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Final Regulation
Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12 VAC5-219
VAC Chapter title(s)	Prescription Drug Price Transparency Regulation
Action title	Promulgation of New Regulation to Implement Chapter 304 of the 2021 Acts of Assembly, Special Session I
Date this document prepared	3/5/2026

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 19 (2022) (EO 19), any instructions or procedures issued by the Office of Regulatory Management (ORM) or the Department of Planning and Budget (DPB) pursuant to EO 19, the Regulations for Filing and Publishing Agency Regulations (1 VAC 7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*.

Brief Summary

Provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.

Chapter 304 (2021 Acts of Assembly, Special Session I) requires the Virginia Department of Health (VDH) to promulgate regulations to govern the collection, reporting, and auditing of prescription price drug information provided by specific entities such as health carriers, pharmacy benefits managers, manufacturers, and wholesale distributors. The legislation also institutes a civil penalty on these entities for failure to report the required information that is based on the severity of the violation. As the requirement to report prescription drug price information is new, there is no existing regulatory chapter, and the VDH intends to promulgate a new regulatory chapter to best fit this mandate. Emergency regulations established in 2022 have expired and are extended until the enactment of the final regulations by Chapter 727 of the 2024 Acts of Assembly.

Substantive changes to subsections B and C of 12VAC5-219-100 remove language providing reporting entities the opportunity to request an informal fact-finding conference (IFFC) at the time the NDSO determines the reporting entity has not submitted information that can be validated. The change has been made to align the Final regulations with the existing IFFC process which requires the commissioner's case decision to be determined before an IFFC can be requested. Changes to 12VAC5-219-130 add a new requirement directing the commissioner to notify a reporting entity upon a determination that such entity's data submission or noncompliance is a failure to report. Updates specify the information to be included in the notice, permit the reporting entity to request an IFFC in accordance with § 2.2-4019 of the Code of Virginia, and clarify the timeframe during which the reporting entity has to request an IFFC. Amendments to subsection A of 12VAC5-219-140 revise the timeframe during which a reporting entity may request an IFFC to clarify that the request can be made within 15 calendar days of the date the commissioner's notice of civil penalty is issued.

Minor changes made between the proposed and final states of the regulatory action correct punctuation errors that were identified in the Proposed regulations. Further changes made between the Proposed and Final stages of this regulatory action update regulatory language in 12VAC5-219-80 to correctly reflect the process by which wholesale acquisition cost (WAC) is determined. The changes to 12VAC5-219-80 were made in response to public comment indicating that the proposed language incorrectly implies that the WAC is negotiated by wholesale distributors, and instead clarifies that the WAC is established by manufacturers. The term "informal fact-finding proceeding" has been amended throughout the Final regulations to "informal fact-finding conference" to promote consistency throughout the regulatory chapter.

Acronyms and Definitions

Define all acronyms used in this form, and any technical terms that are not also defined in the "Definitions" section of the regulation.

"Board" means the Board of Health.

"Data sharing agreement" or "DSA" means a formal and legally binding document that outlines the terms of sharing data between two or more parties, and which (i) defines the data to be shared; (ii) the purpose of sharing the data; (iii) responsibilities, rights, and usage limitations; and (iv) outlines associated costs for data sharing between parties.

"Final regulations" or "Regulations" means the regulations governing prescription drug price transparency in Virginia (12VAC5-219).

"IFFC" means an informal fact-finding conference as provided for in § 2.2-4019 of the Code of Virginia.

"Memorandum of Understanding" or "MOU" means a non-formal and non-legally binding agreement between two or more parties that outlines each party's intentions, roles, and objectives.

"NDSO" means Nonprofit data services organization.

"OAG" means Office of the Attorney General.

"VDH" means the Virginia Department of Health.

Statement of Final Agency Action

Provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) that the agency has "adopted final amendments" to the regulation; 3) the name of the agency taking the action; and 4) the title of the regulation. A suggested statement is, "On [insert date] the Board/Department of [insert name] adopted final amendments to the [title of regulation(s)]."

On March 19, 2026, the State Board of Health adopted final regulations for Prescription Drug Price Transparency Regulation (12VAC5-219).

Mandate and Impetus

List all changes to the information reported on the Agency Background Document submitted for the previous stage regarding the mandate for this regulatory change, and any other impetus that specifically prompted its initiation. If there are no changes to previously reported information, include a specific statement to that effect.

Promulgation of regulations that establish reporting requirements for prescription drug price transparency in Virginia is required by Chapter 304 (2021 Acts of Assembly, Special Session I). Emergency promulgation of this new regulatory chapter became effective on January 17, 2022, in accordance with § 2.2-4011 (B) of the Code of Virginia. The emergency regulations expired on July 16, 2023, and have been extended until December 31, 2029. The impetus for this regulatory action is to make the emergency regulation permanent.

