Virginia Health Information

Prescription Drug Price Transparency Regulation (12VAC5-219-10)

Submission Manual (Version 1.0)

Data Submission Requirements

Revision History

Date	Version	Description	Author
8/27/2021	1.0	Initial version subject to final comment period	VHI

Definitions (12VAC5-219-10)

- **Biologic** - a therapeutic drug, made from a living organism such as human, animal, yeast or microorganisms, which is licensed under a Biologic License Application by the FDA.
- **Biosimilar** - has the same meaning as ascribed to the term in § 54.1-3442.02 of the Code of Virginia.
- **Brand-Name Drug** - has the same meaning as ascribed to the term in §§ 54.1-3436.1 and 54.1-3442.02 of the Code of Virginia.
- **Carrier** - has the same meaning as ascribed to the term in § 38.2-3407.10 of the Code of Virginia.
- **Commissioner** - means the State Health Commissioner.
- **Department** - means the State Department of Health.
- **Discount** - any price concessions offered or provided by a reporting entity for a prescription drug, including rebates, reductions in price, coupons, out-of-pocket cost assistance, premium assistance, or copay assistance, that has the effect of reducing the cost of a prescription drug.
- **Drug Product** - a finished dosage form, such as a tablet or solution, that contains a prescription generally, but not necessarily, in association with inactive ingredients and that has been issued a National Drug Code by the FDA.
- **Enrollee** - has the same meaning as ascribed to the term in § 38.2-3407.10 of the Code of Virginia.
- **FDA** - the U.S. Food and Drug Administration.
- **Generic Drug** - has the same meaning as ascribed to the term in § 54.1-3436.1 of the Code of Virginia.
- **Health Benefit Plan** - has the same meaning as ascribed to the term in § 38.2-3438 of the Code of Virginia.
- **IRS** - the U.S. Internal Revenue Service.
- **Launched** - the month and year on which a manufacturer acquired or first marketed a prescription drug for sale in the United States.
- **Manufacturer** - has the same meaning as ascribed to the term in § 54.1-3401 of the Code of Virginia.
- **New Prescription Drug** - has the same meaning as ascribed to the term in § 54.1-3442.02 of the Code of Virginia.

- **Outpatient Prescription Drug** - a prescription drug that may be obtained only by prescription and dispensed by a pharmacy licensed to dispense prescription drugs in Virginia, including from a retail, outpatient, mail order or other delivery setting. Outpatient prescription drug excludes prescription drugs provided as part of or incident to and in the same setting as inpatient and outpatient hospital services, hospice services, and dental services.
- **Pharmacy Benefits Management** - has the same meaning as ascribed to the term in § 38.2-3407.15:4 of the Code of Virginia.
- **Pharmacy Benefits Manager (PBM)** - has the same meaning as ascribed to the term in § 38.2-3407.15:4 of the Code of Virginia.
- **Premium** - the amount members pay to a carrier or health benefit plan for their medical and prescription drug insurance.
- **Price** - the amount of money an individual consumer pays at retail for a prescription drug in the absence of a discount.
- **Prescription Drug** - has the same meaning as ascribed to the term in § 54.1-3401 of the Code of Virginia. "Prescription Drug" includes biologics and biosimilars for which a prescription is needed.
- **Rebate** - has the same meaning as ascribed to the term in § 38.2-3407.22 of the Code of Virginia.
- **Reporting Entity** - carriers, PBMs, and manufacturers. Submission required by wholesale distributors may be determined by VDH in the future.
- **Specialty Drug** - a prescription drug that:

  1. Has a price for a 30-day equivalent supply equal to or greater than the current minimum specialty tier eligibility threshold under Medicare Part D as determined by the U.S. Centers for Medicare and Medicaid Services; and

  2. Is:

     a. Prescribed for a person with a chronic, complex, rare, or life-threatening medical condition;

     b. Requires specialized supply chain features, product handling, or administration by the dispensing pharmacy; or

     c. Requires specialized clinical care, including intensive clinical monitoring or expanded services for patients such as intensive patient counseling, intensive patient education, or ongoing clinical support beyond traditional dispensing activities.

