Amended 0, Repealed 0; or Recently Enacted State Statutes: New 14, Amended 13, Repealed 2.

Number of Sections Adopted at the Request of a Nongovernmental Entity: New 0, Amended 0, Repealed 0.

Number of Sections Adopted on the Agency's own Initiative: New 0, Amended 0, Repealed 0.

Number of Sections Adopted in Order to Clarify, Streamline, or Reform Agency Procedures: New 0, Amended 0, Repealed 0.

Number of Sections Adopted using Negotiated Rule Making: New 14, Amended 13, Repealed 2; Pilot Rule Making: New 0, Amended 0, Repealed 0; or Other Alternative Rule Making: New 0, Amended 0, Repealed 0.

Date Adopted: December 29, 2020.

Mike Kreidler
Insurance Commissioner

OTS-2680.3

Chapter 284-180 WAC

((PHARMACY)) HEALTH CARE BENEFIT MANAGERS

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

WAC 284-180-110 Purpose. ~~((These regulations implement chapter 19.340 RCW))~~ (1) The purpose of this chapter is to establish uniform regulatory standards for health care benefit managers including, but not limited to, the processes and procedures for registration ((and regulation of pharmacy)) of 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 health care benefit managers 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 a health care benefit manager.

[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), § 284-180-110, filed 12/20/16, effective 1/1/17.]

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

WAC 284-180-120 Applicability and scope. (1) This chapter applies to ((pharmacy)) health care benefit managers as defined in RCW ((19.340.010)) 48.200.020.

~~((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)) health care benefit managers providing services to, or 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)) on behalf of:

- (a) Self-insured health plans; ((and))
- (b) Medicare plans;
- (c) Medicaid; and
- (d) Union plans.

[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), § 284-180-120, filed 12/20/16, effective 1/1/17.]

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

WAC 284-180-130 Definitions. Except as defined in other sub-chapters 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 48.200.020.

(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.

~~((2))~~ (4) "Employee benefits programs" has the same meaning as the definition of employee benefits program in RCW 48.200.020.

(5) "Generally available for purchase" means available for purchase by multiple pharmacies within the state of Washington from national or regional wholesalers.

~~((3))~~ (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.

(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 benefit 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.

~~((4))~~ (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 ~~((19.340))~~ 48.200 RCW are properly followed and in fulfilling its duties as required under chapter ~~((19.340))~~ 48.200 RCW.

~~((5))~~ (15) "Person" has the same meaning as the definition of person in RCW 48.200.020.

(16) "Pharmacy benefit manager" has the same meaning as the definition of pharmacy benefit manager in RCW 48.200.020.

(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.

~~((6))~~ (18) "Radiology benefit manager" has the same meaning as the definition of radiology benefit manager in RCW 48.200.020.

(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.

~~((7))~~ (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)~~ 48.200.280.

~~((8))~~ (21) "Unsatisfied" means that the network pharmacy did not receive the reimbursement that it requested at the first tier appeal.

(22) "Utilization review" has the same meaning as the definition of utilization review in RCW 48.43.005.

[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), § 284-180-130, filed 12/20/16, effective 1/1/17.]

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

WAC 284-180-210 Registration and renewal fees. (1) The registration, renewal and oversight activities for ~~((pharmacy))~~ health care benefit managers must be self-supporting. Each ~~((pharmacy))~~ health care benefit manager must contribute a sufficient amount to the commissioner's regulatory account to pay the reasonable costs, including overhead, of regulating ~~((pharmacy))~~ health care benefit managers.

(2) The registration fee is two hundred dollars.

(3) For the renewal fee, the commissioner will charge a proportional share of the annual cost of renewal and oversight activities to all ~~((pharmacy))~~ health care benefit managers. The ~~((pharmacy))~~ health care benefit managers' proportional share shall be based on their Washington state annual gross ~~((pharmacy))~~ health care 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.~~

~~(6))~~ If an unexpended balance of ~~((pharmacy))~~ health care 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.

[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), § 284-180-210, filed 12/20/16, effective 1/1/17.]

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

WAC 284-180-220 ((Pharmacy)) Health care benefit manager registration. (1) Beginning January 1, 2017, ~~((and thereafter))~~ through December 31, 2021, to conduct business in this state, pharmacy benefit managers must register with the commissioner and must annually renew the registration.