Legal Basis

Identify (1) the promulgating agency, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia and Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating agency to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

Subsection D of § 32.1-23.4 of the Code of Virginia requires the VDH to adopt regulations to implement the provisions of § 32.1-23.4, which must include (i) provisions related to the specification of prescription drugs for the purpose of data collection and procedures for auditing information provided by health carriers, Pharmacy Benefit Managers, wholesale distributors, and manufacturers; and (ii) a schedule of civil penalties for failure to report information required pursuant to §§ 32.1-23.4, 38.2-3407.15:6, 38.2-3407.22, 54.1-3436.1, or 54.1-3442.02, which shall be based on the level of severity of the violation.

Purpose

Explain the need for the regulatory change, including a description of: (1) the rationale or justification, (2) the specific reasons the regulatory change is essential to protect the health, safety, or welfare of citizens, and (3) the goals of the regulatory change and the problems it is intended to solve.

Promulgation of regulations by the VDH that specify the standards for Virginia's prescription drug price transparency and reporting requirements is required by Chapter 304 (2021 Acts of Assembly, Special Session I). The regulations are essential to protect the health, safety, or welfare of citizens as they provide regulatory standards regarding prescription drug pricing, which is a driver of increased healthcare costs in the Commonwealth. The goal of the regulatory change is to encourage transparency of prescription drug price information, make prescription drug price information available to consumers for

comparison, and to identify the factors related to prescription drugs that contribute to increased health care costs in the Commonwealth.

Substance

Briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of Changes" section below.

The regulation must contain the specification of prescription drugs for the purpose of data collection and procedures for auditing information provided by health carriers, pharmacy benefits managers, wholesale distributors, and manufacturers as well as a schedule of civil penalties for failure to report the information required that is based on the severity of the violation. The specification must include information required pursuant to §§ 32.1-23.4, 38.2-3407.15:6, 54.1-3436.1, and 54.1-3442.02 of the Code of Virginia.

The following changes have been made from the proposed stage to the final stage:

12VAC5-219-80. Wholesale distributor reporting requirements.
Amendments clarify that the WAC is established by the manufacturer and removes regulatory language that implies the WAC is negotiated between wholesale distributors and manufacturers, clarify data element definitions for "Current year minus one WAC" and "Current year WAC," and correct punctuation errors present in the proposed language.

12VAC5-219-100. Data validation; notification; response.
Changes remove the opportunity for reporting entities to request an IFFC when an NDSO notifies the entity that it cannot validate the data submitted as required under the regulatory chapter. Technical amendments update incorrect references to regulatory provisions in subsection C, and specify in subsection D that the commissioner is permitted, but is not required, to determine a reporting entity's second failure to correct inaccurate or incorrect data submission as a failure to report.

12VAC5-219-110. Audit; corrective action plan.
Updates (i) to subsection D replaces "deficiencies" with "incomplete or inaccurate information;" (ii) to subsection E remove language allowing a reporting entity to request an IFFC to dispute the NDSO's determination that such entity has not provide complete or accurate information during an audit; and (iii) to subdivision 2 of subsection H are technical and replace mandated language with permissive language.

12VAC-219-120. Sanctions.
Updates conform regulatory language to the *Form and Style Guidelines* by utilizing negative construction when prohibiting reporting entities from violating the provisions of the regulatory chapter.

12VAC5-219-130. Civil Penalty.
Subsection A has been amended to require the commissioner to notify a reporting entity in writing of a determination of failure to report, outlines the information to be contained within the notification, and adjusts the timeframe during which an IFFC can be requested by a reporting entity. A new subsection has been added permitting the commissioner to reduce or waive a civil penalty imposed upon a reporting entity. Technical changes update remaining subsection headers and provisional references in subsections C and D.

12VAC5-219-140. Informal fact-finding proceeding.
Substantial changes adjust the timeframe during which a reporting entity may request an IFFC to clarify that the request can be made within 15 calendar days of the date the commissioner's notice of civil penalty is issued, and remove subsection B which outlines the responsibility of the reporting entity to identify the reasons for a failure to report information required under the regulatory chapter. Technical amendments update references to regulatory provisions that have been amended under the Final stage of the regulatory action.

Regulatory language referencing an “informal fact-finding proceeding” has been updated throughout the Final regulations to refer to an “informal fact-finding conference.” The changes have been made to enhance readability and to ensure consistency in the terms used in the regulatory chapter.

Issues

Identify the issues associated with the regulatory change, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, include a specific statement to that effect.