  It is presumed that a prescription drug, appearing on Medicare Part D's specialty tier is a specialty drug.
- **Spending** - the amount of money, expressed in U.S. dollars, expended after discounts.
- **Therapeutically Equivalent** - a generic drug that is:

  1. Approved as safe and effective;

  2. Adequately labeled;

  3. Manufactured in compliance with 21 CFR Part 210, 21 CFR Part 211, and 21 CFR Part 212; and

  4. Either:

     a. A pharmaceutical equivalent to a brand-name drug in that it:

i. Contains identical amounts of the identical active drug ingredient in the identical dosage form and route of administration; and

ii. Meets compendial or other applicable standards of strength, quality, purity, and identity; or

b. A bioequivalent to a brand-name drug in that:

i. It does not present a known or potential bioequivalence problem, and they meet an acceptable in vitro standard; or

ii. If it does present such a known or potential problem, it is shown to meet an appropriate bioequivalence standard.

- **USAN Council** - the United States Adopted Names Council.
- **Utilization Management** - strategies, including drug utilization review, prior authorization, step therapy, quantity or dose limits, and comparative effectiveness reviews to reduce a patient's exposure to inappropriate drugs and lower the cost of treatment.
- **Virginia Health Information (VHI)** - has the same meaning as ascribed to the term in § 32.1-23.4 of the Code of Virginia.
- **Wholesale Acquisition Cost (WAC)** - has the same meaning as ascribed to the term in §§ 54.1-3436.1 and 54.1-3442.02 of the Code of Virginia.
- **Wholesale Distributor** - has the same meaning as ascribed to the term in § 54.1-3401 of the Code of Virginia.
- **30-day Equivalent Supply** - the total daily dosage units of a prescription drug recommended by its prescribing label as approved by the FDA for 30 days or less. If there is more than one such recommended daily dosage, the largest recommended daily dosage will be considered for purposes of determining a 30-day equivalent supply.. "30-day equivalent supply" includes a 30-day supply and a single course of treatment under subsection B of § 54.1-3442.02 of the Code of Virginia.

Registration (12VAC5-219-20)

A. Each reporting entity shall furnish to and maintain with VHI:

1. Its legal name and any fictitious names under which it operates;
2. Its current mailing address of record; and
3. Its current electronic mailing address of record.
4. Its contact name, title, phone number, and email address

B. The reporting entity shall notify VHI in writing of any change in its legal name or addresses of record within 30 calendar days of such change.

C. Each reporting entity shall notify VHI of its business closing, discontinuation of business as a carrier, PBM, or manufacturer, or acquisition at least 30 days prior to such closure, discontinuation, or acquisition.

1. A reporting entity shall file any report otherwise due on April 1 for the preceding calendar year pursuant to Part II (12VAC5-219-50 et seq.) of this chapter prior to its closure, discontinuation, or acquisition if the reporting entity plans or anticipated that between January 1 and April 1:

a. Its business will close;

b. Its business as a carrier, PBM, or manufacturer will be discontinued; or

c. Its acquisition will result in the discontinuation of its business as a carrier, PBM, or manufacturer.

2. The legal entity acquiring a reporting entity shall ensure that it complies with the provisions of this chapter.

3. The commissioner shall deem the failure to comply with subdivision C 1 of this section as a failure to report pursuant to Part II (12VAC5-219-50 et seq.) of this chapter.

Notice (12VAC5-219-30)

A. VHI shall send to the reporting entity at the last known electronic mailing address of record:

1. An annual notice on or before March 1 regarding its reporting obligations under Part II (12VAC5-219-50 et seq.) of this chapter. Failure to receive this notice does not relieve the reporting entity of the obligation to timely report;

2. Any notices pursuant to subsection C of 12VAC5-219-90; and

3. Any notices pursuant to Article 1 (12VAC5-219-100 et seq.) of Part III of this chapter.

B. If VHI determines that it will accept an alternate drug group system other than Medi-Span© for reports due pursuant to Part II (12VAC5-219-50 et seq.) of this chapter:

1. The department shall publish a general notice in the Virginia Register that contains VHI's determination and the effective date of this determination; and

2. VHI shall notify every reporting entity of VHI's determination by electronic mail at its electronic mailing address of record.

