Chapter 182-52 WAC
PRESCRIPTION DRUG AFFORDABILITY BOARD

NEW SECTION

WAC 182-52-0005 Prescription drug affordability board—Purpose. The prescription drug affordability board conducts reviews of drug prices, performs drug affordability reviews, and sets upper payment limits for prescription drugs.

NEW SECTION

WAC 182-52-0010 Prescription drug affordability board—Definitions. The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

"Authority" means the health care authority, as defined in WAC 182-02-045.

"Biological product" has the same meaning as in 42 U.S.C. Sec. 262(i)(1).

"Biologics" means biological products and biosimilars.

"Biosimilar" has the same meaning as in 42 U.S.C. Sec. 262(i)(2).

"Board" means the prescription drug affordability board.

"Brand name drug" means specific legend drug products that are sold by a manufacturer under certain trademarks or patents.

"Confidential information" means:

(a) Specific information collected by the authority that is not publicly available for the purposes of this chapter; or

(b) Proprietary data provided by manufacturers in accordance with this chapter that is not subject to public disclosure.

"Conflict of interest" means an association, including a financial or personal association, that has the potential to bias or appear to bias an individual's decisions in board matters or activities.

"Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

(a) Recognized in the official national formulary, or the United States Pharmacopoeia, or any supplement to them;

(b) Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in human beings or other animals; or

(c) Intended to affect the structure or any function of the body of human beings or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of human beings or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

(d) The term "device" does not include software functions excluded under 21 U.S.C. Sec. 360j(o). See 21 U.S.C. Sec. 321(h)(1) of the Federal Food, Drug, and Cosmetic Act.

"Drug" means a substance:

(a) Recognized as drugs in the official United States Pharmacopeia, official Homeopathic Pharmacopoeia of the United States, or official national formulary, or any supplement to any of them;

(b) Intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings;

(c) Other than food, minerals, or vitamins intended to affect the structure of any function of the body of human beings; and

(d) Intended for use as a component of any article specified in (a), (b), or (c) of this definition. "Drug" does not include devices or their components, parts, or accessories.

"Excess costs" means costs of appropriate utilization of a prescription drug that exceed the therapeutic benefit relative to other alternative treatments; or, costs of appropriate utilization of a prescription drug that are not sustainable to public and private health care systems over a 10-year time frame.

"Generic drug" has the same meaning as in RCW 69.48.020.

"Health carrier" or **"carrier"** has the same meaning as in RCW 48.43.005.

"Legend drug" means brand drug, generic drug, or biological product which is required by state law or regulation of the pharmacy quality assurance commission to be dispensed on prescription only or are restricted to use by practitioners only.

"Manufacturer" means a person, corporation, or other entity engaged in the manufacture of prescription drugs sold in or into Washington state. "Manufacturer" does not include a private label distributor or retail pharmacy that sells a drug under the retail pharmacy's store, or a prescription drug repackager.

"Out-of-pocket costs" means the amount of money the patient, another person on behalf of the patient, or entity on behalf of the patient paid to the pharmacy each time a prescription is filled, excluding the amount paid by insurance. Out-of-pocket costs include deductibles, coinsurance, and copayments for covered drugs plus all costs for drugs that are not covered.

"Prescription drug" means a drug regulated under chapter 69.41 or 69.50 RCW, including generic drugs, brand name drugs, specialty drugs, and biological products.

"Publicly available" means information that is available to the general public, whether through internet search, Freedom of Information Act request or similar request, or through purchase or subscription, and includes information submitted to or reviewed by the Food and Drug Administration, information contained in financial statements, and information published or otherwise made available through drug information resources. "Publicly available" does not include trade secrets as defined by RCW 19.108.010 and information protected by copyright law. Publicly available information includes:

(a) Drug name;

(b) Drug class;

(c) Price and pricing;

(d) Course of treatment;

(e) Manufacturer name;

(f) Price increase over time;

(g) Competitors; and

(h) Competitor price and pricing.

"Rebate" means negotiated price concessions, discounts, however characterized, that accrue directly or indirectly to a reporting entity in connection with utilization of prescription drugs by reporting entity members including, but not limited to, rebates, administrative

fees, market share rebates, price protection rebates, performance-based price concessions, volume-related rebates, other credits, and any other negotiated price concessions or discounts that are reasonably anticipated to be passed through to a reporting entity during a coverage year, and any other form of price concession prearranged with a covered manufacturer, dispensing pharmacy, pharmacy benefit manager, rebate aggregator, group purchasing organization, or other party which are paid to a reporting entity and are directly attributable to the utilization of certain drugs by reporting entity members.