The primary advantage to the public in implementing the new provisions is increased transparency about prescription drug pricing. The primary disadvantage to the public in implementing the new provisions is that businesses subject to the reporting requirements may incur increased expenses for compliance; there is no primary disadvantage in implementing the new provisions to individual private citizens. The primary advantage to VDH or the Commonwealth in implementing the new provisions is increased transparency about prescription drug pricing and the availability of data for research. The primary disadvantage to VDH or the Commonwealth in implementing the new provisions is the fiscal impact of data collection and of adjudication in the event a reporting entity fails to comply.

Pertinent matters of interest to the regulated community, government officials, and the public are issues that were raised by stakeholders prior to the publication of the emergency regulation, during the public comment following the publication of the emergency regulation, and during the initial submission of reports on or before April 1, 2022. VDH discovered there were a number of reporting entities that met the definition of “manufacturer” that did not control the WAC for prescription drugs, so they had no data responsive to the legislative mandate but there was no statutory flexibility for VDH to exempt these entities from reporting. Other stakeholders raised concerns about the interplay between the mandates of Chapter 304 (2021 Acts of Assembly, Special Session I) and of Employee Retirement Income Security Act of 1974 (ERISA). Additionally, the nonprofit data services organization (NDSO) is in the process of analyzing the 2025 submissions from reporting entities and working with a subcontractor to validate the accuracy and completeness of submission; the results of that analysis will help inform additional potential revisions to the regulatory text.

Issues raised by stakeholders during the public comment period of the Proposed stage of this regulatory recommended that (i) the requirement in 12VAC5-219-20 directing reporting entities to register with the NDSO be removed as the information provided to the NDSO for registration is collected by the Commonwealth (Board of Pharmacy) during the licensing process for wholesale distributors; and (ii) 12VAC5-219-80 of the Proposed regulations be amended to reflect the correct process by which the WAC is established.

The recommended changes were not made to 12VAC5-219-20 in the Final regulations as removing the requirement impacts all reporting entities, not just wholesale distributors, and is not duplicative for other reporting entities that submit prescription drug price information. The information collected at the time a reporting entity is licensed varies between different licensing authorities, and the information collected by a licensing authority may not be the information needed by the NDSO for prescription drug price reporting registration. The NDSO is not a state agency of the Commonwealth and does not have the authority to access state agency systems and information unless specifically authorized by law, regulation, rule, contract, or other policy. This arrangement will require the NDSO to obtain the information needed for registration from various licensing authorities, which may or may not be authorized to collect and share

the information needed by the NDSO for registration. Furthermore, it creates additional administrative burdens for the VDH and licensing authorities that provide the information to coordinate to establish DSAs or MOUs, complete regulatory actions, or advocate for statutory changes related to the transmission of the information needed by the NDSO for reporting entity registration. Additionally, removing the requirement for all reporting entities restricts the NDSO's ability to maintain an accurate list of reporting entities that can be used to ensure that such entities adhere to statutory and regulatory mandates, and to ensure that consumers are provided with accurate and complete data to compare prescription drug price information.

Requirements More Restrictive than Federal

List all changes to the information reported on the Agency Background Document submitted for the previous stage regarding any requirement of the regulatory change which is more restrictive than applicable federal requirements. If there are no changes to previously reported information, include a specific statement to that effect.

The regulations do not conflict with federal requirements.

President Donald Trump signed Executive Order 14273 on April 15, 2025, which requires federal agencies to identify and analyze approaches to reduce prescription drug costs for Americans and report findings to the President of the United States; including:

- Medicare price adjustments to address "pill penalties" and stabilize Part D premiums;
- Align US pricing and competition models with other nations;
- Increase prescription drug price transparency and efficiency initiatives;
- Reduce out-of-pocket costs paid by American consumers; and
- Reevaluate the role of PBMs in the pharmaceutical supply chain.

Agencies, Localities, and Other Entities Particularly Affected

List all changes to the information reported on the Agency Background Document submitted for the previous stage regarding any other state agencies, localities, or other entities that are particularly affected by the regulatory change. If there are no changes to previously reported information, include a specific statement to that effect.

Other State Agencies Particularly Affected

There are no other state agencies particularly affected by the regulatory change.

Localities Particularly Affected

There are no localities particularly affected by the regulatory change.

Other Entities Particularly Affected

Other entities particularly affected by the regulatory change include reporting entities and consumers of prescription drugs.

Public Comment

Summarize all comments received during the public comment period following the publication of the previous stage, and provide the agency's response. Include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency. If no comment was received, enter a specific statement to that effect.