C. The department shall send notices pursuant to Part III (12VAC5-219-100 et seq.) of this chapter and case decisions to the last known electronic mailing address of record and mailing address of record.

D. VHI shall provide any record requested by the commissioner or department related to the enforcement or administration of § 32.1-23.4 of the Code of Virginia or this chapter no more than 10 business days after the request, except as otherwise agreed to between VHI and the commissioner or the department.

VHI shall notify each reporting entity in writing at least 30 calendar days before any change in the report collection method.

Allowable Variances (12VAC5-219-40)

A. The commissioner may authorize a variance to Part II (12VAC5-219-50 et seq.) of this chapter.

B. A variance shall require advance written approval from the commissioner.

C. The department, VHI, or a reporting entity may request a variance at any time. The request for a variance shall include:

1. A citation to the specific standard or requirement from which a variance is request;

2. The nature and duration of the variance requested;

3. A description of how compliance with the current standard or requirement is economically burdensome and constitutes an impractical hardship unique to the requester;

4. Statements or evidence why the purpose of the standard or requirement would not be frustrated if the variance were granted;

5. Proposed alternatives to meet the purpose of the standard or requirement; and

6. Other information, if any, believed by the request to be pertinent to the request.

D. The requester shall provide additional information as may be required and requested by the commissioner to evaluate the variance request.

E. The requester may withdraw a request for a variance at any time.

F. The commissioner shall notify the requester in writing of the commissioner's decision on the variance request. If granted, the commissioner:

1. Shall identify:

a. The standard or requirement to which a variance has been granted;

b. To whom the variance applies; and

c. The effective date and expiration date of the variance; and

2. May attach conditions to a variance that, in the sole judgment of the commissioner, satisfies, supports, or furthers the purpose of the standard or requirement.

G. The commissioner may rescind or modify a variance if:

1. The impractical hardship unique to the requester changes or no longer exists;

2. Additional information becomes known that alters the basis for the original decision, including if the requester elected to fail to comply with the standard or requirement prior to receiving a variance;

3. The requester fails to meet any conditions attached to the variance; or

4. Results of the variance fail to satisfy, support, or further the purpose of the standard or requirement.

H. If a variance is denied, expires, or is rescinded, the commissioner, the department, or VHI, as applicable, shall enforce the standard or requirement to which the variance was granted.

Reporting Requirements

Data Submission Requirements - General

The Virginia Department of Health (VDH) contracts with Virginia Health Information (VHI) to develop, collect, analyze and disseminate the Prescription Drug Price Transparency data.

In order to satisfy the new Prescription Drug Price Transparency requirements, carriers, manufacturers, and pharmacy benefits managers in Virginia will perform the following steps:

Authorized users representing above referenced entities will submit the required data elements (detailed accordingly below) in a .csv file, not to exceed 10 MB, via secure upload to https://www.vhi.org/drug_price. Entities will report prescription drug price transparency regulation data to VHI on an annual basis by April 1st of each year. If a reporting file does exceed 10 MB, authorized users can either submit multiple files or contact VHI for an alternative means of submission.

Data Submission Requirements - Specific

I. Carrier Reporting Requirements

A. Every carrier offering a health benefit plan shall report annually by April 1 to VHI the following information on total annual spending on prescription drugs, before enrollee cost sharing, for each health benefit plan offered by the carrier in the Commonwealth:

1. For covered outpatient prescription drugs that were prescribed to enrollees during the immediately preceding calendar year:
   a. The names of the 25 most frequently prescribed outpatient prescription drugs;
   b. The names of the 25 outpatient prescription drugs covered at the greatest cost, calculated using the total annual spending by such health benefit plan for each outpatient prescription drug covered by the health benefit plan; and
   c. The names of the 25 outpatient prescription drugs that experienced the greatest year-over-year increase in cost, calculated using the total annual spending by a health benefit plan for each outpatient prescription drug covered by the health benefit plan;
2. The percent increase in annual net spending for prescription drugs after accounting for aggregated discounts;
3. The percent increase in premiums that were attributable to each health care service, including prescription drugs;
4. The percentage of specialty drugs with utilization management requirements; and
5. The premium reductions that were attributable to specialty drug utilization management.