"Therapeutic alternative" means a drug product that contains a different chemical structure than the drug prescribed but is in the same pharmacologic or therapeutic class and can be expected to have a similar therapeutic effect and adverse reaction profile when administered to individuals in a therapeutically equivalent dose.

"Therapeutic equivalent" means a drug product of the identical base or salt as the specific drug product prescribed with essentially the same efficacy and toxicity when administered to an individual in the same dosage regimen.

NEW SECTION

WAC 182-52-0015 Prescription drug affordability board—Board members. (1) The prescription drug affordability board has five governor-appointed members with expertise in health care economics or clinical medicine. Once appointed, board members serve a five-year term.

(2) The governor may reappoint board members for additional terms.

(3) Board members cannot be an employee of, a board member of, or a consultant to any of the following:

(a) Prescription drug manufacturer;

(b) Pharmacy benefit manager;

(c) Health carrier;

(d) Prescription drug wholesale distributor; or

(e) Trade association related to (a) through (d) of this subsection.

(4) Board members can be replaced or removed under the following circumstances including, but not limited to:

(a) Failure to participate;

(b) Unprofessional/unethical behavior; or

(c) Conflict of interest.

(5) If a board member violates subsection (3) or (4) of this section or other board established policies, the member may be removed from the board.

(6) Following appointment, board members must submit a conflict of interest disclosure form provided by the authority. The conflict of interest disclosure form must be submitted on an annual basis by July 1st of each year while the member is active with the board. Board members must keep their disclosure statements current and provide updated information within 30 calendar days whenever circumstances change.

(7) Board members must recuse themselves from any board activity in which they have a conflict of interest or the appearance of a con-

flict of interest, whether or not it is disclosed in the conflict of interest disclosure form.

(8) Following appointment and prior to participating in board activities, board members must enter into a personal services contract with the authority to be compensated for participation in the work of the board.

NEW SECTION

WAC 182-52-0020 Prescription drug affordability board—Procedures. (1) The board determines by member vote who will be the board chair and vice chair.

(2) The board chair remains as the chair for the duration of their term unless there are violations as stated in WAC 182-52-0015(4).

(3) The board chair may, if they choose, step down from their chair responsibilities but can continue to be an active board member.

(4) In the absence of the board chair, the vice chair acts in their place for that meeting.

(5) If board member vacancies exist, business continues as necessary with the remaining board members, as long as a quorum exists.

(6) A simple majority of the board's membership constitutes a quorum for the purpose of conducting business. If only three board members are present for a vote, the vote must be unanimous in order to pass.

NEW SECTION

WAC 182-52-0025 Prescription drug affordability board—Meetings. (1) The board meets at least once annually, and additionally as defined by board policy.

(2) All board meetings must be open and public, except that the board may hold executive sessions to the extent permitted by chapter 42.30 RCW.

(a) Before convening an executive session, the board chair must publicly announce the purpose for excluding the public from the executive session.

(b) The board chair must announce the executive session place, date, and time.

(c) The executive session may be extended or have the date and time changed by announcement from the board chair.

NEW SECTION

WAC 182-52-0030 Prescription drug affordability board—Advisory groups—Purpose, participation, application process, and operations. (1) The prescription drug affordability board advisory groups provide

stakeholder input to the board regarding the affordability of prescription drugs.

(2) Utilizing administrative support from the authority, the board will establish advisory groups consisting of relevant stakeholders and subject matter experts for each drug selected for a drug affordability review conducted by the board.

(a) Advisory groups will consist of patients and patient advocates for the condition treated by the drug and one representative of the prescription drug industry. Additional group members, as selected by the board may include, but are not limited to, relevant stakeholders and experts in the following subject matters:

(i) The pharmaceutical business model;

(ii) Supply chain business model;

(iii) The practice of medicine or clinical training;

(iv) Health care consumer or patient perspectives;

(v) Health care cost trends and drivers;

(vi) Clinical and health services research;

(vii) The state's health care marketplace; or

(viii) Health care provider who specializes in treating the condition for the drug being reviewed.

