Chapter 284-180 WAC
PHARMACY BENEFIT MANAGERS

WAC
SUBCHAPTER A
GENERAL PROVISIONS
284-180-110 Purpose. These regulations implement chapter 19.340 RCW including, but not limited to, the processes and procedures for registration and regulation of pharmacy benefit managers by the office of the insurance commissioner (commissioner).


284-180-120 Applicability and scope. This chapter applies to pharmacy benefit managers as defined in RCW 19.340.010.

(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) Self-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 284-180-130 Definitions. Except as defined in other subchapters and unless the context requires otherwise, the following definitions apply throughout this chapter:
(1) "Corporate umbrella" means an arrangement consisting of, but not limited to, subsidiaries and affiliates operating under common ownership or control.
(2) "Generically available for purchase" means available for purchase by multiple pharmacies within the state of Washington from national or regional wholesalers.
(3) "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) "Oversight activities" includes all work done by the commissioner to ensure that the requirements of chapter 19.340 RCW are properly followed and in fulfilling its duties as required under chapter 19.340 RCW.
(5) "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 multsource generic drug reimbursement amounts. However, dispensing fees are not included in the calculation of predetermined reimbursement costs for multi-source generic drugs.
(6) "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) "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.
(8) "Unsatisfied" means that the network pharmacy did not receive the reimbursement that it requested at the first tier appeal.

WAC 284-180-140  Computation of time. In computing any period of time prescribed by this rule, 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 284-180-150  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.


SUBCHAPTER B  REGISTRATION AND RENEWAL

WAC 284-180-210  Registration and renewal fees. (1) The registration, renewal and oversight activities for pharmacy benefit managers must be self-supporting. Each pharmacy benefit manager must contribute a sufficient amount to the commissioner's regulatory account to pay the reasonable costs, including overhead, of regulating pharmacy 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 benefit managers. The pharmacy benefit managers' proportional share shall be based on their Washington state annual gross pharmacy 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 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 benefit manager registration. (1) Beginning January 1, 2017, and thereafter, to conduct business in this state, pharmacy benefit managers must register with the commissioner and must annually renew the registration.

(2) Pharmacy benefit managers must register using the commissioner's electronic system, which is available at www.insurance.wa.gov.

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

(4) The registration is not complete until the commissioner receives both the complete registration form and the correct registration fee.


WAC 284-180-230  Pharmacy benefit manager renewal. (1) Pharmacy benefit managers must annually renew their registrations by paying the renewal fee. Pharmacy benefit managers must access invoices through 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) The renewal is not complete until the commissioner receives the correct renewal fee.


WAC 284-180-240  Providing and updating registration information. (1) At the time of registration, a pharmacy benefit manager must provide its legal name as well as any and all additional names that it uses to conduct business.

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

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

(a) This information includes, but is not limited to:
(i) Any and all additional names that pharmacy benefit managers use to conduct business; and
(ii) The email address for official communications between the commissioner and the pharmacy benefit manager.

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

SUBCHAPTER C

ENFORCEMENT

WAC 284-180-310 Pharmacy benefit manager records. (1) Pharmacy benefit managers must maintain records and make them available to the commissioner upon request. Records include, but are not limited to:
(a) Registration and renewal materials that pharmacy benefit managers submit to the commissioner to request registration and renewal; and
(b) Information about appeals under chapter 19.340 RCW.
(2) These materials are subject to review by the commissioner's representatives.
(3) The commissioner may require pharmacy benefit managers to provide copies of records.
(4) When the commissioner requests copies of records for inspection, pharmacy benefit managers must transmit these documents to the commissioner electronically.

WAC 284-180-320 Deadline to provide copies of records. If the commissioner requests records for inspection for a purpose other than to resolve an appeal under RCW 19.340.100(6), a pharmacy benefit manager must make the records available to the commissioner within fifteen 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.

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.

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.