B. In determining which outpatient prescription drugs are reportable under subdivision A 1 of this section, the carrier shall:

1. Average the frequency of prescription for all drug products of an outpatient prescription drug for such health benefit plan to determine which outpatient prescription drugs are reportable under subdivision A 1 a;

2. Average the cost, calculated using the total annual spending by such health benefit plan for all drug products of an outpatient prescription drug covered by the health benefit plan, to determine which outpatient prescription drugs are reportable under subdivision A 1 b; and

3. Average the year-over-year increase in cost, calculated using the total annual spending by a health benefit plan for all drug products of an outpatient prescription drug covered by the health benefit plan, to determine which outpatient prescription drugs are reportable under subdivision A 1 c.

C. A carrier may not disclose the identity of a specific health benefit plan or the price charged for a specific prescription drug or class of prescription drugs when submitting a report pursuant to subsection A of this section. A carrier shall use a health benefit plan unique identifier as described in subsection E of this section in lieu of the health benefit plan's identity when submitting a report pursuant to subsection A of this section.

D. Every carrier offering a health benefit plan shall require each PBM with which it enters into a contract for pharmacy benefits management to comply with 12VAC5-219-60.

E. Every carrier shall provide the information specified in subsection B and C of this section on a form prescribed by the department that includes the following data elements:

Carrier					
	Data Element Name	**Field Type**	**Min Length**	**Max Length**	**Data Element Definition**
Carrier	Carrier tax identification number	char	9	9	The 9-digit tax Taxpayer Identification Number used by the IRS.
Carrier	Carrier name	varchar	1	75	The legal name of the reporting entity.
Carrier	Health benefit plan category	char	2	2	The 2-digit health plan category identifier. The first digit corresponds to the insurance line and valid values are D (Medicaid); R (Medicare); C (commercial); and O (other). The second digit corresponds to the insurance policy type and valid values include I (individual); F

					(fully insured group); S (self insured group); and C (Commonwealth of Virginia employees).
Carrier	Health benefit plan unique identifier	char	5	5	A unique 5-digit incremental number assigned by a carrier to a health benefit plan within a given health benefit plan category for the purpose of anonymizing the health benefit plan's identity.
Carrier	Proprietary drug name	varchar	1	50	The brand or trademark name of the prescription drug reported to the FDA.
Carrier	Non-proprietary drug name	varchar	1	50	The generic name of the prescription drug assigned by the USAN Council.
Carrier	WAC unit	varchar	1	10	The lowest identifiable quantity of the prescription drug that is dispensed, exclusive of any diluent without reference to volume measures pertaining to liquids.
Carrier	Drug group	char	2	2	The first two digits of the Medi-Span© Generic Product Identifier assigned to the proprietary prescription drug.
Carrier	Brand-name or generic	char	1	1	Whether the prescription drug is brand-name or generic. Use of a value of ‘1’ to indicate brand-name and a value of ‘2’ to indicate generic
Carrier	Net spending increase	int	1	3	The percent year-over-year increase in annual net spending for prescription drugs after accounting for aggregated discounts or other reductions in price.
Carrier	Premium increase	int	1	3	The percent year-over-year increase in premiums that were attributable to each health care service, including prescription drugs.
Carrier	Specialty drugs with utilization management	int	1	3	The percentage of specialty drugs with utilization management requirements.
Carrier	Premium reductions	int	1	3	The percent year-over-year of premium reductions that were attributable to specialty drug utilization management.
Carrier	Comments	varchar	0	999	A text field for any additional information the carrier wishes to provide.

