WAC 182-51-0100 Definitions. For the purposes of this chapter:

(1) "Authority" means the health care authority.

(2) "Calendar days" means the same as in WAC 182-526-0010.

(3) "Calendar year" means the period from January 1st to December 31st of each year.

(4) "Confidential information" means information collected by the authority according to RCW 43.71C.020 through 43.71C.080, which is not subject to public disclosure under chapter 42.56 RCW and must be held confidential by all data recipients, according to WAC 182-51-0900.

(5) "Course of treatment" means the duration of the actual administration of a drug to treat a condition.

(6) "Covered drug" means any prescription drug that:

(a) A covered manufacturer intends to introduce to market at a wholesale acquisition cost of $10,000 or more for a course of treatment lasting less than one month or a 30-day supply, whichever period is longer; or

(b) Meets all of the following:

(i) Has been introduced to market;

(ii) Is manufactured by a covered manufacturer; and

(iii) Has a wholesale acquisition cost of more than $100 for a course of treatment lasting less than one month or a 30-day supply, and, taking into account only price increases that take effect on or after October 1, 2019, the manufacturer increases the wholesale acquisition cost such that:

(A) The new wholesale acquisition cost is 20 percent higher than the wholesale acquisition cost on the same day of the month, 12 months before the date of the proposed increase; or

(B) The new wholesale acquisition cost is 50 percent higher than the wholesale acquisition cost on the same day of the month, 36 months before the date of the proposed increase.

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

(8) "Data" means all data provided to the authority under RCW 43.71C.020 through 43.71C.080 and any analysis prepared by the authority.

(9) "Data recipient" means an individual or entity authorized to receive data under RCW 43.71C.100.

(10) "Data submission guide" means the document that identifies the data required under chapter 43.71C RCW, and provides instructions for submitting this data to the authority, including guidance on required format for reporting, for each reporting entity.

(11) "Food and drug administration (FDA) approval date" means the deadline for the FDA to review applications for new drugs or new biologics after the new drug application or biologic application is accepted by the FDA as complete in accordance with the Prescription Drug User Fee Act of 1992 (106 Stat. 4491; P.L. 102-571).

(12) "Health plan," "health carrier," and "carrier" mean the same as in RCW 48.43.005.

(13) "Introduced to market" or "introduce to market" means to make available for purchase in Washington state.

(14) "Pharmacy benefit manager" means the same as defined in RCW 48.200.020.

(15) "Pharmacy services administrative organization" means an entity that:

(a) Contracts with a pharmacy to act as the pharmacy's agent with respect to matters involving a pharmacy benefit manager, third-party payor, or other entities, including negotiating, executing, or administering contracts with the pharmacy benefit manager, third-party payor, or other entities; and

(b) Provides administrative services to pharmacies.

(16) "Pipeline drug" means a drug or biologic product, not yet approved by the Food and Drug Administration, for which a manufacturer intends to seek initial approval from the Food and Drug Administration under an original new drug application under 21 U.S.C. Sec. 355(b) or under a biologics license application under 42 U.S.C. Sec. 262.

(17) "Prescription drug" means a drug regulated under chapter 69.41 or 69.50 RCW that is prescribed for outpatient use and distributed in a retail setting, including generic, brand name, specialty drugs, and biological products.

(18) "Private label distributor" means a firm that does not participate in the manufacture or processing of a drug but instead markets and distributes under its own trade name, and labels a drug product made by someone else.

(19) "Public domain" means information that is available to the general public, whether through internet search, Freedom of Information Act 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. "Public domain" does not include trade secrets as defined by RCW 19.108.010 and information protected by copyright law.

(20) "Qualifying price increase" means a price increase described in subsection (6)(b) of this section.

(21) "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.

(22) "Reporting entity" means carriers, covered manufacturers, health carriers, health plans, pharmacy benefit managers, and pharmacy services administrative organizations, which are required to or voluntarily submit data according to chapter 43.71C RCW.

(23) "Wholesale acquisition cost" means, with respect to a prescription drug, the manufacturer's list price for the drug to wholesalers or direct purchasers in the United States, excluding any discounts, rebates, or reductions in price, for the most recent month for which the information is available, as reported in wholesale acquisition cost guides or other publications containing prescription drug prices.

[Statutory Authority: RCW 41.05.021, 41.05.160, and 43.71C.110. WSR 22-17-075, § 182-51-0100, filed 8/16/22, effective 9/16/22. Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 21-18-046, § 182-51-0100,

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