

## WSR 21-06-099

## PROPOSED RULES

## HEALTH CARE AUTHORITY

[Filed March 2, 2021, 3:04 p.m.]

Original Notice.

Preproposal statement of inquiry was filed as WSR 20-22-098.

Title of Rule and Other Identifying Information: WAC 182-51-0100 Definitions, 182-51-0600 Manufacturers—Data and price reporting, and 182-51-0900 Data confidentiality.

Hearing Location(s): On April 6, 2021, at 10:00 a.m. In response to the coronavirus disease 2019 (COVID-19) public health emergency, the agency will not provide a physical location for this hearing. This promotes social distancing and the safety of the citizens of Washington state. A virtual public hearing, without a physical meeting space, will be held instead. To attend the virtual public hearing, you must register at the following link <https://attendee.gotowebinar.com/register/1443618498460852747>, Webinar ID 560-087-099. After registering, you will receive a confirmation email containing the information about joining the webinar.

Date of Intended Adoption: Not sooner than April 7, 2021.

Submit Written Comments to: Health Care Authority (HCA), Rules Coordinator, P.O. Box 42716, Olympia, WA 98504-2716, email [arc@hca.wa.gov](mailto:arc@hca.wa.gov), fax 360-586-9727, by April 6, 2021.

Assistance for Persons with Disabilities: Contact Amber Lougheed, phone 360-725-1349, fax 360-586-9727, telecommunication[s] relay service 711, email [amber.lougheed@hca.wa.gov](mailto:amber.lougheed@hca.wa.gov), by March 19, 2021.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: HCA is amending these rules to change the timeframe manufacturers have to report to HCA new covered drugs being introduced to market in Washington and to add the contents of the prescription drug pricing transparency program's nondisclosure agreement.

Reasons Supporting Proposal: See purpose.

Statutory Authority for Adoption: RCW 41.05.021, 41.05.160, and 43.71C.110.

Statute Being Implemented: RCW 41.05.021, 41.05.160, 43.71C.010, 43.71C.050, and 43.71C.100.

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

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

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: Donna Sullivan, P.O. Box 45502, Olympia, WA 98504-5502, 360-725-1564.

A school district fiscal impact statement is not required under RCW 28A.305.135.

A cost-benefit analysis is not required under RCW 34.05.328. RCW 34.05.328 does not apply to HCA rules unless requested by the joint administrative rules review committee or applied voluntarily.

This rule proposal, or portions of the proposal, is exempt from requirements of the Regulatory Fairness Act because the proposal:

Is exempt under RCW 19.85.025(3) as the rule content is explicitly and specifically dictated by statute.

March 2, 2021  
Wendy Barcus  
Rules Coordinator

**OTS-2847.2**

AMENDATORY SECTION (Amending WSR 20-19-079, filed 9/15/20, effective 10/16/20)

**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 (~~July 28~~) 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.

~~((5))~~ (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.

~~((6))~~ (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.

~~((7))~~ (8) "Data recipient" means an individual or entity authorized to receive data under RCW 43.71C.100.

~~((8))~~ (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.

~~((9))~~ (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).

~~((10))~~ (11) "Health plan," "health carrier," and "carrier" mean the same as in RCW 48.43.005.

~~((11))~~ (12) "Introduced to market" means marketed in Washington state.

~~((12))~~ (13) "Pharmacy benefit manager" means the same as defined in RCW 19.340.010.

~~((13))~~ (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 administering contracts with the pharmacy benefit manager, third-party payor, or other entities; and

(b) Provides administrative services to pharmacies.

~~((14))~~ (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.

~~((15))~~ (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.

~~((16))~~ (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.

~~((17))~~ (18) "Qualifying price increase" means a price increase described in subsection (3)(b) of this section.

~~((18))~~ (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.

~~((19))~~ (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.

~~((20))~~ (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 and 2019 c 334. WSR 20-19-079, § 182-51-0100, filed 9/15/20, effective 10/16/20.]