II. Pharmacy Benefits Manager (PBM) Reporting Requirements

A. Every PBM providing pharmacy benefits management under contract to a carrier shall report annually by April 1 to VHI the following information for each prescription drug upon which the carrier is reporting pursuant to 12VAC5-219-50:

1. The aggregate amount of rebates received by the PBM;

2. The aggregate amount of rebates distributed to the relevant health benefit plan; and

3. The aggregate amount of rebates passed on to enrollees of each health benefit plan at the point of sale that reduced the enrollees' applicable deductible, copayment, coinsurance, or other cost-sharing amount.

B. Every PBM shall provide the information specified in subsection A of this section on a form prescribed by the department that includes the following data elements:

Pharmacy Benefits Manager (PBM)					
	Data Element Name	**Field Type**	**Min Length**	**Max Length**	**Data Element Definition**
PBM	PBM tax identification number	char	9	9	The 9-digit tax Taxpayer Identification Number used by the IRS.
PBM	PBM name	varchar	1	75	The legal name of the reporting entity.
PBM	Carrier name	varchar	1	75	The legal name of the carrier to whom rebates were distributed or passed on.
PBM	Proprietary drug name	varchar	1	50	The brand or trademark name of the prescription drug reported to the FDA.
PBM	Non-proprietary drug name	varchar	1	50	The generic name of the prescription drug assigned by the USAN Council.
PBM	Drug group	char	2	2	The first two digits of the Medi-Span© Generic Product Identifier assigned to the proprietary prescription drug
PBM	Brand-name or generic	char	1	1	Whether the prescription drug is brand-name or generic. Use of a value of ‘1’ to indicate brand-name and a value of ‘2’ to indicate generic

PBM	Total rebates	int	1	10	Total aggregate rebates received or negotiated directly with the manufacturer in the last calendar year, for business in the Commonwealth.
PBM	Total rebates distributed	int	1	10	Total aggregate rebates distributed to the relevant health benefit plan in the last calendar year, for business in the Commonwealth.
PBM	Total rebates passed on	int	1	10	Total aggregate rebates passed on to all enrollees of a health benefit plan at the point of sale that reduced the enrollees' applicable deductible, copayment, coinsurance, or other cost-sharing amount in the last calendar year, for business in the Commonwealth.
PBM	Comments	varchar	0	999	A text field for any additional information the PBM wishes to provide.

III. Manufacturer Reporting Requirements

A. Every manufacturer shall report annually by April 1 to VHI on each of its:

1. Brand-name prescription drug and biologic, other than a biosimilar, with:

a. A WAC of $100 or more for a 30-day supply or a single course of treatment; and

b. Any increase of 15% or more in the WAC of such brand-name drug or biologic over the preceding calendar year;

2. Biosimilar with an initial WAC that is not at least 15% less than the WAC of the referenced brand biologic at the time the biosimilar is launched and that has not been previously been reported to VHI; and

3. Generic drug with a price increase that results in an increase in the WAC equal to 200% or more during the preceding 12-month period, when the WAC of such generic drug is equal to or greater than $100, annually adjusted by the Consumer Price Index for All Urban Consumers, for a 30-day supply.

a. For the purposes of subdivision A 3, a price increase is the difference between the WAC of the generic drug after increase in the WAC and the average WAC of such generic drug during the previous 12 months.

B. For each prescription drug identified in subsection A of this section, a manufacturer shall report:

1. The name of the prescription drug;

2. Whether the prescription drug is a brand name or generic;

3. The effective date of the change in WAC;

4. Aggregate, company-level research and development costs for the most recent year for which final audit data is available;

5. The name of each of the manufacturer's new prescription drugs approved by the FDA within the previous three calendar years;

6. The name of each of the manufacturer's prescription drugs that, within the previous three calendar years, became subject to generic competition and for which there is a therapeutically equivalent generic version; and

7. A concise statement regarding the factor or factors that caused the increase in WAC.

C. Every manufacturer shall provide the information specified in subsection B of this section on a form prescribed by the department that includes the following data elements:

