RULE-MAKING ORDER
PERMANENT RULE ONLY

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

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FILED

DATE: September 15, 2020
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WSR 20-19-079

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: To implement the Washington Prescription Drug Pricing Transparency Program as required under Chapter 43.71C RCW.

Citation of rules affected by this order:

New: 182-51-0050, 182-51-0100, 182-51-0200, 182-51-0300, 182-51-0400, 182-51-0500, 182-51-0600, 182-51-0700, 182-51-0800, 182-51-0900, 182-51-1000, 182-51-1100, 182-51-1200, 182-51-1300, 182-51-1400, 182-51-1500, 182-51-1600, 182-51-1700,182-51-1800

Repealed:

Amended:

Suspended:

Statutory authority for adoption: RCW 41.05.021, 41.05.160, and ESSHB 1224, Chapter 334, Laws of 2019

Other authority: N/A

PERMANENT RULE (Including Expedited Rule Making)

Adopted under notice filed as WSR 20-15-146 on July 21, 2020 (date).

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

Proposed/Adopted	WAC Subsection	Reason
WAC 182-51-0050(3)		
Proposed	(3) Reporting entities must comply with the authority's processes for submitting data as outlined in the authority's data submission guides as published on the authority's website.	To clarify in rule the function of the data submission guides.
Adopted	(3) ~~Reporting entities must comply with the authority's processes for submitting data as outlined in the authority's data submission guides as published on the authority's website.~~ 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.	
WAC 182-51-0100 New subsection (3)		
Proposed	N/A	To clarify what HCA means by this term as it is used in this chapter.
Adopted	(3) "Calendar year" means the period from January 1 to December 31 of each year.	

	(4) "Covered drug" means…	Because of this addition, the subsequent subsections were renumbered.
WAC 182-51-0100(3)(a)		
Proposed	(3)(a) A covered manufacturer intends to introduce to the market 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	To clarify that the introduction to market is in Washington state.
Adopted	~~(3)~~(4)(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	
WAC 182-51-0100(3)(b)(i)		
Proposed	(3)(b) Meets all of the following: (i) Is currently on the market;	To clarify that the introduction to market is in Washington state.
Adopted	~~(3)~~(4)(b) Meets all of the following: (i) Is currently on the market in Washington State;	
WAC 182-51-0100(3)(b)(iii)		
Proposed	(3)(b)(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 after July 28, 2019, the manufacturer increases the wholesale acquisition cost at least: (A) Twenty percent, including the proposed increase and the cumulative increase over one calendar year before the date of the proposed increase; or (B) Fifty percent, including the proposed increase and the cumulative increase over three calendar years before the date of the proposed increase.	To more clearly define what HCA means by "covered drug" in regards to its new wholesale acquisition cost.
Adopted	~~(3)~~ (4)(b)(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 after July 28, 2019, the manufacturer increases the wholesale acquisition cost ~~at least~~ such that: (A) The new wholesale acquisition cost is twenty percent~~, including the proposed increase and the cumulative increase over one calendar year~~ 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 ~~F~~ fifty percent~~, including the proposed increase and the~~	

	~~cumulative increase over three calendar years~~ higher than the wholesale acquisition cost on the same day of the month, thirty-six months before the date of the proposed increase.	
WAC 182-51-0100(7)		
Proposed	(7) "Data submission guide" means the document that contains the required data, required format, and instructions on submitting the data to be reported to the authority for each submitter type.	To more clearly define the Data Submission Guides as instructional documents that only provide guidance to reporting entities.
Adopted	~~(7)~~(8) "Data submission guide" means the document that ~~contains the required data, required format, and instructions on submitting the data to be reported to the authority for each submitter type~~ 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.	
WAC 182-51-0100(10)		
Proposed	(10) "Introduced to market" means made available for purchase in Washington state.	To remove the implication that "introduced to market" means available for purchase.
Adopted	~~(10)~~(11) "Introduced to market" means ~~made available for purchase~~ marketed in Washington state.	
WAC 182-51-0100(11)		
Proposed	(11) "New drug" means a drug for which a manufacturer is seeking initial approval under an original new drug application under 21 U.S.C. Sec. 355(b), under an abbreviated new drug application under 21 U.S.C. Sec. 355(j), or under a biologics license application under 42 U.S.C. Sec. 262. Each product listed on the application must be considered a new drug for purposes of reporting according to RCW 43.71C.060.	HCA removed the definition of "new drug" and replaced it with a definition of "pipeline drug" to better align with statute. The subsection was moved to maintain alphabetical order.
Adopted	~~(11) "New drug" means a drug for which a manufacturer is seeking initial approval under an original new drug application under 21 U.S.C. Sec. 355(b), under an abbreviated new drug application under 21 U.S.C. Sec. 355(j), or under a biologics license application under 42 U.S.C. Sec. 262. Each product listed on the application must be considered a new drug for purposes of reporting according to RCW 43.71C.060.~~ (14) "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.	

WAC 182-51-0100(14)		
Proposed	(14) "Prescription drug" means a drug regulated under chapter 69.41 or 69.50 RCW, including generic, brand name, specialty drugs, and biological products that are prescribed for outpatient use and distributed in a retail setting.	To improve clarity, HCA moved the clause "that are prescribed for outpatient use and distributed in a retail setting."
Adopted	~~(14)~~(15) "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 ~~that are prescribed for outpatient use and distributed in a retail setting~~.	
WAC 182-51-0100(17)		
Proposed	(17) "Rebate" means negotiated price concessions, discounts, refunds or revenue, 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 or refunds, 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.	To remove any association between rebates and refunds or revenue from the definition.
Adopted	~~(17)~~(18) "Rebate" means negotiated price concessions, discounts, ~~refunds or revenue,~~ 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 ~~or refunds~~, 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.	
WAC 182-51-0200(3)		
Proposed	(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 and may result in fines as described in WAC 182-51-1100.	To remove reference to punitive action being taken for failing to maintain accurate contact information.
Adopted	(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 ~~and may result in fines as described in WAC 182-51-1100~~.	
WAC 182-51-0300(1)		
Proposed	(1) No later than October 1st of each year, a health carrier must submit to the authority the prescription drug cost and utilization data for one or more previous calendar years for each health plan it offered in the state in the required format in accordance with the authority's applicable data submission guide.	To clarify the time periods reporting entities are required to submit data and to clarify that the Data Submission Guides are only guidelines for submitting data.
Adopted	(1) No later than October ~~1st of each year~~ 16, 2020, a health carrier must submit to the authority the prescription drug cost and utilization data for ~~one or more previous calendar years~~ calendar years 2018 and 2019, for each health plan it offered in ~~the~~ Washington state in calendar years 2018 and 2019, following the guidelines set in ~~the required format in accordance with~~ the authority's applicable data submission guide.	
WAC 182-51-0300 New subsection (2)		
Proposed	N/A	To clarify reporting deadlines for reporting entities. The subsections were renumbered to compensate for the new subsection.
Adopted	(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…	
WAC 182-51-0300(3)		
Proposed	(3) The authority may assess fines for not complying with the requirements in this section. See WAC 182-51-1000.	To fix an erroneous cross-reference.
Adopted	~~(3)~~(4) The authority may assess fines for not complying with the requirements in this section. See WAC 182-51-~~1000~~1100.	
WAC 182-51-0400(1)		