WAC 284-180-400 Appeals by network pharmacies to pharmacy benefit managers. A network pharmacy may appeal a reimbursement to a pharmacy benefit manager (first tier appeal) if the reimbursement for the drug is less than the net amount the network pharmacy paid to the supplier of the drug. "Network pharmacy" has the meaning set forth in RCW 19.340.100(1)(d). "Pharmacy benefit manager" has the meaning set forth in RCW 19.340.010(6)(a). A pharmacy benefit manager must process the network pharmacy's appeal as follows:
(1) A pharmacy benefit manager must include language in the pharmacy provider contract and on the pharmacy benefit manager's web site fully describing the right to appeal under RCW 19.340.100. The description must include, but is not limited to:
(a) Contact information, including:
(i) A telephone number by which the pharmacy may contact the pharmacy benefit manager during normal business hours and speak with an individual responsible for processing appeals;
(ii) A summary of the specific times when the pharmacy benefit manager will answer calls from network pharmacies at that telephone number;
(iii) A fax number that a network pharmacy can use to submit information regarding an appeal; and
(iv) An email address that a network pharmacy can use to submit information regarding an appeal.
(b) A detailed description of the actions that a network pharmacy must take to file an appeal; and
(c) A detailed summary of each step in the pharmacy benefit manager's appeals process.
(2) The pharmacy benefit manager must reconsider the reimbursement. A pharmacy benefit manager's review process must provide the network pharmacy or its representatives with the opportunity to submit information to the pharmacy benefit manager including, but not limited to, documents or written comments. The pharmacy benefit manager must review and investigate the reimbursement and consider all information submitted by the network pharmacy or its representatives prior to issuing a decision.
(3) The pharmacy benefit manager must complete the appeal within thirty calendar days from the time the network pharmacy submits the appeal. If the network pharmacy does not receive the pharmacy benefit manager's decision within that time frame, then the appeal is deemed denied.
(4) The pharmacy benefit manager must uphold the appeal of a network pharmacy with fewer than fifteen retail outlets within the state of Washington, under its corporate umbrella, if the pharmacy demonstrates that they are unable to purchase therapeutically equivalent interchangeable product from a supplier doing business in the state of Washington.
at the pharmacy benefit manager's list price. "Therapeutically equivalent" is defined in RCW 69.41.110(7).

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

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

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

(a) Persons who are natural persons representing themselves;

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

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

(d) Public officials in their official capacity;

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

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

(g) Other persons designated by a person to whom the proceedings apply.


**WAC 284-180-420 Appeals by network pharmacies to the commissioner.** The following procedure applies to brief adjudicative proceedings before the commissioner for actions involving a network pharmacy's appeal of a pharmacy benefit manager's decision in a first tier appeal regarding reimbursement for a drug subject to predetermined reimbursement costs for multisource generic drugs, unless the matter is converted to a formal proceeding as provided in WAC 284-180-440(3).

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

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

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

The petition for review must include:

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

(ii) The network pharmacy's federal identification number, unified business identifier number, business address, and mailing address;

(iii) The documents from the first tier review, including the documents that the pharmacy submitted to the pharmacy benefit manager as well as the documents that the pharmacy benefit manager provided to the pharmacy in response to the first tier review; and

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

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

(d) The network pharmacy must file the petition for review with the commissioner within thirty days of receipt of the pharmacy benefit manager's decision; and

(e) The network pharmacy making the appeal must have less than fifteen retail outlets within the state of Washington under its corporate umbrella. The petition for review that the network pharmacy 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. An appeal before the commissioner is deemed complete when a presiding officer issues an initial order on behalf of the commissioner to both the network pharmacy and pharmacy benefit manager under subsection (7) 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


[Ch. 284-180 WAC p. 4]
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) Hearings by telephone. If the presiding officer chooses to conduct a hearing, then the presiding officer may choose to conduct the hearing telephonically. The conversation will be recorded and will be part of the record of the hearing.

(7) Presiding officer.

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

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

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

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

(8) 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).

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

(1) Request for review of initial order. A party to a brief adjudicative proceeding under WAC 284-180-420 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.

(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, under the use of discretion, allows additional time to submit the evidence.
(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(2).
(ii) Proof of service is required under WAC 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 documenta-
information to other parties or electronically notifies other parties that the information is available for them to access.

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

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

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

(i) An acknowledgment of service;

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

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

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

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

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