(b) To the extent possible, advisory group members will have experience serving underserved communities and reflect the diversity of the state with regard to race, ethnicity, immigration status, income, wealth, disability, age, gender identity, sexual orientation, and geography.

(3) Advisory group members are chosen by the authority. Once members complete the conflict of interest form, they serve on the advisory group(s) through conclusion of the current affordability review. The authority may remove or replace advisory group members for, among other reasons:

(a) Failure to participate;

(b) Unprofessional/unethical behavior; or

(c) Conflict of interest.

(4) Advisory group members cannot be an employee of, a board member of, or a consultant to any of the following:

(a) Prescription drug manufacturer (with the exception that one representative from the prescription drug industry can serve on an advisory group and may be an employee, consultant, or board member of a prescription drug manufacturer or related trade association and will not be deemed to have a conflict of interest, see subsection (2) of this section).

(b) Pharmacy benefit manager;

(c) Health carrier;

(d) Prescription drug wholesale distributor; or

(e) Trade association related to (a) through (d) of this subsection.

(5) If an advisory group member violates any of subsection (4) of this section, the member may be removed from the advisory group(s).

(6) To become a member of advisory groups, the authority will establish an application process to be maintained and posted on the authority's website.

(7) Advisory groups meet on a frequency as determined necessary by the board.

(8) Participation in advisory groups is voluntary. Members of the advisory groups are not compensated.

NEW SECTION

WAC 182-52-0035 Prescription drug affordability board—Review of drug prices. (1) By June 30th of each year, using data considered relevant by the board, the board must identify legend drugs and biologics that:

(a) Have been on the market for at least seven years;

(b) Are dispensed at a retail, specialty, or mail-order pharmacy; and

(c) Are not designated by the FDA under 21 U.S.C. Sec. 360bb as a drug solely for the treatment of a rare disease or condition.

(2) The legend drugs and biologics must meet the following thresholds:

(a) Brand name drugs and biologic products that must have:

(i) A wholesale acquisition cost of $60,000 or more per year or course of treatment lasting less than 12 months; or

(ii) A wholesale acquisition cost increase of 15 percent or more in any 12-month period or for a course of treatment lasting less than 12 months, or a 50 percent cumulative increase during any 36-month period.

(b) A biosimilar product with an initial wholesale acquisition cost that is less than 15 percent lower than the wholesale acquisition cost of the reference biological product, on the date the biosimilar becomes available on the market; and

(c) Generic drugs with a wholesale acquisition cost of $100 or more, for a 30-day supply or course of treatment less than 30 days, that has an increase in price of 200 percent or more in the preceding 12 months.

NEW SECTION

WAC 182-52-0040 Prescription drug affordability board—Affordability review requirements. (1) The board may choose to conduct an affordability review of up to 24 legend drugs or biologics per year and consider the following:

(a) The class of the prescription drug and whether any therapeutically equivalent prescription drugs are available for sale;

(b) Input from relevant advisory groups as listed in this chapter; and

(c) The out-of-pocket cost for the drug.

(2) For drugs chosen for the affordability review, the board must determine whether the drug has led or will lead to excess costs to patients or to public or private health care systems. The board may examine publicly available and confidential information from the prescription drug manufacturer and other sources.

(3) The board, or the authority as directed by the board, may request information from the manufacturer. The requested information must be sent to the authority in the form and manner as published by the authority within 30 calendar days of the date on the request.

(4) The authority may assess a fine against a manufacturer for each failure to comply with a request for information from the board

or the authority on behalf of the board. See WAC 182-52-0075 for information on notification of violation and fine(s).

NEW SECTION

WAC 182-52-0045 Prescription drug affordability board—Drug publication and conducting affordability reviews. Drugs selected for an affordability review are published on the board's website before initiating the affordability review.

(1) When conducting an affordability review, the board will consider:

(a) The relevant factors contributing to the price paid for the prescription drug, including the wholesale acquisition cost, discounts, rebates, and other price concessions;

(b) The average out-of-pocket cost for the drug;

(c) The effect of the price on consumers' access to the drug in the state;

(d) Orphan drug status;

(e) The dollar value and accessibility of patient assistance programs offered by the manufacturer for the drug;

(f) The price and availability of therapeutic alternatives;

(g) Input from:

(i) Patients affected by the condition or disease treated by the drug; and

(ii) Individuals with medical or scientific expertise related to the condition or disease treated by the drug;

(h) Any other information the drug manufacturer or other relevant entity chooses to provide; and

(i) The impact of pharmacy benefit manager policies on the price consumers pay for the drug.