Proposed	(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 in the required format in accordance with the authority's applicable data submission guide.	To clarify that the Data Submission Guides are only guidelines for submitting data.
Adopted	(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 ~~in the required format in accordance with~~, following the guidelines set in the authority's applicable data submission guide.	
WAC 182-51-0400 New subsection (4)		
Proposed	N/A	To clarify that the information submitted according to this section is not subject to public disclosure. The proposed subsection (4) was renumbered to (5) to compensate for the new subsection. HCA also corrected an erroneous cross-reference in newly numbered subsection (5).
Adopted	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-~~1000~~1100.	
WAC 182-51-0600(1)		
Proposed	(1) On or before October 1, 2020, a covered manufacturer must submit to the authority all data specified in RCW 43.71C.050 and 43.71C.070 in accordance with the applicable data submission guide for each covered drug as the drug existed between July 28, 2019, and December 31, 2020.	To change reporting deadlines for reporting entities and to clarify that the Data Submission Guides are only guidelines for submitting data.
Adopted	(1) On or before ~~October 1~~ December 31, 2020, a covered manufacturer must submit to the authority all data specified in RCW 43.71C.050 and 43.71C.070 ~~in accordance with~~, 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 ~~December 31~~ August 17, 2020.	
WAC 182-51-0600(2)		
Proposed	(2) Beginning October 1, 2020, and monthly thereafter, a covered manufacturer must submit to the authority all data specified in RCW 43.71C.050 and 43.71C.070 in accordance with the applicable data submission guide, for each covered drug as follows: (a) Each report related to a covered drug introduced to market or a qualifying price increase with an effective date between January 1st and January 31st, inclusive, is due by November 30th of the prior year;	To clarify reporting deadlines for reporting entities, specifically for reporting new covered drugs and qualifying price increases for covered drugs. HCA also clarified that the Data Submission Guides are only guidelines for submitting data.

	(b) Each report related to a covered drug introduced to market or a qualifying price increase with an effective date between February 1st and February 28th, or in a leap year February 29th, inclusive, is due by December 31st of the prior year; (c) Each report related to a covered drug introduced to market or a qualifying price increase with an effective date between March 1st and March 31st, inclusive, is due by January 31st of the same year; (d) Each report related to a covered drug introduced to market or a qualifying price increase with an effective date between April 1st and April 30th, inclusive, is due by February 28th, or in a leap year February 29th, of the same year; (e) Each report related to a covered drug introduced to market or a qualifying price increase with an effective date between May 1st and May 31st, inclusive, is due by March 31st of the same year; (f) Each report related to a covered drug introduced to market or a qualifying price increase with an effective date between June 1st and June 30th, inclusive, is due by April 30th of the same year; (g) Each report related to a covered drug introduced to market or a qualifying price increase with an effective date between July 1st and July 31st, inclusive, is due by May 31st of the same year; (h) Each report related to a covered drug introduced to market or a qualifying price increase with an effective date between August 1st and August 31st, inclusive, is due by June 30th of the same year; (i) Each report related to a covered drug introduced to market or a qualifying price increase with an effective date between September 1st and September 30th, inclusive, is due by July 31st of the same year; (j) Each report related to a covered drug introduced to market or a qualifying price increase with an effective date between October 1st and October 31st, inclusive, is due by August 31st of the same year; (k) Each report related to a covered drug introduced to market or a qualifying price increase with an effective date between November 1st and November 30th, inclusive, is due by September 30th of the same year; and (l) Each report related to a covered drug introduced to market or a qualifying price increase with an effective date between December 1st and	

	December 31st, inclusive, is due by October 31st of the same year.	
Adopted	(2) Beginning October 16, 2020, ~~and monthly thereafter,~~ a covered manufacturer must submit to the authority all data specified in RCW 43.71C.050 and 43.71C.070 ~~in accordance with~~, following the guidelines set in the authority's applicable data submission guide, for each covered drug as follows: (a) ~~Each report related to a covered drug introduced to market or a qualifying price increase with an effective date between January 1st and January 31st, inclusive, is due by November 30th of the prior year~~ Sixty days in advance of a qualifying prices increase for a covered drug marketed in Washington State; or; (b) ~~Each report related to a covered drug introduced to market or a qualifying price increase with an effective date between February 1st and February 28th, or in a leap year February 29th, inclusive, is due by December 31st of the prior year;~~ Thirty days in advance of a new covered drug's introduction to market in Washington State. ~~(c) Each report related to a covered drug introduced to market or a qualifying price increase with an effective date between March 1st and March 31st, inclusive, is due by January 31st of the same year;~~ ~~(d) Each report related to a covered drug introduced to market or a qualifying price increase with an effective date between April 1st and April 30th, inclusive, is due by February 28th, or in a leap year February 29th, of the same year;~~ ~~(e) Each report related to a covered drug introduced to market or a qualifying price increase with an effective date between May 1st and May 31st, inclusive, is due by March 31st of the same year;~~ ~~(f) Each report related to a covered drug introduced to market or a qualifying price increase with an effective date between June 1st and June 30th, inclusive, is due by April 30th of the same year;~~ ~~(g) Each report related to a covered drug introduced to market or a qualifying price increase with an effective date between July 1st and July 31st, inclusive, is due by May 31st of the same year;~~ ~~(h) Each report related to a covered drug introduced to market or a qualifying price increase with an effective date between August 1st and August 31st, inclusive, is due by June 30th of the same year;~~	