(2) ~~((Pharmacy))~~ Beginning January 1, 2022, and thereafter, to conduct business in this state, health care benefit managers must register and have an approved registration with the commissioner. To continue conducting business in this state, previously registered pharmacy benefit managers must submit an application and registration fee to register as a health care benefit manager. Health care benefit managers must annually renew their registration.

(3) Health care benefit managers must ~~((register))~~ apply for registration using the commissioner's electronic system, which is available at www.insurance.wa.gov.

~~((3))~~ (4) The registration period is valid from the date of approval of registration through June 30th of the same fiscal year.

~~((4))~~ (5) The registration application is not complete until the commissioner receives ~~((both))~~ the complete registration form, any supporting documentation if required by the commissioner, and the correct registration fee.

(6) 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.

[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), § 284-180-220, filed 12/20/16, effective 1/1/17.]

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

WAC 284-180-230 ((Pharmacy)) Health care benefit manager renewal. (1) ~~((Pharmacy))~~ Health care benefit managers must annually renew their registrations ~~((by paying))~~ and pay the health care benefit manager's renewal fee ~~((. Pharmacy benefit managers must access invoices through))~~ using the commissioner's electronic system, which is available at www.insurance.wa.gov.

(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).~~

(4-)) Health care benefit managers must renew their registrations by:

(a) No later than March 1st of each year, submitting a complete renewal form and supporting documents for 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.

(c) 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.

(3) The renewal application is not complete until the commissioner receives the complete renewal form, supporting documentation if 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 addition to potential violations if a health care benefit manager 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.

[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), § 284-180-230, filed 12/20/16, effective 1/1/17.]

AMENDATORY SECTION (Amending WSR 18-13-023, filed 6/8/18, effective 7/9/18)

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

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

(a) The 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 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-)):~~

(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 and registrations that the health care benefit manager has held and those that are active;

(e) Identifying any areas of specialty, such as a pharmacy benefit management, radiology benefit management, laboratory benefit management, mental health care benefit management, or any other areas of specialty identified in the application;

(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; and

(i) Any additional information requested by the commissioner.

(2) Registered ((pharmacy)) health care 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)) the health care benefit manager(~~s-use~~) uses to conduct business; and

(ii) The email address for official communications between the commissioner and the ((pharmacy)) health care 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) Any change in the information provided to obtain or renew a registration is a material change and must be reported within thirty days of any change, ((pharmacy)) by the health care benefit manager(~~s must report changes to the commissioner~~) using the commissioner's electronic system.

[Statutory Authority: RCW 48.02.060, 48.02.220 and chapter 19.340 RCW. WSR 18-13-023, § 284-180-240, filed 6/8/18, effective 7/9/18. 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), § 284-180-240, filed 12/20/16, effective 1/1/17.]

**SUBCHAPTER C
((ENFORCEMENT)) RECORDS AND NOTICES**

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

WAC 284-180-310 ((Pharmacy)) Health care benefit manager records. (1) ((Pharmacy)) Health care benefit managers must maintain all records for a period of seven years from the date of creation and make them available to the commissioner upon request. Records include, but are not limited to:

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

(b) Health care benefit managers that engage in pharmacy benefit management must also maintain information about appeals under chapter ((19.340)) 48.200 RCW.

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

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

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

[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), § 284-180-310, filed 12/20/16, effective 1/1/17.]

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

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 ((19.340.100(6), a pharmacy)) 48.200.280, a health care benefit manager must make the records available to the commissioner within fifteen business days from the date on the written 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 business days after receipt of the commissioner's inquiry using the commissioner's electronic company complaint system.

[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), § 284-180-320, filed 12/20/16, effective 1/1/17.]

NEW SECTION

WAC 284-180-325 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 health care benefit manager. The information must be easy to find on the carriers' website with a link from the web page utilized for enrollees. The carrier is required to update the information on their website within thirty business days of any change, such as addition or removal of a health care benefit manager or a change in the services provided by a health care 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 health care 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 health care benefit managers utilized by the carrier.