(2) In performing an affordability review of a drug the board may consider the following factors:

(a) Life-cycle management;

(b) The average cost of the drug in the state;

(c) Market competition and context;

(d) Projected revenue;

(e) Off-label usage of the drug; and

(f) Any additional factors identified by the board.

(3) All confidential information collected by the board or the authority under this section is not subject to public disclosure under chapter 42.56 RCW.

NEW SECTION

WAC 182-52-0050 Prescription drug affordability board—Data and confidentiality. (1) For the purpose of reviewing drug prices and conducting affordability reviews, the board (as established in chapter 70.405 RCW) and the health care cost transparency board (established in chapter 70.390 RCW) may access all data collected under RCW

43.71C.020 through 43.71C.080 and any analysis prepared by the authority.

(2) Advisory group members may not access or review any confidential information.

(3) The confidential information provided by manufacturers under this chapter is not subject to public disclosure under chapter 42.56 RCW.

(4) Any confidential information provided under this chapter may not be publicly released. Recipients of data under subsection (1) of this section must:

(a) Follow all rules adopted by the authority regarding appropriate data use and protection; and

(b) Acknowledge that the recipient may be responsible for liability arising from misuse of the data and that the recipient does not have any conflicts under the Ethics in Public Service Act that would prevent the recipient from accessing or using the data.

NEW SECTION

WAC 182-52-0055 Prescription drug affordability board—Authorization to assess fines. (1) RCW 70.405.040 allows the authority to assess a fine(s) against a manufacturer for failure to comply with the requirements of this chapter. See WAC 182-52-0065 for fine(s) for failing to comply with information request(s) and WAC 182-52-0070 for the amount of the fine(s) based on culpability.

(2) The authority may grant an extension of time to an information request deadline under WAC 182-52-0060.

NEW SECTION

WAC 182-52-0060 Prescription drug affordability board—Extension of deadlines. (1) The authority may grant:

(a) An extension of time for an information request submission deadline; or

(b) Permission to correct a previously submitted and accepted request.

(2) Extensions:

(a) The manufacturer or subcontractor may request an extension of time for an information request submission deadline or the resubmission of a request due to circumstances beyond their control affecting the manufacturer's or subcontractor's ability to submit the information by the deadline.

(b) The request for an extension must contain a detailed explanation as to the reason the manufacturer or subcontractor is unable to meet the information request deadline.

(c) The manufacturer or subcontractor must submit a request for an extension to the authority at least 10 calendar days before the applicable deadline unless the manufacturer or subcontractor is unable to meet this deadline due to circumstances beyond their control. If unable to meet the deadline, the manufacturer or subcontractor must

notify the authority in writing as soon as the manufacturer or subcontractor determines that an extension is necessary.

(d) The authority may approve an extension on a case-by-case basis based on the specific circumstances or other circumstances beyond the control of the manufacturer. The authority provides written notification of an approval or denial to the manufacturer or subcontractor within 15 calendar days from the date the authority receives the request from the manufacturer or subcontractor. If the authority does not approve a request for an extension, the written notification includes the reason for the denial. Only the authority can approve or deny a request for an extension.

(e) The manufacturer or subcontractor may not appeal the authority's decision to deny an extension.

NEW SECTION

WAC 182-52-0065 Prescription drug affordability board—Fine(s) for failure to comply with information request(s). (1) The authority may assess a fine of up to $100,000 against a manufacturer for each failure to comply with a request for information from the board or the authority as directed by the board.

(2) The assessment of a fine under this section is subject to review under the Administrative Procedure Act, chapter 34.05 RCW.

NEW SECTION

WAC 182-52-0070 Prescription drug affordability board—Amount of fine(s) based on culpability. (1) In determining the amount of any fine, the authority considers the level of culpability associated with the violation. The levels of culpability, in the order of least severe to most severe, are as follows:

(a) **Did not know.** The manufacturer did not know (and, by exercising reasonable diligence, could not have known) the violation had occurred.

(b) **Reasonable cause.** The manufacturer knew, or by exercising reasonable diligence should have known, that the violation had taken place, but the manufacturer did not act with willful neglect.