	~~(i) Each report related to a covered drug introduced to market or a qualifying price increase with an effective date between September 1st and September 30th, inclusive, is due by July 31st of the same year;~~ ~~(j) Each report related to a covered drug introduced to market or a qualifying price increase with an effective date between October 1st and October 31st, inclusive, is due by August 31st of the same year;~~ ~~(k) Each report related to a covered drug introduced to market or a qualifying price increase with an effective date between November 1st and November 30th, inclusive, is due by September 30th of the same year; and~~ ~~(l) Each report related to a covered drug introduced to market or a qualifying price increase with an effective date between December 1st and December 31st, inclusive, is due by October 31st of the same year.~~	
WAC 182-182-51-0600 New subsection (3)		
Proposed	N/A	To allow for the possibility that reporting entities may not be able to report the information required in this section and to give guidelines surrounding that possibility. The proposed subsection (3) was renumbered to (4) to compensate for the new subsection.
Adopted	(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….	
WAC 182-182-51-0600(4)		
Proposed	(4) The authority may assess fines for not complying with the requirements in this section. See WAC 182-51-1000.	To correct an erroneous cross-reference.
Adopted	~~(4)~~(5) The authority may assess fines for not complying with the requirements in this section. See WAC 182-51-~~1000~~1100.	
WAC 182-51-0700 Title and (1)		
Proposed	**WAC 182-51-0700 Manufacturers—Notice of new drug applications.** (1) On or before October 1, 2020, a manufacturer must submit to the authority all data specified in RCW 43.71C.060(1) in accordance with the applicable data submission guide for all new drug	To change reporting deadlines for reporting entities and to clarify that the Data Submission Guides are only guidelines for submitting

	applications or biologic license applications submitted on or after October 1, 2019, through September 30, 2020, for which the manufacturer has received an FDA approval date.	data. HCA also clarified that this section pertains to biologic license applications.
Adopted	**WAC 182-51-0700 Manufacturers—Notice of new drug applications and biologic license applications.** (1) On or before ~~October 1~~ December 31, 2020, a manufacturer must submit to the authority all data specified in RCW 43.71C.060(1) ~~in accordance with~~, following the guidelines set in the authority's applicable data submission guide for all new drug applications or biologic license applications for pipeline drugs submitted on or after October 1, 2019, through ~~September 30~~ October 15, 2020, for which the manufacturer has received an FDA approval date.	
WAC 182-51-0700(2)		
Proposed	(2) Beginning October 1, 2020, a manufacturer must submit to the authority all data specified in RCW 43.71C.060(1) in accordance with the applicable data submission guide for all new drug applications or biologic license applications submitted on or after October 1, 2020, within sixty calendar days of the manufacturer receiving the FDA approval date as follows: (a) All new drug applications or biologic license applications for which the manufacturer has received an FDA approval date between January 1st and January 31st, inclusive, is due by November 30th of the prior year; (b) All new drug applications or biologic license applications for which the manufacturer has received an FDA approval date between February 1st and February 28th, or in a leap year February 29th, inclusive, is due by December 31st of the prior year; (c) All new drug applications or biologic license applications for which the manufacturer has received an FDA approval date between March 1st and March 31st, inclusive, is due by January 31st of the same year; (d) All new drug applications or biologic license applications for which the manufacturer has received an FDA approval date between April 1st and April 30th, inclusive, is due by February 28th, or in a leap year February 29th, of the same year; (e) All new drug applications or biologic license applications for which the manufacturer has received an FDA approval date between May 1st and May 31st, inclusive, is due by March 31st of the same year; (f) All new drug applications or biologic license applications for which the manufacturer has received	To clarify reporting deadlines for reporting entities and to clarify that the Data Submission Guides are only guidelines for submitting data.

	an FDA approval date between June 1st and June 30th, inclusive, is due by April 30th of the same year; (g) All new drug applications or biologic license applications for which the manufacturer has received an FDA approval date between July 1st and July 31st, inclusive, is due by May 31st of the same year; (h) All new drug applications or biologic license applications for which the manufacturer has received an FDA approval date between August 1st and August 31st, inclusive, is due by June 30th of the same year; (i) All new drug applications or biologic license applications for which the manufacturer has received an FDA approval date between September 1st and September 30th, inclusive, is due by July 31st of the same year; (j) All new drug applications or biologic license applications for which the manufacturer has received an FDA approval date between October 1st and October 31st, inclusive, is due by August 31st of the same year; (k) All new drug applications or biologic license applications for which the manufacturer has received an FDA approval date between November 1st and November 30th, inclusive, is due by September 30th of the same year; and (l) All new drug applications or biologic license applications for which the manufacturer has received an FDA approval date between December 1st and December 31st, inclusive, is due by October 31st of the same year.	
Adopted	2) Beginning October 16, 2020, a manufacturer must submit to the authority all data specified in RCW 43.71C.060(1) ~~in accordance with~~, following the guidelines set in the authority's applicable data submission guide for all new drug applications or biologic license applications for pipeline drugs submitted on or after October 16, 2020, within sixty calendar days of the manufacturer receiving the FDA approval date. ~~as follows:~~ ~~(a) All new drug applications or biologic license applications for which the manufacturer has received an FDA approval date between January 1st and January 31st, inclusive, is due by November 30th of the prior year;~~ ~~(b) All new drug applications or biologic license applications for which the manufacturer has received an FDA approval date between February 1st and February 28th, or in a leap year February 29th, inclusive, is due by December 31st of the prior year;~~	