Commenter	Comment	Agency response
Bryan Hannon, Health Care Distribution Alliance	On behalf of the Healthcare Distribution Alliance (HDA), the national trade association representing pharmaceutical wholesale distributors, thank you for the opportunity to provide comments on the proposed rules to implement Chapter 304 of the 2021 Acts of the Assembly, Special Session I. HDA was proud to work closely with lawmakers, including Delegate Sickles, to advance sensible price transparency legislation in 2021. As a full partner in the implementation of the law, HDA is committed to ensuring that the rulemaking process aligns with the legislative intent and supports the consistent and effective execution of the statute. First, we are concerned that 12VAC5-219-80 of the proposed rules incorrectly implies that wholesale distributors negotiate wholesale acquisition cost (WAC). Distributors are the logistics providers in the supply chain, safely and efficiently delivering medicines to more than 5,800 locations across Virginia. Distributors play no role in setting – or negotiating – a product's WAC. Instead, WAC is established solely by the manufacturer and communicated to distributors. We respectfully request that the draft rules be revised to accurately reflect this process and avoid mischaracterizing the role of wholesale distributors. Please see Appendix A for suggested edits. Additionally, 12 VAC 5-219-20 of the proposed rules require all reporting entities, including wholesale distributors, to register with the commonwealth's nonprofit data services organization (NDSO). This requirement is duplicative, as wholesale distributors are already	On behalf of the VDH, I would like to thank the Healthcare Distribution Alliance (HDA) for submitting its comments regarding the proposed rules to implement Chapter 304 of the 2021 Acts of Assembly, Special Session I. We acknowledge HDA's role in supporting the development of the original legislation and appreciate your continued partnership in ensuring the successful and accurate implementation of the statute. Your detailed feedback regarding the characterization of wholesale distributors' role in setting wholesale acquisition cost (WAC), as well as your concerns regarding duplicative registration requirements, has been received and will be taken under consideration as we move forward in the rulemaking process. Thank you again for your thoughtful input and continued engagement.

	licensed under § 54.1-3435, and the Board of Pharmacy's licensing process collects the same information that would be submitted to the NDSO. Since the Commonwealth already maintains this information, we respectfully recommend removing the redundant registration requirement for wholesale distributors in the final rules. Thank you for your consideration of these recommended changes. I am available for any questions or comments. Sincerely, Bryan D. Hannon Director, State Government Affairs Appendix A - HAD Recommended amendment to 12VAC5-219 Regulations 12VAC5-219-80 Wholesale distributor reporting requirements A. For the purposes of this section, "cost" means the expense incurred and the monetary value of the resources used or consumed in the provision of a prescription drug by a wholesale drug distributor. B. If the department determines that data received from carriers, PBMs, and manufacturers is insufficient, the department may request wholesale distributors to report the information specified in subsection C of this section. 1. The department shall publish a general notice in the Virginia Register of Regulations that contains the department's determination, the request for wholesale distributor reporting, and the deadline for wholesale distributors to report pursuant to subsection C of this section. 2. The NDSO shall notify every wholesale distributor of the department's determination and request by email at the wholesale	

	distributor's email address of record. C. If requested by the department pursuant to subsection B of this section and no more than 45 calendar days after the publication of the general notice pursuant to subdivision B 1 of this section, a wholesale distributor shall report for the 25 costliest prescription drugs dispensed in the Commonwealth, including each drug product of a reportable prescription drug: 1. The WAC ~~directly negotiated with~~ established by a manufacturer in the last calendar year; 2. The WAC ~~directly negotiated with~~ established by a manufacturer in the current calendar year; 3. Aggregate total discounts directly negotiated with a manufacturer in the last calendar year, for business in the Commonwealth; and 4. Aggregate total discounts, dispensing fees, and other fees negotiated in the last calendar year with pharmacies. D. In determining which prescription drugs are reportable under subsection C of this section, the wholesale distributor shall average the cost for all drug products of a dispensed prescription drug. E. A wholesale distributor shall report on all drug products of a prescription drug determined to be reportable pursuant to subsections C and D of this section. F. A wholesale distributor shall provide the information specified in subsection C of this section on a form prescribed by the department that includes the following data elements:	

	Data Element Name / Data Element Description Wholesale distributor tax identification number/ The nine-digit Taxpayer Identification Number used by the IRS. Wholesale distributor name/ The legal name of the reporting entity. Proprietary drug name/ The brand or trademark name of the prescription drug reported to the FDA. Nonproprietary drug name/ The generic name of the prescription drug assigned by the USAN Council. WAC Unit/ The lowest identifiable quantity of the prescription drug that is dispensed, exclusive of any diluent without reference to volume measures pertaining to liquids. NDC/ The NDC assigned to each drug product of a prescription drug. Current year minus one WAC/ WAC in U.S. dollars, for each prescription drug ~~for which the wholesale distributor has negotiated with a manufacturer~~ in the last calendar year, related to prescriptions under a health benefit plan issued in the Commonwealth. Current year WAC/ WAC in U.S. dollars, for each prescription drug ~~for which the wholesale distributor has negotiated with a manufacturer~~ in the current calendar year, related to prescriptions under a health benefit plan issued in the Commonwealth. Total manufacturer discounts/ Total aggregate discounts for each prescription drug directly negotiated with a manufacturer in the last calendar year, for business in the Commonwealth.	

