

WSR 22-13-045

PROPOSED RULES

HEALTH CARE AUTHORITY

[Filed June 7, 2022, 2:45 p.m.]

Original Notice.

Preproposal statement of inquiry was filed as WSR 22-03-057.

Title of Rule and Other Identifying Information: WAC 182-51-0050 Authority and purpose, 182-51-0100 Definitions, 182-51-0200 Reporting entity registration, 182-51-0300 Health carriers—Cost utilization data reporting, 182-51-0400 Pharmacy benefit managers—Data reporting, 182-51-0600 Manufacturers—Data and price reporting, 182-51-1200 Extension of deadlines, and 182-51-1600 Process to appeal determination of a violation and assessed fines.

Hearing Location(s): On July 26, 2022, at 10:00 a.m. In response to the coronavirus disease 2019 (COVID-19) public health emergency, the health care authority (HCA) continues to hold public hearings virtually without a physical meeting place. This promotes social distancing and the safety of Washington state residents. To attend the virtual public hearing, you must register in advance https://us02web.zoom.us/webinar/register/WN_okdBeytITLCb2dmAfv3rBA. If the link above opens with an error message, please try using a different browser. After registering, you will receive a confirmation email containing information about joining the public hearing.

Date of Intended Adoption: Not sooner than July 27, 2022.

Submit Written Comments to: HCA Rules Coordinator, P.O. Box 42716, Olympia, WA 98504-2716, email arc@hca.wa.gov, fax 360-586-9727, by July 26, 2022, by 11:59 p.m.

Assistance for Persons with Disabilities: Contact HCA rules coordinator, phone 360-725-1306, fax 360-586-9727, telecommunication[s] relay service 711, email arc@hca.wa.gov, by July 15, 2022.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: The agency is amending sections of chapter 182-51 WAC, the drug price transparency program, to increase program clarity by adding definitions and rewording requirements.

Reasons Supporting Proposal: See purpose.

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

Statute Being Implemented: RCW 41.05.021, 41.05.160, 43.71C.110.

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: Brian Jensen, P.O. Box 42716, Olympia, WA 98504-2716, 360-725-0815; Implementation and Enforcement: Julie Colacurcio, P.O. Box 45502, Olympia, WA 98504-5502, 360-725-9585.

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.

June 7, 2022
Wendy Barcus
Rules Coordinator

OTS-3573.4

Chapter 182-51 WAC
((PRESCRIPTION)) DRUG ((PRICING)) PRICE TRANSPARENCY PROGRAM

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

WAC 182-51-0050 Authority and purpose. (1) Under the authority of chapter 43.71C RCW, this chapter implements the Washington ((~~pre-~~scription)) drug ((~~pricing~~)) price transparency program.

(2) The purpose of the Washington ((~~prescription~~)) drug ((~~pricing~~)) price transparency program is to ((~~provide notice and disclosure of information~~)) improve transparency relating to the cost and ((~~pricing~~)) price of prescription drugs ((~~in order~~)) to provide accountability to the state for rising drug costs and a consumer's ability to afford prescription drugs ((~~pricing~~)).

(3) The authority publishes a data submission guide to the authority's website, detailing the data elements to report as required by chapter 43.71C RCW, and how to submit the data.

[Statutory Authority: RCW 41.05.021, 41.05.160 and 2019 c 334. WSR 20-19-079, § 182-51-0050, filed 9/15/20, effective 10/16/20.]

AMENDATORY SECTION (Amending WSR 21-18-046, filed 8/25/21, effective 9/25/21)

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) "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 ((~~the~~)) market ((~~in Washington state~~)) at a wholesale acquisition cost of ((~~ten thou-~~

~~sand dollars))~~ \$10,000 or more for a course of treatment lasting less than one month or a ~~((thirty-day))~~ 30-day supply, whichever period is longer; or

(b) Meets all of the following:

(i) ~~((Is currently on the))~~ Has been introduced to market ~~((in Washington state))~~;

(ii) Is manufactured by a covered manufacturer; and

(iii) Has a wholesale acquisition cost of more than ~~((one hundred dollars))~~ \$100 for a course of treatment lasting less than one month or a ~~((thirty-day))~~ 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 ~~((twenty))~~ 20 percent higher than the wholesale acquisition cost on the same day of the month, ~~((twelve))~~ 12 months before the date of the proposed increase; or

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

~~((+6))~~ (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.

~~((+7))~~ (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.

~~((+8))~~ (9) "Data recipient" means an individual or entity authorized to receive data under RCW 43.71C.100.

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

~~((+10))~~ (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).

~~((+11))~~ (12) "Health plan," "health carrier," and "carrier" mean the same as in RCW 48.43.005.

~~((+12))~~ (13) "Introduced to market" or "introduce to market" means ~~((marketed))~~ to make available for purchase in Washington state.

~~((+13))~~ (14) "Pharmacy benefit manager" means the same as defined in RCW ~~((19.340.010))~~ 48.200.020.

~~((+14))~~ (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.

~~((+15))~~ (16) "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))~~ (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.

~~((17))~~ (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.

~~((18))~~ (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 ~~((5))~~ (6)(b) of this section.

~~((19))~~ (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.

~~((20))~~ (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.

~~((21))~~ (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 ~~((of))~~ containing prescription drug ~~((pricing))~~ prices.

[Statutory Authority: RCW 41.05.021 and 41.05.160. WSR 21-18-046, § 182-51-0100, filed 8/25/21, effective 9/25/21. 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.]

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

WAC 182-51-0200 Reporting entity registration. (1) (~~No later than August 1st of each year,~~) A reporting entity must register with the authority and provide the required contact information as defined in the applicable data submission guide. Reregistration is required only if ((there is a change in)) the contact information previously provided has changed.