	~~(c) All new drug applications or biologic license applications for which the manufacturer has received an FDA approval date between March 1st and March 31st, inclusive, is due by January 31st of the same year;~~ ~~(d) All new drug applications or biologic license applications for which the manufacturer has received an FDA approval date between April 1st and April 30th, inclusive, is due by February 28th, or in a leap year February 29th, of the same year;~~ ~~(e) All new drug applications or biologic license applications for which the manufacturer has received an FDA approval date between May 1st and May 31st, inclusive, is due by March 31st of the same year;~~ ~~(f) All new drug applications or biologic license applications for which the manufacturer has received an FDA approval date between June 1st and June 30th, inclusive, is due by April 30th of the same year;~~ ~~(g) All new drug applications or biologic license applications for which the manufacturer has received an FDA approval date between July 1st and July 31st, inclusive, is due by May 31st of the same year;~~ ~~(h) All new drug applications or biologic license applications for which the manufacturer has received an FDA approval date between August 1st and August 31st, inclusive, is due by June 30th of the same year;~~ ~~(i) All new drug applications or biologic license applications for which the manufacturer has received an FDA approval date between September 1st and September 30th, inclusive, is due by July 31st of the same year;~~ ~~(j) All new drug applications or biologic license applications for which the manufacturer has received an FDA approval date between October 1st and October 31st, inclusive, is due by August 31st of the same year;~~ ~~(k) All new drug applications or biologic license applications for which the manufacturer has received an FDA approval date between November 1st and November 30th, inclusive, is due by September 30th of the same year; and~~ ~~(l) All new drug applications or biologic license applications for which the manufacturer has received an FDA approval date between December 1st and December 31st, inclusive, is due by October 31st of the same year.~~	
WAC 182-51-0700 New subsection (3)		
Proposed	N/A	To clarify in rule how HCA determines when a new drug has the potential to have a
Adopted	(3) <u>The authority considers fifty-thousand dollars per biennium to be a significant impact on state</u>	

	expenditures. Reporting entities may anticipate a request for additional information per RCW 43.71C.060 (3) from the authority for products expected to exceed fifty-thousand dollars per biennium. To improve efficiency in reporting, manufacturers who submit a new drug application or a biologics license application for a pipeline drug or a biologics license application for a biological product that is expected to cost the state more than fifty-thousand dollars per biennium may submit the data elements in RCW 43.71C.060 (3) at the same time they submit the notice of the new drug application. (4) A manufacturer may limit….	significant impact on state expenditures. The proposed subsection (4) was renumbered to (5) to compensate for the new subsection.
WAC 182-51-0700(4)		
Proposed	(4) The agency may assess fines for not complying with the requirements in this section. See WAC 182-51-1000.	To correct an erroneous cross-reference.
Adopted	~~(4)~~(5) The agency may assess fines for not complying with the requirements in this section. See WAC 182-51-~~1000~~1100.	
WAC 182-51-0800(1)		
Proposed	(1) No later than October 1st of each year, a pharmacy services administrative organization representing a pharmacy or pharmacy chain in the state must submit to the authority the data specified in RCW 43.71C.080 following the guidelines set in the authority's applicable data submission guide.	To clarify reporting deadlines for reporting entities.
Adopted	(1) No later than October 16, 2020, and October 1st of each year thereafter, a pharmacy services administrative organization representing a pharmacy or pharmacy chain in ~~the~~ Washington state must submit to the authority the data specified in RCW 43.71C.080 following the guidelines set in the authority's applicable data submission guide.	
WAC 182-51-0800(2)		
Proposed	(2) Any pharmacy services administrative organization whose revenue is generated from flat service fees not connected to drug prices or volume, and paid by the pharmacy, is exempt from reporting, subject to audit by the authority. These organizations must petition the authority for exemption from the reporting requirements according to the frequency listed and the format required in the authority's applicable data submission guide.	To clarify that the Data Submission Guides are only guidelines for submitting data.
Adopted	(2) Any pharmacy services administrative organization whose revenue is generated from flat service fees not connected to drug prices or volume, and paid by the pharmacy, is exempt from reporting, subject to audit by the authority. These organizations must petition	

	the authority for exemption from the reporting requirements according to the frequency listed and the ~~format required~~ formatting guidelines in the authority's applicable data submission guide.	
WAC 182-51-0800(3)		
Proposed	(3) The authority may assess fines for not complying with the requirements in this section. See WAC 182-51-1000.	To correct an erroneous cross-reference.
Adopted	(3) The authority may assess fines for not complying with the requirements in this section. See WAC 182-51-~~1000~~1100.	
WAC 182-51-1000(2)		
Proposed	(2) The authority develops data submission guides and has final approval authority over them.	To provide the opportunity for reporting entities to comment on changes HCA makes to the data submission guides.
Adopted	(2) The authority develops data submission guides and has final approval authority over them. The authority provides reporting entities the opportunity to comment on changes to data requirements in the applicable data submission guide, at least thirty days before the effective date of the change.	
WAC 182-51-1100(1)		
Proposed	(1) RCW 43.71C.090 allows the authority to assess a fine of up to one thousand dollars per day for failure to comply with the requirements of RCW 43.71C.020 through 43.71C.080 and the requirements of this chapter.	To improve usability.
Adopted	(1) RCW 43.71C.090 allows the authority to assess a fine of up to one thousand dollars per day for failure to comply with the requirements of RCW 43.71C.020 through 43.71C.080 and the requirements of this chapter. See WAC 182-51-1300 for fines for failing to comply with reporting requirements and WAC 182-51-1400 for the amount of fines based on culpability.	
WAC 182-51-1100(2)		
Proposed	(2) The authority may, at its sole discretion, grant an extension of time to a reporting requirement deadline under WAC 182-51-1200.	To remove redundant language.
Adopted	(2) The authority may~~, at its sole discretion,~~ grant an extension of time to a reporting requirement deadline under WAC 182-51-1200.	
WAC 182-51-1200(1)		
Proposed	(1) The authority may, at its sole discretion, grant:	To remove redundant language.
Adopted	(1) The authority may~~, at its sole discretion,~~ grant:	
WAC 182-51-1200(1)(b)		
Proposed	(b) The request for an extension must be for no more than one reporting period and must contain a detailed explanation as to the reason the reporting entity is unable to meet the reporting requirements for that period.	To remove a restriction on how long reporting entities may ask for an extension.