	Total pharmacy discounts, dispensing fees, and other fees/ Total aggregate discounts, dispensing fees, and other fees for each prescription drug negotiated in the last calendar year with a pharmacy. Comments/ A text field for any additional information the wholesale distributor wishes to provide G. The commissioner, the department, and the NDSO may not disclose: 1. The identity of a specific wholesale distributor; 2. The price charged for a specific prescription drug or class of prescription drugs; or 3. The amount of any discount or fee provided for a specific prescription drug or class of prescription drugs.	
Meagan Altizer, VA Tech	Support Drug Pricing Transparency Reporting - This bill represents an important step toward increasing transparency and accountability in prescription drug pricing, which directly impacts the affordability of health care for Virginians. By requiring health carriers, pharmacy benefit managers, drug manufacturers, and wholesale distributors to report comprehensive cost data, the legislation ensures that policymakers, providers, and the public have access to accurate information about how drug prices are determined. Partnering with a nonprofit data services organization to compile and publish this information further strengthens public trust, providing an objective and accessible source of data. The inclusion of civil penalties for noncompliance emphasizes the seriousness of the	On behalf of the VDH, I would like to thank you for submitting comments regarding the proposed rules to implement Chapter 304 of the 2021 Acts of Assembly, Special Session I. Your support of the proposed changes as well as your feedback related to the impact of prescription drug pricing on health care affordability, the provision of accessible data to consumers, strengthening of public trust through publication of data, and implementation of civil penalties to guarantee process integrity have been received and will be taken under consideration as we move forward in the rulemaking process.

	reporting requirements and helps guarantee the integrity of the process. Ultimately, this bill empowers the state to identify cost drivers in the pharmaceutical supply chain and pursue meaningful reforms that protect patients from rising drug costs.	

Detail of Changes Made Since the Previous Stage

*List all changes made to the text since the previous stage was published in the Virginia Register of Regulations and the rationale for the changes. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. * Put an asterisk next to any substantive changes.*

Current chapter-section number	New chapter-section number, if applicable	New requirement from previous stage	Updated new requirement since previous stage	Change, intent, rationale, and likely impact of updated requirements
	12VAC5-219-80	This chapter does not currently exist in the VAC. Changes outlined below have been made since the proposed stage. **Corrected language to specify that the WAC is established by a manufacturer.** The changes below do not impose new requirements. **Technical amendment.**	None. Technical amendments only.	**Change:** Subdivisions 1 and 2 of subsection C have been reworded to specify that the WAC is established by the manufacturer and is not negotiated between a manufacturer and wholesale distributor. Amendments to the Data Elements Definitions for "Current year minus one WAC" and "Current year WAC" strike language basing the definition on the WAC negotiated between a wholesale distributor and manufacturer and replace with language basing the definitions upon the WAC price for each prescription drug. A technical amendment adds a period after the word "provide" at the end of the Data Element Definition for the data element "Comments" in subsection F.

				Intent: To clarify the correct process by which the WAC is established and how WAC data elements are reported. The technical amendment ensures correct punctuation throughout the regulation. **Rationale:** The Final regulations should specify the conditions under which the WAC is determined and reported, in order to clarify the duties applicable to reporting entities. The Final regulations should also contain correct punctuation and should conform to the *Form and Style Guidelines* published by the Virginia Registrar of Regulations. **Likely Impact:** The requirements applicable to reporting entities, the Commissioner, and the NDSO will be easier to locate, read, and understand. The Final provisions will be easier to read and understand.
	12VAC5-219-100	This chapter does not currently exist in the VAC. Changes outlined below have been made since the proposed stage. This change does not impose a new requirement. **Technical amendments.**	The following substantive changes have been made between the Proposed and Final stages: **Subsections C & B – opportunity for reporting entity to request an IFFC has been removed.**	**Change:** Subsections B & C have been updated in response to feedback from the OAG to remove the opportunity for a reporting entity to request an IFFC when the NDSO has notified such entity that the data submitted cannot be validated. Technical changes to subdivisions 2, 3, and 4 of subsection C rectify an incorrect reference to subdivision A 1 and update the language to reference the correct provision as subdivision A 2. A technical

