RULE-MAKING ORDER
PERMANENT RULE ONLY

CR-103P (December 2017)
(Implements RCW 34.05.360)

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: April 22, 2021
TIME: 2:55 PM

WSR 21-10-008

Agency: Health Care Authority

Effective date of rule:

Permanent Rules

☒ 31 days after filing.

☐ Other (specify) _____ **(If less than 31 days after filing, a specific finding under RCW 34.05.380(3) is required and should be stated below)**

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?

☐ Yes ☒ No If Yes, explain:

Purpose: 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.

Citation of rules affected by this order:

New:
Repealed:
Amended: 182-51-0100, 182-51-0600, and 182-51-0900
Suspended:

Statutory authority for adoption: RCW 41.05.021, 41.05.160

Other authority: 43.71C.010, 43.71C.050, 43.71C.100, and 43.71C.110

PERMANENT RULE (Including Expedited Rule Making)

Adopted under notice filed as WSR 21-06-099 on March 2, 2021 (date).

Describe any changes other than editing from proposed to adopted version:

Proposed/Adopted	WAC Subsection	Reason
WAC 182-51-0900(3)(g)		
Proposed	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.	HCA made this change as a result of stakeholder comments.
Adopted	Share information received according to this chapter~~,~~ ~~including a legislator or legislative staff member,~~ with any person who ~~either~~ is not authorized to receive confidential information ~~or has not signed a nondisclosure agreement with the authority~~ as specified by this chapter.	

If a preliminary cost-benefit analysis was prepared under RCW 34.05.328, a final cost-benefit analysis is available by contacting:

Name:
Address:
Phone:
Fax:
TTY:

Email:
Web site:
Other:

Note: If any category is left blank, it will be calculated as zero. No descriptive text.

Count by whole WAC sections only, from the WAC number through the history note. A section may be counted in more than one category.

The number of sections adopted in order to comply with:

	New	Amended	Repealed
Federal statute:			
Federal rules or standards:			
Recently enacted state statutes:		3	

The number of sections adopted at the request of a nongovernmental entity:

New	Amended	Repealed

The number of sections adopted on the agency's own initiative:

New	Amended	Repealed

The number of sections adopted in order to clarify, streamline, or reform agency procedures:

New	Amended	Repealed

The number of sections adopted using:

	New	Amended	Repealed
Negotiated rule making:			
Pilot rule making:			
Other alternative rule making:		3	

Date Adopted: April 22, 2021

Name: Wendy Barcus

Title: HCA Rules Coordinator

Signature:

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.

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 prices 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.

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 access 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 received according to this chapter with any person who is not authorized to receive confidential information as specified by this chapter.