Adopted	(b) The request for an extension ~~must be for no more than one reporting period and~~ must contain a detailed explanation as to the reason the reporting entity is unable to meet the reporting requirements for that period.	
WAC 182-51-1200(1)(d)		
Proposed	(d) The authority may approve a request for extenuating circumstances. The authority provides written notification of the approval or denial to the requestor within fifteen 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.	To clarify what extensions are for.
Adopted	(d) The authority may approve a request for <u>an extension for a period of time based on the specific circumstances or other</u> extenuating circumstances. The authority provides written notification of the approval or denial to the requestor within fifteen 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.	
WAC 182-51-1300(2)		
Proposed	(2) Unless the authority has approved an extension, the authority may assess a fine for failure to comply with general reporting requirements contained in chapter 43.71C RCW and this chapter including, but not limited to, the following:	To clarify that HCA will also not asses a fine if HCA has received a request to correct previously submitted data.
Adopted	(2) Unless the authority has approved an extension <u>or has received a request to correct previously submitted data</u>, the authority may assess a fine for failure to comply with general reporting requirements contained in chapter 43.71C RCW and this chapter including, but not limited to, the following:	
WAC 182-51-1300(3)		
Proposed	(3) Unless the authority has approved an extension, the authority may assess fines for failure to comply with data file requirements outlined in the applicable data submission guide in effect for the required reporting period including, but not limited to, the following:	To clarify that HCA will also not asses a fine if HCA has received a request to correct previously submitted data.
Adopted	(3) Unless the authority has approved an extension <u>or has received a request to correct previously submitted data</u>, the authority may assess fines for failure to comply with data file requirements outlined in the applicable data submission guide in effect for the required reporting period including, but not limited to, the following:	

WAC 182-51-1300(4) and (5)		
Proposed	(4) Upon failing to comply with a reporting requirement in this chapter, the authority first issues a warning notice to a reporting entity. The authority sends the warning notice to the reporting entity's last known email or physical address. The warning notice describes the failure to comply with the requirements of this chapter and gives the reporting entity ten days to become compliant or request an extension of time to report the required data according to WAC 182-51-1200(2). (5) A reporting entity that fails to comply with the same reporting requirement in this chapter for which it previously received a warning notice may be assessed a fine of up to one thousand dollars per day. Failure to comply with each reporting requirement for the reporting period is a different occurrence with a separate fine.	The clarify the process HCA uses to work with reporting entities who fail to comply with reporting requirements laid out in this chapter, HCA moved this information to WAC 182-51-1500. Due to this change, subsection (6) was renumbered to (3).
Adopted	~~(4) Upon failing to comply with a reporting requirement in this chapter, the authority first issues a warning notice to a reporting entity. The authority sends the warning notice to the reporting entity's last known email or physical address. The warning notice describes the failure to comply with the requirements of this chapter and gives the reporting entity ten days to become compliant or request an extension of time to report the required data according to WAC 182-51-1200(2).~~ ~~(5) A reporting entity that fails to comply with the same reporting requirement in this chapter for which it previously received a warning notice may be assessed a fine of up to one thousand dollars per day. Failure to comply with each reporting requirement for the reporting period is a different occurrence with a separate fine.~~	
WAC 182-51-1400 New subsection (4)		
Proposed	N/A	To clarify how fines accrue.
Adopted	<u>(4) Fines continue to accrue daily until the reporting entity comes into compliance, settles through an informal dispute resolution conference under WAC 182-51-1700, or files a formal appeal under WAC 182-51-1800.</u>	
WAC 182-51-1500 Title and new subsection (1)		
Proposed	**WAC 182-51-1500 Notice of violation and fine.**	To provide for a warning notice sent to reporting entities that gives reporting entities thirty days to become compliant or request
Adopted	**WAC 182-51-1500 ~~N~~ <u>Preliminary n</u>otice of violation and fine<u>(s)</u>.** (1) <u>Upon failing to comply with a reporting requirement in this chapter, the authority first issues a warning notice to a reporting entity. The</u>	

	authority sends the warning notice to the reporting entity's last known email or physical address. The warning notice describes the failure to comply with the requirements of this chapter and gives the reporting entity thirty days to become compliant or request an extension of time to report the required data according to WAC 182-51-1200(2). ~~(1)~~(2) When a reporting entity fails….	an extension before a preliminary notice of violation and fine(s) is sent. The proposed subsection (1) was renumbered to (2) to compensate for the new subsection.
WAC 182-51-1500(1)		
Proposed	(1) When a reporting entity fails to comply with reporting requirement(s) after receiving a warning notice, the authority may assess a fine and notifies the reporting entity. The authority mails the notice of violation to the reporting entity's last known address by certified mail, return receipt requested.	To clarify the preliminary notice of violation and fine(s) process.
Adopted	~~(1)~~(2) When a reporting entity fails to comply with reporting requirement(s) after receiving a warning notice, the authority may assess a fine ~~and notifies the reporting entity~~(s) as established in WAC 182-51-1400. The authority mails ~~the~~ a preliminary notice of violation and fine(s) to the reporting entity's last known address by certified mail, return receipt requested.	
WAC 182-51-1500(2)		
Proposed	(2) The notice of violation includes the following information: (a) The specific reasons and criteria that support the imposition of the assessed fine(s); (b) The legal authority that supports the imposition of a fine or fines; (c) The amount of the fine(s); (d) The date when the fine(s) and other actions imposed will take effect, if not appealed; and (e) An explanation of the reporting entity's appeal rights.	To clarify what information is included in the preliminary notice of violation and fine(s).
Adopted	~~(2)~~(3) The preliminary notice of violation and fine(s) includes the following information: (a) The specific reasons and criteria that support the imposition of the assessed fine(s); (b) The legal authority that supports the imposition of a fine or fines; (c) The amount of the fine(s) as of the date of the preliminary notice of violation and fine(s); (d) ~~The date when the fine(s) and other actions imposed will take effect, if not appealed~~ Notice that fines will continue to accrue at the assessed daily rate, per WAC 182-51-1400, until the reporting entity either complies with the reporting requirements or	