				amendment to subdivision 2 of subsection D replaces “shall” with “may” as the commissioner is authorized to deem a reporting entity’s failure to correct incorrect or inaccurate data as a failure to report, but is permitted not to act on such determination. **Intent:** To ensure the Final regulations contain accurate references to regulatory provisions that support prescription drug price transparency requirements. The technical amendment has been made due to feedback from the OAG in February 2026. An IFFC may be requested after the commissioner has made a case decision. **Rationale:** Correcting the error will direct readers to applicable provisions that require the NDSO to notify a reporting entity when it cannot validate the data submitted in accordance with the regulatory chapter. The technical amendment has been made due to feedback from the OAG in February 2026, which clarified that the IFFC should occur after a case decision has been made by the commissioner. **Likely Impact:** The Final regulations will be easier to read and understand, and will align with current law related to the ability to request and conduct an IFFC.

	12VAC-219-110	This chapter does not currently exist in the VAC. Changes outlined below have been made since the proposed stage. This change does not impose a new requirement. **Technical amendments.**	None. Technical amendments only.	**Change:** Updates to (i) subsection D replace "deficiencies" with "incomplete or inaccurate information;" and (ii) subsection E remove language allowing a reporting entity to request an IFFC to dispute the NDSO's determination that such entity has not provide complete or accurate information during an audit. Technical changes to subdivision 2 of subsection H replace mandated language with permissive language. **Intent:** Technical changes have been made due to feedback from the OAG in February 2026, clarified that the IFFC should occur after a case decision has been made by the commissioner. **Rationale:** Technical amendments have been made due to feedback from the OAG in February 2026, which determined (i) the word "deficiencies" implied that the there is a legal determination that regulations are not satisfied; and (ii) specified that the IFFC should occur after a case determination is made by the commissioner. **Likely Impact:** The Final regulations will align with the legal and regulatory insight provided by the Commonwealth's chief legal authority (OAG).
	12VAC5-219-120	This chapter does not currently exist in	None. Technical amendments only.	**Change:** A technical update to subsection A

		the VAC. Changes outlined below have been made since the proposed stage.		conforms regulatory language to the *Form and Style Guidelines* by utilizing negative form construction to express a prohibition on a reporting entity's ability to violate the provisions of the regulatory chapter. **Intent:** To conform the Final regulations to the *Form and Style Guidelines* published by the Virginia Registrar of Regulations. **Rationale:** The Final regulations should conform to the *Form and Style Guidelines* to ensure consistency throughout the Virginia Administrative Code. **Likely Impact:** The Final regulations will conform to *Form and Style Guidelines* and will be easier to read and follow.
	12VAC5-219-130	This chapter does not currently exist in the VAC. Changes outlined below have been made since the proposed stage. This change imposes a new requirement. **State Health Commissioner to notify reporting entities of failure to report.** This change does not impose a new requirement. **Technical amendments.**	The following sections of the Proposed regulations have substantive changes: **Subsection A - State Health Commissioner to notify reporting entities of failure to report.** **Strike subsection D of proposed regulations.**	**Change:** Changes to subsection A require the commissioner to notify a reporting entity in writing of the commissioner's determination of a failure to report, and outlines the information to be contained within the notification sent to the reporting entity – (i) the dates during which the reporting entity has been deemed to have failed to report; (ii) the data elements alleged not to have been reported; (iii)any information in the commissioner's possession that may be relied upon for making an adverse determination; (iv) state the commissioner's intent to

		Strike subsection D of proposed regulations.		impose civil penalties or sanctions; (v) state the reporting entity's right to appeal by using an IFFC under the provisions of the Administrative Process Act (§2.2-400 et seq.); and (vi) state that the reporting entity shall either remit payment of a civil penalty or appeal by requesting an IFFC in accordance with § 2.2-4019 of the Code of Virginia. Subsection D has been stricken to align with correction action plan and notification timelines. These changes have been made in response to feedback provided by the OAG in February 2026. A new subsection (subsection B) has been added permitting the commissioner to waive or reduce a civil penalty imposed upon a reporting entity. Remaining subsection headers are updated to align with the changes to subsection B. Further technical changes update provisional references in subsections C and D to align with changes made between the Proposed and Final stages of the regulatory action. **Intent:** To ensure that (i) reporting entities are notified of the commissioner's determination of a failure to report, the imposition of sanctions and civil penalties, the reduction or waiver of civil penalties; (ii) the opportunity to request an informal fact-finding proceeding in

