

WSR 21-13-167
EXPEDITED RULES
HEALTH CARE AUTHORITY
[Filed June 23, 2021, 10:33 a.m.]

Title of Rule and Other Identifying Information: WAC 182-51-0100 Definitions.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: To correct a typographical error.

Reasons Supporting Proposal: The health care authority (HCA) is amending this rule to correct an erroneous cross-reference in subsection (18). The cross-reference should refer to WAC 182-51-0100 (5)(b), rather than subsection (3)(b).

Statutory Authority for Adoption: RCW 41.05.021, 41.05.160.

Statute Being Implemented: RCW 41.05.021, 41.05.160.

Rule is not necessitated by federal law, federal or state court decision.

Name of Proponent: HCA, governmental.

Name of Agency Personnel Responsible for Drafting: Jason Crabbe, P.O. Box 42716, Olympia, WA 98504-2716, 360-725-9563; Implementation and Enforcement: Julie Colacurcio, P.O. Box 45506, Olympia, WA 98504-5506, 360-725-9585.

Agency Comments or Recommendations, if any, as to Statutory Language, Implementation, Enforcement, and Fiscal Matters: Not applicable.

This notice meets the following criteria to use the expedited adoption process for these rules:

Corrects typographical errors, make address or name changes, or clarify language of a rule without changing its effect.

Explanation of the Reason the Agency Believes the Expedited Rule-Making Process is Appropriate: This rule making is for correction purposes only as allowed by RCW 34.05.353 (1)(c).

NOTICE

THIS RULE IS BEING PROPOSED UNDER AN EXPEDITED RULE-MAKING PROCESS THAT WILL ELIMINATE THE NEED FOR THE AGENCY TO HOLD PUBLIC HEARINGS, PREPARE A SMALL BUSINESS ECONOMIC IMPACT STATEMENT, OR PROVIDE RESPONSES TO THE CRITERIA FOR A SIGNIFICANT LEGISLATIVE RULE. IF YOU OBJECT TO THIS USE OF THE EXPEDITED RULE-MAKING PROCESS, YOU MUST EXPRESS YOUR OBJECTIONS IN WRITING AND THEY MUST BE SENT TO Wendy Barcus, HCA Rules Coordinator, P.O. Box 42716, Olympia, WA 98504-2716, phone 360-725-1306, fax 360-586-9272, email arc@hca.wa.gov, AND RECEIVED BY August 24, 2021.

June 23, 2021
Wendy Barcus
Rules Coordinator

OTS-3120.1

AMENDATORY SECTION (Amending WSR 21-10-008, filed 4/22/21, effective 5/23/21)

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) "Covered drug" means any prescription drug that:
 - (a) A covered manufacturer intends to introduce to the market in Washington state at a wholesale acquisition cost of ten thousand dollars or more for a course of treatment lasting less than one month or a thirty-day supply, whichever period is longer; or
 - (b) Meets all of the following:
 - (i) Is currently on the market in Washington state;
 - (ii) Is manufactured by a covered manufacturer; and
 - (iii) Has a wholesale acquisition cost of more than one hundred dollars for a course of treatment lasting less than one month or a thirty-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 twenty percent higher than the wholesale acquisition cost on the same day of the month, twelve months before the date of the proposed increase; or
 - (B) The new wholesale acquisition cost is fifty percent higher than the wholesale acquisition cost on the same day of the month, thirty-six months before the date of the proposed increase.
- (6) "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.
- (7) "Data" means all data provided to the authority under RCW 43.71C.020 through 43.71C.080 and any analysis prepared by the authority.
- (8) "Data recipient" means an individual or entity authorized to receive data under RCW 43.71C.100.
- (9) "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.
- (10) "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).
- (11) "Health plan," "health carrier," and "carrier" mean the same as in RCW 48.43.005.
- (12) "Introduced to market" means marketed in Washington state.
- (13) "Pharmacy benefit manager" means the same as defined in RCW 19.340.010.
- (14) "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 admin-

istering contracts with the pharmacy benefit manager, third-party payor, or other entities; and

(b) Provides administrative services to pharmacies.

(15) "Pipeline drug" means a drug or biologic product containing a new molecular entity, 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 to be marketed in Washington state.

(16) "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.

(17) "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.

(18) "Qualifying price increase" means a price increase described in subsection ~~((3))~~ (5)(b) of this section.

(19) "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.

(20) "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.

(21) "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 of prescription drug pricing.

[Statutory Authority: RCW 41.05.021, 41.05.160, 43.71C.010, 43.71C.050, 43.71C.100, and 43.71C.110. WSR 21-10-008, § 182-51-0100, filed 4/22/21, effective 5/23/21. Statutory Authority: RCW 41.05.021, 41.05.160 and 2019 c 334. WSR 20-19-079, § 182-51-0100, filed 9/15/20, effective 10/16/20.]