	settles through an informal dispute resolution conference; and (e) An explanation of the reporting entity's ~~appeal~~ right~~s~~ to request an informal dispute resolution conference under WAC 182-51-1700.	
WAC 182-51-1600(1)		
Proposed	(1) Each reporting entity to whom the authority issues a notice of a violation and fine may request a hearing to be conducted in accordance with this chapter and chapter 182-526 WAC.	To clarify the difference between the preliminary notice of violation and fine(s) and the final notice of violation and fine(s) and to clarify the difference between the informal dispute resolution process under WAC 182-51-1700 and the formal administrative hearing process under WAC 182-51-1800.
Adopted	(1) Each reporting entity to whom the authority issues a preliminary notice of a violation and fine(s) may request ~~a hearing to be conducted in accordance with this chapter and chapter 182-526 WAC~~ and informal dispute resolution conference under WAC 182-51-1700.	
WAC 182-51-1600(2) and (3)		
Proposed	(2) A reporting entity must submit a request for a hearing to the authority in writing, in a manner that provides proof of receipt, within twenty-eight calendar days after receipt of written notice provided under WAC 182-51-1500. (3) The request for hearing must specify: (a) The name of the reporting entity requesting the hearing and the reporting entity's, or representative's, mailing address, telephone number, and email address (if available); (b) The items, facts, or conclusions in the notice of violation being contested; and (c) The basis for contesting the authority's action, including any mitigating factors upon which the reporting entity relies and the outcome the reporting entity is seeking.	To clarify the process reporting entities may use to dispute or appeal notices of violation and fine(s). HCA added clarity surrounding the options reporting entities have and the timeliness requirements.
Adopted	(2) ~~A reporting entity must submit a request for a hearing to the authority in writing, in a manner that provides proof of receipt, within twenty-eight calendar days after receipt of written notice provided under WAC 182-51-1500.~~ ~~(3) The request for hearing must specify:~~ ~~(a) The name of the reporting entity requesting the hearing and the reporting entity's, or representative's, mailing address, telephone number, and email address (if available);~~ ~~(b) The items, facts, or conclusions in the notice of violation being contested; and~~	

	~~(c) The basis for contesting the authority's action, including any mitigating factors upon which the reporting entity relies and the outcome the reporting entity is seeking.~~ If the reporting entity requests an informal dispute resolution conference under WAC 182-51-1700, the reporting entity must complete 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 calendar days after receipt of the preliminary notice of violation and fine(s). Upon receipt for 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 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.	
WAC 182-51-1700(1)		
Proposed	(1) A reporting entity may informally dispute the authority's determination of a violation under this chapter. Reporting entities must submit the request for dispute resolution in writing, and it must include the following: (a) The supporting evidence for each assessed violation; and (b) The relief sought for each disputed violation.	To clarify that this subsection is regarding the preliminary notice of violation and fine(s). HCA removed the final sentence in this subsection due to amending subsection (2) and adding a new subsection (3).
Adopted	(1) A reporting entity may informally dispute the authority's <u>preliminary</u> determination of a violation under this chapter. ~~Reporting entities must submit the request for dispute resolution in writing, and it must include the following:~~ ~~(a) The supporting evidence for each assessed violation; and~~ ~~(b) The relief sought for each disputed violation.~~	
WAC 182-51-1700(2)		
Proposed	(2) The dispute may include a request for a dispute resolution conference. (a) If the agency grants the reporting entity's request for a dispute resolution conference, the conference occurs within sixty calendar days of the	To clarify how reporting entities may request an informal resolution conference and what

	date the reporting entity received the authority's written acceptance of the request for a dispute resolution conference. (b) The reporting entity must notify the authority of who will attend the dispute resolution conference on the reporting entity's behalf at least five business days before the conference.	information should be in the request. Due to the additional subsections, proposed subsection (3) was renumbered to (6).
Adopted	(2) ~~The dispute may include a request for a dispute resolution conference.~~ ~~(a)~~ A reporting entity must submit a request for an informal dispute resolution conference to the authority in writing, in a manner that provides proof of receipt, within twenty-eight calendar days after receipt of the preliminary notice of violation and fine(s). (3) Requests should specify: (a) The name of the reporting entity requesting the informal dispute resolution conference and the reporting entity's, or representative's, mailing address, telephone number, and email address (if available); (b) The items, facts, or conclusions in the preliminary notice of violation being contested; and (c) The basis for contesting the authority's action, including any mitigating factors upon which the reporting entity relies and the outcome the reporting entity is seeking. (4) If the agency grants the reporting entity's request for a dispute resolution conference, the conference occurs within sixty calendar days of the date the reporting entity received the authority's written acceptance of the request for a dispute resolution conference. ~~(b)~~ (5) The reporting entity must notify the authority of who will attend the dispute resolution conference on the reporting entity's behalf at least five business days before the conference.	
WAC 182-51-1700 New subsection (7)		
Proposed	N/A	To clarify when HCA issues the final notice of violation and fine(s). Due to the addition of this subsection, proposed subsection (4) was renumbered to (8).
Adopted	(7) Upon completion or termination of the informal dispute resolution process, the authority will issue a final notice of violation and fine(s).	
WAC 182-51-1800(1)		

Proposed	(1) A reporting entity has a right to an administrative hearing (formal appeal), and any resulting appeals process available under chapters 34.05 RCW and 182-526 WAC, if the authority assesses a fine against the reporting entity under any section of chapter 43.71C RCW and this chapter. To the extent that there may be a conflict between the general provisions contained in chapter 182-526 WAC and this chapter, the more specific provisions in this chapter apply.	To clarify that reporting entities have the right to a formal administrative hearing when they receive a final notice of violation and fine(s).
Adopted	(1) A reporting entity has a right to an administrative hearing (formal appeal), and any resulting appeals process available under chapters 34.05 RCW and 182-526 WAC, if the authority assesses a <u>final notice of violation and fine(s)</u> against the reporting entity under any section of chapter 43.71C RCW and this chapter. To the extent that there may be a conflict between the general provisions contained in chapter 182-526 WAC and this chapter, the more specific provisions in this chapter apply.	
WAC 182-51-1800(2)		
Proposed	(2) A reporting entity may appeal both the assessed violation(s) and the amount of the fine(s) assessed in the notice of violation and fine.	To clarify that this subsection is regarding the final notice of violation and fine(s).
Adopted	(2) A reporting entity may appeal both the assessed violation(s) and the amount of the fine(s) assessed in the <u>final</u> notice of violation and fine<u>(s)</u>.	
WAC 182-51-1800 New subsections (3) and (4)		
Proposed	N/A	To clarify how reporting entities may request a formal administrative hearing and what information should be in the request. Because of this addition, the subsequent subsections were renumbered.
Adopted	<u>(3) A reporting entity must submit a request for formal hearing to the authority in writing, in a manner that provides proof of receipt, within twenty-eight calendar days after receipt of the final notice of violation and fine(s) under WAC 182-51-1700.</u> <u>(4) Requests should specify:</u> <u>(a) The name of the reporting entity requesting the hearing and the reporting entity's, or representative's, mailing address, telephone number, and email address (if available);</u> <u>(b) The items, facts, or conclusions in the final notice of violation being contested; and</u> <u>(c) The basis for contesting the authority's action, including any mitigating factors upon which the reporting entity relies and the outcome the reporting entity is seeking.</u>	

