(Effective June 10, 2024)

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 any entity 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.

"Data recipient" means an individual or entity authorized to receive data under chapter 70.405 RCW.

"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.

"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 deducti-

bles, 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 an entity in connection with utilization of prescription drugs 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 an entity during a coverage year, and any other form of price concession prearranged with a manufacturer, dispensing pharmacy, pharmacy benefit manager, rebate aggregator, group purchasing organization, or other party which are paid to an entity and are directly attributable to the utilization of certain drugs.

"Therapeutic alternative" means a drug product that may contain a different chemical or biological structure than the drug prescribed 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.

[Statutory Authority: RCW 41.05.021, 41.05.160, chapter 70.405 RCW, and 2022 c 153. WSR 24-02-078, § 182-52-0010, filed 1/2/24, effective 6/10/24.]