				accordance with the Administrative Process Act (Chapter 40 (§2.2-4000 et seq.) of Title 2.2 of the Code of Virginia; (iii) the Final regulations align with the legal and regulatory insight provided by the Commonwealth's chief legal authority (OAG). **Rationale:** Including a procedural step by which reporting entities are notified of the commissioner's case decision and adverse action ensures that reporting entities are notified and aware of a failure to report, applicable penalties, and the opportunity to request an IFFC in accordance with § 2.2-4019 of the Code of Virginia. The regulations should align with feedback provided by the Commonwealth's chief legal authority (OAG). **Likely Impact:** The Final regulations will be easier to read, follow, and understand; and will also align with the legal and regulatory insight provided by the Commonwealth's chief legal authority (OAG).
	12VAC5-219-140	This chapter does not currently exist in the VAC. Changes outlined below have been made since the proposed stage. This change does not impose a new requirement. **Technical amendments.**	The following sections of the Proposed regulations have substantive changes: **Subsection A – adjusts the timeframe during which a reporting entity may request an IFFC.**	**Change:** Revisions to subdivision 2 of subsection A adjust the timeframe during which a reporting entity may request an IFFC by providing 15 calendar days from the date the commissioner's notice of civil penalty is issued rather than initiating the timeframe from the date the notice is received by

				the reporting entity. Subsection B has been removed and technical amendments update provisional references in subdivisions 1 and 2 of subsection C to align with the changes to subsection headers in 12VAC5-219-130 that have been made between the Proposed and Final stages of this regulatory action. **Intent:** To ensure timelines for requesting an IFFC are consistent throughout the Final regulations, and to ensure that references to other regulatory provisions are accurate and direct readers to the correct requirements. Changes to subsection A rectify inconsistency in subsections A and D which cite the number of days the reporting entity has to request an IFFC (14 vs 15 calendar days). **Rationale:** The Final regulations should provide a clear and consistent timeframe during which a reporting entity may request an IFFC. **Likely Impact:** Reporting entities will have a better understanding of when to request an IFFC as permitted in § 2.2-4019 of the Code of Virginia. The Final regulations will be easier to read, follow, and understand.

Detail of All Changes Proposed in this Regulatory Action

*List all changes proposed in this action and the rationale for the changes. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. * Put an asterisk next to any substantive changes.*

Current chapter-section number	New chapter-section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of updated requirements
	12VAC5-219-80	This chapter does not currently exist in the VAC. Changes outlined below have been made since the proposed stage. **Corrected language to specify that the WAC is established by a manufacturer.** The changes below do not impose new requirements. **Technical amendment.**	**Change:** Subdivisions 1, and 2 of subsection C have been updated to specify that the WAC is established by the manufacturer and is not negotiated between a manufacturer and wholesale distributor. Amendments to the Data Elements Definitions for "Current year minus one WAC" and "Current year WAC" strike language basing the definition on the WAC negotiated between a wholesale distributor and manufacturer and replace with language basing the definitions upon the WAC price for each prescription drug. A technical amendment adds a period after the word "provide" at the end of the Data Element Definition for the data element "Comments" in subsection F. **Intent:** To clarify the correct process by which the WAC is established and how WAC data elements are reported. The technical amendment ensures correct punctuation throughout the regulation. **Rationale:** The Final regulations should specify the conditions under which the WAC is determined and reported, in order to clarify the duties applicable to reporting entities. The Final regulations should also contain correct punctuation and should conform to the *Form and Style Guidelines* published by the Virginia Registrar of Regulations. **Likely Impact:** The requirements applicable to reporting entities, the Commissioner, and the NDSO will be easier to locate, read, and understand.

			The Final provisions will be easier to read and understand.
	12VAC5-219-100	This chapter does not currently exist in the VAC. Changes outlined below have been made since the proposed stage. The following substantive changes have been made between the Proposed and Final stages: **Subsections C & B – opportunity for reporting entity to request an IFFC has been removed.** This change does not impose a new requirement. **Technical amendments.**	**Change:** Subsections B & C have been updated in response to feedback from the OAG to remove the opportunity for a reporting entity to request an IFFC when the NDSO has notified such entity that the data submitted cannot be validated. Technical amendments to subdivisions 2, 3, and 4 of subsection C rectify an incorrect reference to subdivision A 1 and update the language to reference the correct provision as subdivision A 2. A technical amendment to subdivision 2 of subsection D replaces “shall” with “may” as the commissioner is authorized to deem a reporting entity’s failure to correct incorrect or inaccurate data as a failure to report, but is not required to act on such determination. **Intent:** To ensure the Final regulations contain accurate references to regulatory provisions that support prescription drug price transparency requirements. The technical amendment has been made due to feedback from the OAG in February 2026. An IFFC may be requested after the commissioner has made a case decision. **Rationale:** Correcting the error will direct readers to applicable provisions that require the NDSO to notify a reporting entity when it cannot validate the data submitted in accordance with the regulatory chapter. The technical amendment has been made due to feedback from the OAG in February 2026, which clarified that the IFFC should occur after a case decision has been made by the commissioner. **Likely Impact:** The Final regulations will be easier to read and understand, and will align with current law related to the ability to request and conduct an IFFC.
	12VAC5-219-110	This chapter does not currently exist in the VAC. Changes	**Change:** Updates to (i) subsection D replace “deficiencies” with “incomplete or inaccurate information;” and (ii)