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:

Federal statute:	New	____	Amended	____	Repealed	____
Federal rules or standards:	New	____	Amended	____	Repealed	____
Recently enacted state statutes:	New	19	Amended	____	Repealed	____

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:

Negotiated rule making:	New	____	Amended	____	Repealed	____
Pilot rule making:	New	____	Amended	____	Repealed	____
Other alternative rule making:	New	19	Amended	____	Repealed	____

Date Adopted: September 15, 2020

Name: Wendy Barcus

Title: HCA Rules Coordinator

Signature:

Chapter 182-51 WAC
PRESCRIPTION DRUG PRICING TRANSPARENCY PROGRAM

NEW SECTION

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

(2) The purpose of the Washington prescription drug pricing transparency program is to provide notice and disclosure of information relating to the cost and pricing of prescription drugs in order to provide accountability to the state for prescription drug 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.

NEW SECTION

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) "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 after July 28, 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) "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) "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) "Data recipient" means an individual or entity authorized to receive data under RCW 43.71C.100.

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

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

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

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

(18) "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) "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) "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.

DATA REPORTING, NOTICES, AND CONFIDENTIALITY

NEW SECTION

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 contact information previously provided.

(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.

NEW SECTION

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 employer-sponsored, self-funded health plan; Taft-Hartley trust health plan; worker's compensation plan; medicare Part D plan; or medicare advantage plan it administers.

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

NEW SECTION

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, following 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 employer-sponsored, self-funded health plan; Taft-Hartley trust health plan; worker's compensation plan; medicare Part D plan; or medicare advantage plan it administers.

(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.

NEW SECTION

WAC 182-51-0500 Pharmacy benefit managers—Compliance. (1) No later than March 1st of each year, each pharmacy benefit manager must file with the authority an attestation in the format required by the authority for the preceding calendar year, stating that the pharmacy benefit manager is in compliance with this chapter.

(2) A pharmacy benefit manager must not cause or knowingly permit the use of any advertisement, promotion, solicitation, representation, proposal, or offer that is untrue, deceptive, or misleading.

NEW SECTION

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 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, 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) Thirty days in advance of a new covered drug's introduction 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.

NEW SECTION

WAC 182-51-0700 Manufacturers—Notice of new drug applications and biologic license applications. (1) On or before December 31, 2020, a manufacturer must submit to the authority all data specified in RCW 43.71C.060(1), following the guidelines set in the authority's applicable data submission guide for all new drug applications or biologic license applications for pipeline drugs submitted on or after October 1, 2019, through October 15, 2020, for which the manufacturer has received an FDA approval date.

(2) Beginning October 16, 2020, a manufacturer must submit to the authority all data specified in RCW 43.71C.060(1), following the guidelines set in the authority's applicable data submission guide for all new drug applications or biologic license applications for pipeline drugs submitted on or after October 16, 2020, within sixty calendar days of the manufacturer receiving the FDA approval date.

(3) The authority considers fifty thousand dollars per biennium to be a significant impact on state expenditures. Reporting entities may anticipate a request for additional information per RCW 43.71C.060(3) from the authority for products expected to exceed fifty thousand dollars per biennium. To improve efficiency in reporting, manufacturers who submit a new drug application or a biologics license application for a pipeline drug or a biologics license application for a biological product that is expected to cost the state more than fifty thousand dollars per biennium may submit the data elements in RCW 43.71C.060(3) at the same time they submit the notice of the new drug application.

(4) A manufacturer may limit the information reported according to this section to information that is in the public domain or publicly reported.

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

NEW SECTION

WAC 182-51-0800 Pharmacy services administrative organizations—Data reporting. (1) No later than October 16, 2020, and October 1st of each year thereafter, a pharmacy services administrative organization representing a pharmacy or pharmacy chain in Washington state must submit to the authority the data specified in RCW 43.71C.080 following the guidelines set in the authority's applicable data submission guide.

(2) Any pharmacy services administrative organization whose revenue is generated from flat service fees not connected to drug prices or volume, and paid by the pharmacy, is exempt from reporting, subject to audit by the authority. These organizations must petition the authority for exemption from the reporting requirements according to the frequency listed and the formatting guidelines in the authority's applicable data submission guide.

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

NEW SECTION

WAC 182-51-0900 Data confidentiality. 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.

NEW SECTION

WAC 182-51-1000 Data submission guides. (1) All data and data files must be submitted to the authority in accordance with the requirements in this chapter and the respective data submission guide for the respective reporting period. Data submission guides are located on the authority's website.

(2) The authority develops data submission guides and has final approval authority over them. The authority provides reporting entities the opportunity to comment on changes to data requirements in the applicable data submission guide, at least thirty days before the effective date of the change.

(3) At its discretion, the authority may grant reporting entities an extension to comply with any changes the authority makes to the data submission guides. Reporting entities must request extensions in accordance with WAC 182-51-1200.

ENFORCEMENT

NEW SECTION

WAC 182-51-1100 Authority to assess fines. (1) RCW 43.71C.090 allows the authority to assess a fine of up to one thousand dollars per day for failure to comply with the requirements of RCW 43.71C.020 through 43.71C.080 and the requirements of this chapter. See WAC 182-51-1300 for fines for failing to comply with reporting requirements and WAC 182-51-1400 for the amount of fines based on culpability.

(2) The authority may grant an extension of time to a reporting requirement deadline under WAC 182-51-1200.

NEW SECTION

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 previously submitted data.

(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 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 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.

NEW SECTION

WAC 182-51-1300 Fines for failure to comply with reporting requirements. (1) The authority may assess fines for failure to comply with the general reporting requirements of this chapter including, but not limited to, failing to report data or reporting erroneous or inaccurate data.

(2) Unless the authority has approved an extension or has received a request to correct previously submitted data, the authority may assess a fine for failure to comply with general reporting requirements contained in chapter 43.71C RCW and this chapter including, but not limited to, the following:

(a) Failure to timely submit required data files; or

(b) Failure to accurately submit all data elements.

(3) Unless the authority has approved an extension or has received a request to correct previously submitted data, the authority may assess fines for failure to comply with data file requirements outlined in the applicable data submission guide in effect for the required reporting period including, but not limited to, the following:

(a) Submitting a data file in an unapproved layout;

(b) Submitting a data element in an unapproved format;

(c) Submitting a data element with unapproved coding;

(d) Failing to submit a required data element;

(e) Failing to comply with the approved data submission schedule; or

(f) Transmitting data files using an unapproved process.

