PROPOSED RULE MAKING

CR-102 (December 2017)
(Implements RCW 34.05.320)
Do **NOT** use for expedited rule making

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STATE OF WASHINGTON
FILED

DATE: July 21, 2020
TIME: 3:27 PM

WSR 20-15-146

Agency: Health Care Authority

☒ **Original Notice**
☐ **Supplemental Notice to WSR _____**
☐ **Continuance of WSR _____**

☒ **Preproposal Statement of Inquiry was filed as WSR** 20-03-078 **; or**
☐ **Expedited Rule Making--Proposed notice was filed as WSR _____; or**
☐ **Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1); or**
☐ **Proposal is exempt under RCW _____.**

Title of rule and other identifying information: (describe subject) 182-51 WAC, Washington Prescription Drug Pricing Transparency Program

Hearing location(s):

Date:	**Time:**	**Location:** (be specific)	**Comment:**
August 25, 2020	10:00 AM	As the Governor's Safe Start plan progresses, it is yet unknown whether by the date of this public hearing restrictions of meeting in public places will be eased. To continue to be safe, this hearing is being scheduled as a virtual only hearing. This will not be an in-person hearing and there is not a physical location available.	To attend the virtual public hearing, please register prior to the event at: https://attendee.gotowebinar.com/register/3388771111368337931 After registering, you will receive a confirmation email containing the information about joining the webinar.

Date of intended adoption: Not sooner than August 26, 2020 (Note: This is **NOT** the **effective** date)

Submit written comments to:
Name: HCA Rules Coordinator
Address: PO Box 42716, Olympia WA 98504-2716
Email: arc@hca.wa.gov
Fax: (360) 586-9727
Other:
By (date) August 25, 2020

Assistance for persons with disabilities:
Contact Amber Lougheed
Phone: (360) 725-1349
Fax: (360) 586-9727
TTY: Telecommunication Relay Services (TRS): 711
Email: amber.lougheed@hca.wa.gov
Other:
By (date) August 7, 2020

Purpose of the proposal and its anticipated effects, including any changes in existing rules: To implement the Washington Prescription Drug Pricing Transparency Program as required under Chapter 43.71C RCW.

Reasons supporting proposal: See Purpose

Statutory authority for adoption: RCW 41.05.021, 41.05.160, 43.71C.110, and ESSHB 1224, Chapter 334, Laws of 2019

Statute being implemented: RCW 41.05.021, 41.05.160, 43.71C.110, and ESSHB 1224, Chapter 334, Laws of 2019

Is rule necessary because of a:

Federal Law?	☐ Yes	☒ No
Federal Court Decision?	☐ Yes	☒ No
State Court Decision?	☐ Yes	☒ No

If yes, CITATION:

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters: N/A

Name of proponent: (person or organization) Health Care Authority

☐ Private
☐ Public
☒ Governmental

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting:	Jason Crabbe	PO Box 42716, Olympia WA 98504-2716	360-725-9563
Implementation:	Annette Schuffenhauer	PO Box 45502, Olympia WA 98504-5502	(360) 725-1254
Enforcement:	Annette Schuffenhauer	PO Box 45502, Olympia WA 98504-5502	(360) 725-1254

Is a school district fiscal impact statement required under RCW 28A.305.135? ☐ Yes ☒ No

If yes, insert statement here:

The public may obtain a copy of the school district fiscal impact statement by contacting:
Name:
Address:
Phone:
Fax:
TTY:
Email:
Other:

Is a cost-benefit analysis required under RCW 34.05.328?

☐ Yes: A preliminary cost-benefit analysis may be obtained by contacting:
Name:
Address:
Phone:
Fax:

TTY:
Email:
Other:

☒ No: Please explain: RCW 34.05.328 does not apply to Health Care Authority rules unless requested by the Joint Administrative Rules Review Committee or applied voluntarily.