(2) It is the responsibility of the reporting entity to maintain current and accurate contact information with the authority.

(3) Failure to register and provide or maintain accurate contact information with the authority may result in a reporting entity's inability to submit required data in compliance with this chapter.

[Statutory Authority: RCW 41.05.021, 41.05.160 and 2019 c 334. WSR 20-19-079, § 182-51-0200, filed 9/15/20, effective 10/16/20.]

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

WAC 182-51-0300 Health carriers—Cost utilization data reporting. (1) No later than October 16, 2020, a health carrier must submit to the authority the prescription drug cost and utilization data for calendar years 2018 and 2019, for each health plan it offered in Washington state in calendar years 2018 and 2019, following the guidelines set in the authority's applicable data submission guide.

(2) Beginning October 1, 2021, and no later than October 1st annually thereafter, a health carrier must submit to the authority the prescription drug cost and utilization data for the previous calendar year for each health plan it offered in Washington state, following the guidelines set in the authority's applicable data submission guide.

(3) A carrier may voluntarily submit the data described in subsection (1) of this section for ~~((any))~~ other health plans it administers such as employer-sponsored, self-funded health plans; Taft-Hartley trust health plans; worker's compensation plans; medicare Part D plans; ((or)) medicare advantage plans ((it administers)); or medicaid managed care plans.

(4) 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, § 182-51-0300, filed 9/15/20, effective 10/16/20.]

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

WAC 182-51-0400 Pharmacy benefit managers—Data reporting. (1) No later than March 1st of each year, a pharmacy benefit manager must submit to the authority all data specified in RCW 43.71C.030, follow-

ing the guidelines set in the authority's applicable data submission guide.

(2) The authority may examine or audit a pharmacy benefit manager's financial records to ensure the information submitted under this section is accurate. Information the authority acquires in an examination of financial records according to this subsection is treated as proprietary and confidential. The information collected according to this subsection is not subject to public disclosure under chapter 42.56 RCW.

(3) A pharmacy benefit manager may voluntarily submit the data described in subsection (1) of this section for ~~((any))~~ other health plans it administers such as employer-sponsored, self-funded health plans; Taft-Hartley trust health plans; worker's compensation plans; medicare Part D plans; ((or)) medicare advantage plans ((it administers)); or medicaid managed care plans.

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

(5) The agency 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, § 182-51-0400, filed 9/15/20, effective 10/16/20.]

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

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, following the guidelines set in the authority's applicable data submission guide for each new covered drug 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 ~~((s))~~ increase for a covered drug ~~((marketed in Washington state))~~ already introduced to market; or

(b) Within ~~((thirty))~~ 30 days of a new covered 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))~~ 60 days before the price increase, that submission must be made as soon as known but no later than the date of the price increase.

(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, 43.71C.010, 43.71C.050, 43.71C.100, and 43.71C.110. WSR 21-10-008, § 182-51-0600, 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, § 182-51-0600, filed 9/15/20, effective 10/16/20.]

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

WAC 182-51-1200 Extension of deadlines. (1) The authority may grant:

(a) An extension of time to a reporting requirement deadline; or
(b) Permission to correct a previously submitted ((data)) and accepted report.

(2) Extensions.

(a) A reporting entity may request an extension of time for submitting a report or the resubmission of a report due to extenuating circumstances affecting the reporting entity's ability to submit the data by the deadline.

(b) The request for an extension must contain a detailed explanation as to the reason the reporting entity is unable to meet the reporting requirements for that period.

(c) A reporting entity must submit a request for an extension to the authority at least ~~((thirty))~~ 30 calendar days before the applicable reporting deadline unless the requestor is unable to meet this deadline due to circumstances beyond the reporting entity's control. If unable to meet this deadline, the reporting entity must notify the authority in writing as soon as the reporting entity determines that an extension is necessary.

(d) The authority may approve a request for an extension for a period of time based on the specific circumstances or other extenuating circumstances. The authority provides written notification of the approval or denial to the requestor within ~~((fifteen))~~ 15 calendar days from when the authority receives the request from the reporting entity. If the authority does not approve a request for an extension, the written notification includes the reason for the denial.

(e) A reporting entity may not appeal the authority's decision to deny an extension.

[Statutory Authority: RCW 41.05.021, 41.05.160 and 2019 c 334. WSR 20-19-079, § 182-51-1200, filed 9/15/20, effective 10/16/20.]

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

WAC 182-51-1600 Process to appeal determination of a violation and assessed fines. (1) Each reporting entity to whom the authority issues a preliminary notice of a violation and fine(s) may request ~~((and))~~ an informal dispute resolution conference under WAC 182-51-1700.

(2) If the reporting entity requests an informal dispute resolution conference under WAC 182-51-1700, the reporting entity must com-

plete the informal dispute resolution process before requesting an administrative hearing.

(3) In lieu of an informal dispute resolution conference, the reporting entity may request a formal appeal under WAC 182-51-1800 in writing, in a manner that provides proof of receipt, within (~~twenty-eight~~) 28 calendar days after receipt of the preliminary notice of violation and fine(s). Upon receipt (~~for~~) of the reporting entity's request, the authority issues a final notice of violation and fine(s) with an explanation of the reporting entity's administrative hearing rights under WAC 182-51-1800.

(4) If the reporting entity does not request an informal dispute resolution conference or formal appeal within (~~twenty-eight~~) 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 reporting entity's administrative hearing rights under WAC 182-51-1800.

[Statutory Authority: RCW 41.05.021, 41.05.160 and 2019 c 334. WSR 20-19-079, § 182-51-1600, filed 9/15/20, effective 10/16/20.]