NEW SECTION

WAC 182-51-1400 Amount of fines based on culpability. (1) In determining the amount of any fine, the authority considers the level of culpability associated with the violation. The levels of culpability, in the order of least severe to most severe, are as follows:

(a) **Did not know.** The reporting entity did not know and by exercising reasonable diligence, could not have known the violation had occurred.

(b) **Reasonable cause.** The reporting entity knew, or by exercising diligence should have known, that the violation had taken place, but the reporting entity did not act with willful neglect.

(c) **Willful neglect - Corrected.** The violation was due to the reporting entity's intentional failure or reckless indifference, and the violation was corrected within thirty calendar days from the date the reporting entity knew or with reasonable diligence should have known of the violation.

(d) **Willful neglect - Uncorrected.** The violation was due to the reporting entity's intentional failure or reckless indifference, and the violation was not corrected within thirty calendar days from the date the reporting entity knew or with reasonable diligence should have known of the violation.

(2) The fine ranges for each level of culpability and the daily cap for violations of a similar nature are as follows:

Culpability category	Fines per violation, per day
Did not know	$250
Reasonable cause	$500
Willful neglect - Corrected	$750
Willful neglect - Not corrected	$1,000

(3) Fines begin to accrue on the first day after the reporting deadline. For those reporting entities granted an extension by the authority, fines begin to accrue on the first day after the extended due date.

(4) Fines continue to accrue daily until the reporting entity comes into compliance, settles through an informal dispute resolution conference under WAC 182-51-1700, or files a formal appeal under WAC 182-51-1800.

NEW SECTION

WAC 182-51-1500 Preliminary notice of violation and fine(s). (1) Upon failing to comply with a reporting requirement in this chapter, the authority first issues a warning notice to a reporting entity. The authority sends the warning notice to the reporting entity's last known email or physical address. The warning notice describes the failure to comply with the requirements of this chapter and gives the reporting entity thirty days to become compliant or request an extension of time to report the required data according to WAC 182-51-1200(2).

(2) When a reporting entity fails to comply with reporting requirement(s) after receiving a warning notice, the authority may assess a fine(s) as established in WAC 182-51-1400. The authority mails a preliminary notice of violation and fine(s) to the reporting entity's last known address by certified mail, return receipt requested.

(3) The preliminary notice of violation and fine(s) includes the following information:

(a) The specific reasons and criteria that support the imposition of the assessed fine(s);

(b) The legal authority that supports the imposition of a fine or fines;

(c) The amount of the fine(s) as of the date of the preliminary notice of violation and fine(s);

(d) Notice that fines will continue to accrue at the assessed daily rate, per WAC 182-51-1400, until the reporting entity either complies with the reporting requirements or settles through an informal dispute resolution conference; and

(e) An explanation of the reporting entity's right to request an informal dispute resolution conference under WAC 182-51-1700.

NEW SECTION

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 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 complete 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 calendar days after receipt of the preliminary notice of violation and fine(s). Upon receipt for 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 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.

NEW SECTION

WAC 182-51-1700 Informal dispute resolution prior to a hearing. (1) A reporting entity may informally dispute the authority's preliminary determination of a violation under this chapter.

(2) A reporting entity must submit a request for an informal dispute resolution conference to the authority in writing, in a manner that provides proof of receipt, within twenty-eight calendar days after receipt of the preliminary notice of violation and fine(s).

(3) Requests should specify:

(a) The name of the reporting entity requesting the informal dispute resolution conference and the reporting entity's, or representative's, mailing address, telephone number, and email address (if available);

(b) The items, facts, or conclusions in the preliminary notice of violation being contested; and

(c) The basis for contesting the authority's action, including any mitigating factors upon which the reporting entity relies and the outcome the reporting entity is seeking.

(4) If the agency grants the reporting entity's request for a dispute resolution conference, the conference occurs within sixty calendar days of the date the reporting entity received the authority's written acceptance of the request for a dispute resolution conference.

(5) The reporting entity must notify the authority of who will attend the dispute resolution conference on the reporting entity's behalf at least five business days before the conference.

(6) The authority may terminate the dispute resolution process at any time.

(7) Upon completion or termination of the informal dispute resolution process, the authority will issue a final notice of violation and fine(s).

(8) Nothing in this chapter prevents settlement discussions between the parties. All settlement discussions are informal and without prejudice to the rights of the participants in the discussions.

NEW SECTION

WAC 182-51-1800 Administrative hearing (formal appeal) right. (1) A reporting entity has a right to an administrative hearing (formal appeal), and any resulting appeals process available under chapters 34.05 RCW and 182-526 WAC, if the authority assesses a final notice of violation and fine(s) against the reporting entity under any section of chapter 43.71C RCW and this chapter. To the extent that there may be a conflict between the general provisions contained in chapter 182-526 WAC and this chapter, the more specific provisions in this chapter apply.

(2) A reporting entity may appeal both the assessed violation(s) and the amount of the fine(s) assessed in the final notice of violation and fine(s).

(3) A reporting entity must submit a request for formal hearing to the authority in writing, in a manner that provides proof of receipt, within twenty-eight calendar days after receipt of the final notice of violation and fine(s) under WAC 182-51-1700.

(4) Requests should specify:

(a) The name of the reporting entity requesting the hearing and the reporting entity's, or representative's, mailing address, telephone number, and email address (if available);

(b) The items, facts, or conclusions in the final notice of violation being contested; and

(c) The basis for contesting the authority's action, including any mitigating factors upon which the reporting entity relies and the outcome the reporting entity is seeking.

(5) At the administrative hearing and on appeal, the reporting entity bears the burden of proving by a preponderance of the evidence that it has complied with applicable laws, rules, regulations, and agreements.

(6) The administrative hearing process is governed by chapters 34.05 RCW and 182-526 WAC.

(7) The authority does not begin the collection process until a decision in the administrative hearing is issued and all levels of appeal have been exhausted.

(8) Interest on owed and outstanding fines continues to accrue at the rate of one percent per month or portion of a month, but it is not collected until a decision in the administrative hearing is issued and all levels of appeal have been exhausted.