Manufacturer					
	Data Element Name	**Field Type**	**Min Length**	**Max Length**	**Data Element Definition**
Manufacturer	Manufacturer tax identification number	char	9	9	The 9-digit tax Taxpayer Identification Number (TIN) used by the IRS.
Manufacturer	Manufacturer name	varchar	1	75	The legal name of the reporting entity.
Manufacturer	Proprietary drug name	varchar	1	50	The brand or trademark name of the prescription drug reported to the FDA.
Manufacturer	Non-proprietary drug name	varchar	1	50	The generic name of the prescription drug assigned by the USAN Council.
Manufacturer	WAC unit	varchar	1	10	The lowest identifiable quantity of the prescription drug that is dispensed, exclusive of any diluent without reference to volume measures pertaining to liquids.
Manufacturer	Drug group	char	2	2	The first two digits of the Medi-Span© Generic Product Identifier assigned to the prescription drug.
Manufacturer	Brand-name drug or generic drug	char	1	1	Whether the report is about a brand-name drug or generic drug. Use of a value of ‘1’ to indicate brand-name and a value of ‘2’ to indicate generic
Manufacturer	Subject to generic competition	char	6	6	The month and year of initial generic competition.
Manufacturer	Date of initial generic competition	char	4	4	The year of market introduction of the prescription drug.
Manufacturer	WAC at market introduction	int	1	10	The manufacturer’s list price to wholesalers or direct purchasers in the United States at market introduction, as reported in wholesale price guides or other publications of prescription pricing data; it does not include discounts or reductions in price. Round to the nearest whole dollar.

Manufacturer	WAC on January 1 of the prior calendar year	int	1	10	The manufacturer's list price in U.S. dollars per unit, to wholesalers or direct purchasers in the United States on January 1 of the prior calendar year, as reported in wholesale price guides or other publications of prescription drug pricing data; it does not include discounts. Round to the nearest whole dollar.
Manufacturer	WAC on December 31 of the prior calendar year	int	1	10	The manufacturer's list price in U.S. dollars per unit, to wholesalers or direct purchasers in the United States on December 31 of the prior calendar year, as reported in wholesale price guides or other publications of prescription drug pricing data; it does not include discounts.
Manufacturer	Effective date of change in WAC	char	6	6	The month and year that the WAC changed.
Manufacturer	Justification for current-year WAC increase	varchar	1	999	The reason or reasons that the manufacturer increased the WAC of the prescription drug compared with last year.
Manufacturer	Research and development costs	int	1	15	Aggregate, company-level research and development costs in U.S. dollars for the most recent year for which final audit data is available.
Manufacturer	Year of research and development costs	char	4	4	The year in which final audit data is available.
Manufacturer	Comments	varchar	0	999	A text field for any additional information the manufacturer wishes to provide.

D. Manufacturers who wish to submit a 10-K form as part of this data collection requirement should contact VHI for instructions on alternative means of submission.

Part III: Enrollment

Data Validation; Notification; Response (12VAC5-219-100)

A. VHI shall:

1. Validate that the data received from each reporting entity pursuant to a report required under Part II (12VAC5-219-40 et seq.) of this chapter is complete no more than 90 calendar days after submission;

2. Notify a reporting entity if VHI cannot validate the data submitted pursuant to a report required under Part II (12VAC5-219-50 et seq.) of this chapter;

3. Send the notification specified in subdivision A 2 of this section no more than 3 business days after completion of the data validation to the reporting entity's email address of record;

4. Identify in the notification specified in subdivision A 2 of this section the specific report and the data elements within the report that are incomplete; and

5. Provide a copy of the notification specified in subdivision A 2 of this section to the commissioner at the same time it is sent to the reporting entity.

B. Each reporting entity notified under subsection A shall make changes necessary to correct the report within 30 calendar days of the notification.

C. If a reporting entity fails to correct the report within 30 calendar days, VHI shall::

1. Notify a reporting entity that it has failed to correct the report;

2. Send the notification specified in subdivision A 1 of this section no more than 2 business days after the reporting entity's failure to report to the reporting entity's email address of record;

3. Identify in the notification specified in subdivision A 1 of this section the specific report and the data elements within the report that have not been corrected; and

4. Provide a copy of the notification specified in subdivision A 1 of this section to the commissioner at the same time it is sent to the reporting entity.