Regulatory Fairness Act Cost Considerations for a Small Business Economic Impact Statement:

This rule proposal, or portions of the proposal, **may be exempt** from requirements of the Regulatory Fairness Act (see chapter 19.85 RCW). Please check the box for any applicable exemption(s):

☐ This rule proposal, or portions of the proposal, is exempt under RCW 19.85.061 because this rule making is being adopted solely to conform and/or comply with federal statute or regulations. Please cite the specific federal statute or regulation this rule is being adopted to conform or comply with, and describe the consequences to the state if the rule is not adopted.
Citation and description:

☐ This rule proposal, or portions of the proposal, is exempt because the agency has completed the pilot rule process defined by RCW 34.05.313 before filing the notice of this proposed rule.

☐ This rule proposal, or portions of the proposal, is exempt under the provisions of RCW 15.65.570(2) because it was adopted by a referendum.

☒ This rule proposal, or portions of the proposal, is exempt under RCW 19.85.025(3). Check all that apply:

- ☐ RCW 34.05.310 (4)(b) (Internal government operations)
- ☐ RCW 34.05.310 (4)(c) (Incorporation by reference)
- ☐ RCW 34.05.310 (4)(d) (Correct or clarify language)
- ☒ RCW 34.05.310 (4)(e) (Dictated by statute)
- ☐ RCW 34.05.310 (4)(f) (Set or adjust fees)
- ☐ RCW 34.05.310 (4)(g) ((i) Relating to agency hearings; or (ii) process requirements for applying to an agency for a license or permit)

☐ This rule proposal, or portions of the proposal, is exempt under RCW _____.
Explanation of exemptions, if necessary:

COMPLETE THIS SECTION ONLY IF NO EXEMPTION APPLIES

If the proposed rule is **not exempt**, does it impose more-than-minor costs (as defined by RCW 19.85.020(2)) on businesses?

☐ No Briefly summarize the agency's analysis showing how costs were calculated. _____

☐ Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses, and a small business economic impact statement is required. Insert statement here:

The public may obtain a copy of the small business economic impact statement or the detailed cost calculations by contacting:

Name:
Address:
Phone:
Fax:
TTY:
Email:
Other:

Date: July 21, 2020	**Signature:** 
Name: Wendy Barcus	
Title: HCA Rules Coordinator	

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) 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.

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) "Covered drug" means any prescription drug that:

(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

(b) Meets all of the following:

(i) Is currently on the market;

(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 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.

(4) "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.

(5) "Data" means all data provided to the authority under RCW 43.71C.020 through 43.71C.080 and any analysis prepared by the authority.

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

(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.

(8) "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).

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

(10) "Introduced to market" means made available for purchase in Washington state.

(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.

(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) "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.

(15) "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.

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

(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.

(18) "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.

(19) "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 and may result in fines as described in WAC 182-51-1100.

NEW SECTION

WAC 182-51-0300 Health carriers—Cost utilization data reporting. (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.

(2) 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.

(3) The authority may assess fines for not complying with the requirements in this section. See WAC 182-51-1000.

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 in the required format in accordance with 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 section 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 agency may assess fines for not complying with the requirements in this section. See WAC 182-51-1000.

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 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.

(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;

(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.

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

(4) The authority may assess fines for not complying with the requirements in this section. See WAC 182-51-1000.

NEW SECTION

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 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.

(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 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.

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

(4) The agency may assess fines for not complying with the requirements in this section. See WAC 182-51-1000.

NEW SECTION

WAC 182-51-0800 Pharmacy services administrative organizations—Data reporting. (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.

(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.

(3) The authority may assess fines for not complying with the requirements in this section. See WAC 182-51-1000.

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.

(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.

(2) The authority may, at its sole discretion, 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, at its sole discretion, 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 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.

(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 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, 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, 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.

(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.

(6) 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.

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

NEW SECTION

WAC 182-51-1500 Notice of violation and fine. (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.

(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.

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 notice of a violation and fine may request a hearing to be conducted in accordance with this chapter and chapter 182-526 WAC.

(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.

NEW SECTION

WAC 182-51-1700 Informal dispute resolution prior to a hearing. (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.

(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 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.

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

(4) 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 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.

(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.

(3) 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.

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

(5) 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.

(6) 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.