(c) **Willful neglect – Corrected.** The violation was due to the manufacturer's intentional failure or reckless indifference, and the violation was corrected within 30 calendar days from the date the manufacturer knew or with reasonable diligence should have known of the violation.

(d) **Willful neglect – Uncorrected.** The violation was due to the manufacturer's intentional failure or reckless indifference, and the violation was not corrected within 30 calendar days from the date the manufacturer knew or with reasonable diligence should have known of the violation.

(2) Culpability and fines.

Culpability Category	Fines Per Violation
Did not know	$25,000

Culpability Category	Fines Per Violation
Reasonable cause	$50,000
Willful neglect – Corrected	$75,000
Willful neglect – Uncorrected	$100,000

NEW SECTION

WAC 182-52-0075 Prescription drug affordability board—Advisory notice, notice of violation, and fine(s). (1) The authority will issue an advisory notice to the manufacturer for the initial request for information directing the manufacturer to comply within 30 calendar days of the request or request an extension of time to provide the required information, in accordance with WAC 182-52-0060.

(2) If the manufacturer fails to comply with the initial request for information within 30 calendar days, the authority may assess a fine(s). The authority will mail a preliminary notice of violation to the manufacturer's last known address in a manner that provides proof of receipt by the manufacturer.

(3) The preliminary notice of violation and fine(s) will include the following information:

(a) The specific reasons and criteria that support the imposition of the assessed fine(s);

(b) The legal authority that supports the imposition of a fine(s);

(c) The amount of the fine(s); and

(d) An explanation of the manufacturer's right to request an informal dispute resolution conference.

NEW SECTION

WAC 182-52-0080 Prescription drug affordability board—Appeal determination of a violation and assessed fine(s). (1) Each manufacturer to whom the authority issues a preliminary notice of violation and fine(s) may request an informal dispute resolution conference. If the manufacturer does request an informal dispute resolution conference, then the manufacturer must complete the process before requesting an administrative hearing.

(2) In lieu of an informal dispute resolution conference, the manufacturer may request an administrative hearing, under WAC 182-52-0090, in writing, in a manner that provides proof of receipt by the authority, within 28 calendar days after receipt of the notice of violation and fine(s). Upon receipt of the manufacturer's request for administrative hearing, the authority will issue a final notice of violation and fine(s) with an explanation of the manufacturer's administrative hearing rights (See WAC 182-52-0090).

(3) If the manufacturer does not request an informal dispute resolution conference or administrative hearing within 28 calendar days after receipt of the preliminary notice of violation and fine(s), the

authority issues a final notice of violation with an explanation of the manufacturer's administrative hearing rights (See WAC 182-52-0090).

NEW SECTION

WAC 182-52-0085 Prescription drug affordability board—Informal dispute resolution process prior to an administrative hearing. (1) The manufacturer may informally dispute the authority's determination of a violation under this chapter.

(2) The manufacturer must submit a request for an informal dispute resolution conference to the authority in writing, in a manner that provides proof of receipt by the authority, within 28 calendar days after receipt of the notice violation and fine(s).

(3) Requests must specify:

(a) The name of the manufacturer requesting the informal dispute resolution conference and the manufacturer's, or representative's, mailing address, telephone number, and email address (if available);

(b) The items, facts, or conclusions in the notice of violation being contested; and

(c) The basis for contesting the authority's action, including any mitigating factors upon which the manufacturer relies and the outcome the manufacturer is seeking.

(4) The conference occurs within 60 calendar days of the date the manufacturer received the authority's written acceptance of the request for a dispute resolution conference.

(5) The manufacturer must notify the authority of who will attend the dispute resolution conference on the manufacturer's behalf at least five business days before the conference.

(6) The authority may terminate the dispute resolution process at any time and will provide the manufacturer with the reason for the termination.

(7) Upon completion or termination of the informal dispute resolution process, the authority will issue a final notice of violation and fine(s).

(8) Nothing in this chapter prevents settlement discussions between the parties. All settlement discussions are informal and without prejudice to the rights of the participants in the discussions.

NEW SECTION

WAC 182-52-0090 Prescription drug affordability board—Administrative hearing rights. A manufacturer has a right to an administrative hearing under chapters 34.05 RCW and 182-526 WAC, if the authority assesses a notice of violation and fine(s) against the manufacturer.