D. If a reporting entity fails to correct the report within 15 calendar days of the second notice:

1. VHI shall provide to the commissioner within 1 business day of the failure to correct:

a. The copy of the original report submitted by the reporting entity;

b. Any subsequent updated reports that the reporting entity may have filed; and

c. Any correspondence between VHI and the reporting entity after the notification sent pursuant to subsection A of this section; and

2. The commissioner shall deem the failure to correct as a failure to report pursuant to Part II (12VAC5-219-50 et seq.) of this chapter.

Audit; Corrective Action Plan (12VAC5-219-110)

A. A reporting entity shall include:

1. A signed, written certification of the accuracy of any notification or report to VHI; or

2. Electronic certification of their notification or report through VHI's online collection tool.

B. VHI may verify the accuracy of finalized data reported by a reporting entity through an audit conducted by VHI, provided that VHI gives notice to the reporting entity at its electronic mailing address of record no fewer than 30 calendar days prior to initiating the audit.

C. VHI shall send a copy of the audit findings to the reporting entity no more than 5 business days after the conclusion of the audit at its email mailing address of record.

D. If any deficiencies are found during the audit:

1. VHI shall:

a. Notify a reporting entity by providing a copy of the audit findings no more than 5 business days after completion of the audit to the reporting entity’s email address of record;

b. Provide a copy of the notification to the commissioner at the same time it is sent to the reporting entity.

2. The reporting entity shall prepare a written corrective action plan addressing each deficiency cited at the time of audit as specified in subsection E of this section.

E. The reporting entity shall submit to VHI and the commissioner a corrective action plan no more than 10 business days after receipt of the audit findings, and shall include in the corrective action plan:

1. A description of the corrective action or actions to be taken for each deficiency and the position title of the employees to implement the corrective action;

2. The deadline for completion of all corrective action, not to exceed 45 business days from the receipt of the audit findings; and

3. A description of the measures implemented to prevent a recurrence of the deficiency.

F. The reporting entity shall ensure that the person responsible for the validity of the corrective action plan signs, dates, and indicates their title on the corrective action plan.

G. VHI shall:

1. Notify the reporting entity if VHI determines any item in the corrective action plan is unacceptable;

2. Grant the reporting entity two opportunities to revise and resubmit a corrective action plan that VHI initially determines to be unacceptable. If the reporting entity revises and resubmits the corrective action plan, the revision is due to VHI and the commissioner no more than 15 business days after VHI has notified the reporting entity pursuant to subdivision 1 of this subsection.

H. If a reporting entity fails to comply with the corrective action plan:

1. VHI shall provide to the commissioner any correspondence between VHI and the reporting entity after the notification sent pursuant to subsection D of this section; and

2. The commissioner shall deem the failure to comply as a failure to report pursuant to Part II (12VAC5-219-50 et seq.) of this chapter.

Disciplinary Action (12VAC5-219-120)

A. A reporting entity may not violate the provisions of this chapter.

B. The commissioner may:

1. For each violation of this chapter, petition an appropriate court for an injunction, mandamus, or other appropriate remedy or imposition of a civil penalty against the reporting entity pursuant to subsection B or C of § 32.1-27 of the Code of Virginia: and

2. For each violation of Part II (12VAC5-219-50 et seq.) of this chapter, levy a civil penalty upon the reporting entity as specified in subsection B of 12VAC5-219-130, in accordance with the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia).

C. Each day that a reporting entity fails to report in violation of this chapter is a sufficient cause for imposition of disciplinary action. If a reporting entity knowingly submits false, inaccurate, or misleading data pursuant to the reporting requirements of this chapter, the commissioner shall deem that submission as a failure to report.

Civil Penalty (12VAC5-219-130)

A. The commissioner may reduce or waive the civil penalty imposed pursuant to this section, if he, in his sole discretion, determines that the violation was reasonable or resulting from good cause.