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**SUBCHAPTER D
((APPEALS)) CONTRACT FILINGS**

AMENDATORY SECTION (Amending WSR 18-13-023, filed 6/8/18, effective 7/9/18)

WAC 284-180-400 Appeals by network pharmacies to ((pharmacy)) health care benefit managers who provide pharmacy benefit management services. A network pharmacy may appeal a reimbursement to a health care benefit manager providing pharmacy benefit ((manager)) management services (first tier appeal) if the reimbursement for the drug is less than the net amount the network pharmacy paid to the supplier of the drug. "Network pharmacy" has the meaning set forth in RCW 19.340.100 (1)(d). "Pharmacy benefit manager" is a health care benefit manager that offers pharmacy benefit management services and has the meaning set forth in RCW ((19.340.010-(6)-(a))) 48.200.020. 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 website fully describing the right to appeal under RCW ((19.340.100)) 48.200.280. If the health care benefit manager provides other health care 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 benefit((s)) 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) Health care benefit managers providing pharmacy benefit management services benefit managers must identify a pharmacy benefit manager employee who is the single point of contact for appeals, and must include the address, phone number, name of the contact person, and valid email address. This includes completing and submitting the form that the commissioner makes available for this purpose at www.insurance.wa.gov.

[Statutory Authority: RCW 48.02.060, 48.02.220 and chapter 19.340 RCW. WSR 18-13-023, § 284-180-400, filed 6/8/18, effective 7/9/18. 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), § 284-180-400, filed 12/20/16, effective 1/1/17.]

NEW SECTION

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 health care benefit manager to file under this chapter.

(4) "Form" means a "health care benefit management contract" or "contract" and 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 chapter 48.200 RCW and this chapter including:

(a) All forms that are part of the contract; and

(b) 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 www.naic.org.

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

WAC 284-180-410 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 ((~~284-180-410~~)) 284-180-500 through ((~~284-180-440~~)) 284-180-540 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.

[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), § 284-180-410, filed 12/20/16, effective 1/1/17.]

NEW SECTION

WAC 284-180-411 Purpose of this subchapter. The purpose of this subchapter 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 health care service contractors, health maintenance organizations, insurers as defined in RCW 48.01.050, and health care benefit managers must submit all health care benefit management contract forms to the commissioner.

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NEW SECTION

WAC 284-180-415 Scope of this subchapter. This subchapter applies to all carriers and health care benefit managers that must file forms under chapter 48.200 RCW.

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AMENDATORY SECTION (Amending WSR 18-13-023, filed 6/8/18, effective 7/9/18)

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)~~) 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 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) Documentation evidencing the net amount paid for the drug by the small pharmacy;

(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

(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 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 ((~~appeal~~)) 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, 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.

(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~~)) 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 ((~~284-180-420~~) 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.

[Statutory Authority: RCW 48.02.060, 48.02.220 and chapter 19.340 RCW. WSR 18-13-023, § 284-180-420, filed 6/8/18, effective 7/9/18. 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), § 284-180-420, filed 12/20/16, effective 1/1/17.]

NEW SECTION

WAC 284-180-421 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).

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NEW SECTION

WAC 284-180-425 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).

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

WAC 284-180-430 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 ((~~284-180-420~~)) 284-180-520, unless the matter is converted to a formal proceeding as provided in WAC ((~~284-180-440~~)) 284-180-540(4).

(1) **Request for review of initial order.** A party to a brief adjudicative proceeding under WAC ((~~284-180-420~~)) 284-180-520 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 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 ((~~284-180-420~~)) 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 ((284-180-440)) 284-180-540(2).

(ii) Proof of service is required under WAC ((284-180-440)) 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 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.

[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), § 284-180-430, filed 12/20/16, effective 1/1/17.]

NEW SECTION

WAC 284-180-431 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.

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NEW SECTION

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.

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NEW SECTION

WAC 284-180-441 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 separate response to each objection, and if appropriate:

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

(b) Revised exhibits and supporting documentation.

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

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

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NEW SECTION

WAC 284-180-445 Rules for revised or replaced forms. If a 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.

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NEW SECTION

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.

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NEW SECTION

WAC 284-180-455 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 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 carrier 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 in-network 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.

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NEW SECTION

WAC 284-180-460 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 in-network 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.

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SUBCHAPTER E APPEALS

NEW SECTION

WAC 284-180-500 Applicability and scope. 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 subchapter 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 subchapter 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.

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NEW SECTION

The following sections of the Washington Administrative Code are decodified and recodified as follows:

Old WAC Number	New WAC Number
284-180-140	284-180-510
284-180-400	284-180-505
284-180-410	284-180-515
284-180-420	284-180-520
284-180-430	284-180-530
284-180-440	284-180-540

REPEALER

The following sections of the Washington Administrative Code are repealed:

WAC 284-180-330	Actions that may result in a fine.
WAC 284-180-340	When a violation is knowing and willful.