AMENDATORY SECTION (Amending WSR 20-19-079, filed 9/15/20, effective 10/16/20)

**WAC 182-51-0600 Manufacturers—Data and price reporting.** (1) On or before December 31, 2020, a covered manufacturer must submit to the authority all data specified in RCW 43.71C.050 and 43.71C.070, ~~((the))~~ following the guidelines set in the authority's applicable data submission guide for each covered drug ~~((as the drug existed between and including July 28, 2019, and August 17))~~ introduced to market, or a covered drug that had a qualifying price increase between and including October 1, 2019, and October 15, 2020.

(2) Beginning October 16, 2020, a covered manufacturer must submit to the authority all data specified in RCW 43.71C.050 and 43.71C.070, following the guidelines set in the authority's applicable data submission guide, for each covered drug as follows:

(a) Sixty days in advance of a qualifying price increase for a covered drug marketed in Washington state; or

(b) Within thirty days ~~((in advance))~~ of a new covered ~~((drug's introduction))~~ drug introduced to market in Washington state.

(3) For any drug approved under section 505(j) of the federal Food, Drug, and Cosmetic Act as it existed on August 18, 2020, or a biosimilar approved under section 351(k) of the federal Public Health Service Act as it existed on August 18, 2020, if submitting data in accordance with subsection (2) (a) of this section is not possible sixty days before the price increase ~~((; or if submitting data in accordance with subsection (2) (b) of this section is not possible thirty days before the introduction to market))~~, that submission must be made as soon as known but no later than the date of the price increase ~~((or introduction to market))~~.

(4) The information submitted according to this section is not subject to public disclosure under chapter 42.56 RCW.

(5) The authority may assess fines for not complying with the requirements in this section. See WAC 182-51-1100.

[Statutory Authority: RCW 41.05.021, 41.05.160 and 2019 c 334. WSR 20-19-079, § 182-51-0600, filed 9/15/20, effective 10/16/20.]

AMENDATORY SECTION (Amending WSR 20-19-079, filed 9/15/20, effective 10/16/20)

**WAC 182-51-0900 Data confidentiality.** (1) The authority provides data only after the data recipient, as defined by this chapter, has signed a nondisclosure agreement. The authority may prohibit ac-

cess to or use of the data by a data recipient who violates the nondisclosure agreement.

(2) Data recipients must keep data confidential by:

(a) Accessing, using, and disclosing information only in accordance with this section and consistent with applicable statutes, regulations, and policies;

(b) Having a public policy purpose to access and use the confidential information according to chapter 43.71C RCW;

(c) Protecting all confidential information against unauthorized use, access, disclosure, or loss by employing reasonable security measures, including physically securing any computers, documents, or other media containing confidential information and viewing confidential information only on secure workstations in nonpublic areas;

(d) Destroying all confidential information when it is no longer needed to perform authorized activities; and

(e) Adhering to the confidentiality requirements in this section after the data recipient is no longer an authorized data recipient under RCW 43.71C.100.

(3) Data recipients must not:

(a) Disclose any confidential information, as defined by WAC 182-51-0100, or otherwise publicly release the confidential information;

(b) Use or disclose any confidential information for any commercial or personal purpose, or any other purpose that is not authorized in chapter 43.17C RCW;

(c) Attempt to identify people who are the subject of the confidential information;

(d) Discuss confidential information in public spaces in a manner in which unauthorized individuals could overhear;

(e) Discuss confidential information with unauthorized individuals, including spouses, domestic partners, family members, or friends;

(f) Have any conflicts of interests under the ethics in public service act that would prevent the data recipient from accessing or using confidential information; and

(g) Share information with any person, including a legislator or legislative staff member, who either is not authorized to receive confidential information or has not signed a nondisclosure agreement with the authority.

[Statutory Authority: RCW 41.05.021, 41.05.160 and 2019 c 334. WSR 20-19-079, § 182-51-0900, filed 9/15/20, effective 10/16/20.]