B. Except as provided in subsection A of this section, the commissioner shall levy a civil penalty upon the reporting entity in an amount of:

1. For the first offense:

a. $500 the first day in which the reporting entity fails to report;

b. $1,000 for the second day in which the reporting entity fails to report;

c. $1,500 for the third day in which the reporting entity fails to report;

d. $2,000 for the fourth day in which the reporting entity fails to report; and

e. $2,500 for the fifth day and each subsequent day in which the reporting entity fails to report; and

2. For the second offense:

a. $1,000 the first day in which the reporting entity fails to report;

b. $1,750 for the second day in which the reporting entity fails to report; and

c. $2,500 for the third and each subsequent day in which the reporting entity fails to report; and

3. For the third and all subsequent offenses, $2,500 for each day in which the reporting entity fails to report.

C. The commissioner shall deem the first day in which the reporting entity fails to report as:

1. April 2 for a reporting entity that fails to submit any information or documentation pursuant to 12VAC5-219-50, 12VAC5-219-60, or 12VAC5-219-70 or for a reporting entity that knowingly submits false, inaccurate, or misleading data pursuant to 12VAC5-219-50, 12VAC5-219-60, or 12VAC5-219-70;

2. The 16th calendar day after notification pursuant to subdivision C 1 of 12VAC5-219-100 for a reporting entity that fails to correct its report submitted pursuant to Part II (12VAC5-219-50 et seq.) of this chapter; and

3. The calendar day immediately succeeding the deadline of a corrective action plan for a reporting entity that fails to comply with its corrective action plan approved pursuant to 12VAC5-219-110.

D. Civil penalties are due 15 calendar days after the date of receipt of the notice of civil penalty imposition or 31 calendar days after the service of a case decision after an informal fact finding proceeding, whichever is later.

E. A reporting entity shall remit a check or money order for a civil penalty payable to the Treasurer of Virginia.

1. If a check, money draft, or similar instrument for payment of a civil penalty is not honored by the bank or financial institution named, the reporting entity shall remit funds sufficient to cover the original civil penalty amount, plus a $50 dishonored payment fee.

2. Unless otherwise provided, the commissioner may not refund civil penalties or fees.

F. A civil penalty imposed pursuant to subsection B of this section is a debt to the Commonwealth and may be sued for and recovered in the name of the Commonwealth.

1. On all past due civil penalties, the commissioner shall assess and charge:

a. Interest at the judgment rate as provided in § 6.2-302 of the Code of Virginia on the unpaid balance unless a higher interest rate is authorized by contract with the debtor or provided otherwise by statute, which shall accrue on the 60th day after the date of the initial written demand for payment;

b. An additional amount that approximates the administrative costs arising under § 2.2-4806 of the Code of Virginia; and

c. Late penalty fees of 10% of the past due civil penalties.

2. The commissioner may refer a past due civil penalty for collection by the Division of Debt Collection of the Office of the Attorney General.

Informal Fact-Finding Proceeding (12VAC5-219-140)

A. A reporting entity may dispute the imposition of a civil penalty pursuant to subdivision B 2 of 12VAC5-219-120 by requesting an informal fact finding proceeding:

1. In writing to the commissioner; and

2. No more than 14 calendar days after the date of receipt of the notice of civil penalty imposition.

B. In requesting an informal fact finding proceeding pursuant to subsection A of this section, a reporting entity:

1. Shall identify with specificity the reason or alleged good cause for its failure to report; and

2. May present factual data, argument, information, or proof in support of its reason or alleged good cause for its failure to report.

C. The request for an informal fact finding proceeding:

1. May not toll the imposition of a civil penalty on a per day basis, as specified in subsection B of 12VAC5-219-130;

2. Shall toll all assessments and charges under subdivision F 1 of 12VAC5-219-130 until a case decision after an informal fact finding proceeding has been served.

D. If a reporting entity does not request an informal fact finding proceeding pursuant to subsection A of this section, the civil penalty imposed pursuant to subdivision B 2 of 12VAC5-219-120 shall be final on the 15th calendar day after the date of receipt of the notice of civil penalty imposition.