		outlined below have been made since the proposed stage. This change does not impose a new requirement. **Technical amendments.**	subsection E remove language allowing a reporting entity to request an IFFC to dispute the NDSO's determination that such entity has not provide complete or accurate information during an audit. Technical changes to subdivision 2 of subsection H replace mandated language with permissive language. **Intent:** Technical changes have been made due to feedback from the OAG in February 2026, clarified that the IFFC should occur after a case decision has been made by the commissioner. **Rationale:** Technical amendments have been made due to feedback from the OAG in February 2026, which determined (i) the word "deficiencies" implied that the there is a legal determination that regulations are not satisfied; and (ii) specified that the IFFC should occur after a case determination is made by the commissioner. **Likely Impact:** The Final regulations will align with the legal and regulatory insight provided by the Commonwealth's chief legal authority (OAG).
	12VAC5-219-120	This chapter does not currently exist in the VAC. Changes outlined below have been made since the proposed stage. This change does not impose a new requirement. **Technical amendments.**	**Change:** A technical update to subsection A conforms regulatory language to the *Form and Style Guidelines* by utilizing negative form construction to express a prohibition on a reporting entity's ability to violate the provisions of the regulatory chapter. **Intent:** To conform the Final regulations to the *Form and Style Guidelines* published by the Virginia Registrar of Regulations. **Rationale:** The Final regulations should conform to the *Form and Style Guidelines* to ensure consistency throughout the Virginia Administrative Code. **Likely Impact:** The Final regulations will conform to *Form and Style*

			Guidelines and will be easier to read and follow.
	12VAC5-219-130	This chapter does not currently exist in the VAC. Changes outlined below have been made since the proposed stage. This change imposes a new requirement. **State Health Commissioner to notify reporting entities of failure to report. Information contained in notice.** This change does not impose a new requirement. **Technical amendments. Strike subsection D of proposed regulations.**	**Change:** Changes to subsection A require the commissioner to notify a reporting entity in writing of the commissioner's determination of a failure to report, and outlines the information to be contained within the notification sent to the reporting entity – (i) the dates during which the reporting entity has been deemed to have failed to report; (ii) the data elements alleged not to have been reported; (iii)any information in the commissioner's possession that may be relied upon for making an adverse determination; (iv) state the commissioner's intent to impose civil penalties or sanctions; (v) state the reporting entity's right to appeal by using an IFFC under the provisions of the Administrative Process Act (§2.2-400 et seq.); and (vi) state that the reporting entity shall either remit payment of a civil penalty or appeal by requesting an IFFC in accordance with § 2.2-4019 of the Code of Virginia. Subsection D has been stricken to align with correction action plan and notification timelines. These changes have been made in response to feedback provided by the OAG in February 2026. A new subsection (subsection B) has been added permitting the commissioner to waive or reduce a civil penalty imposed upon a reporting entity. Remaining subsection headers are updated to align with the changes to subsection B. Further technical changes update provisional references in subsections C and D to align with changes made between the Proposed and Final stages of the regulatory action. **Intent:** To ensure that (i) reporting entities are notified of the commissioner's determination of a failure to report, the imposition of sanctions and civil penalties, the reduction or waiver of civil penalties; (ii) the opportunity to request an informal fact-finding proceeding in accordance with the Administrative Process Act (Chapter 40 (§2.2-4000 et

			seq.) of Title 2.2 of the Code of Virginia; (iii) the Final regulations align with the legal and regulatory insight provided by the Commonwealth's chief legal authority (OAG). **Rationale:** Including a procedural step by which reporting entities are notified of the commissioner's case decision and adverse action ensures that reporting entities are notified and aware of a failure to report, applicable penalties, and the opportunity to request an IFFC in accordance with § 2.2-4019 of the Code of Virginia. The regulations should align with feedback provided by the Commonwealth's chief legal authority (OAG). **Likely Impact:** The Final regulations will be easier to read, follow, and understand; and will also align with the legal and regulatory insight provided by the Commonwealth's chief legal authority (OAG).
	12VAC5-219-140	This chapter does not currently exist in the VAC. Changes outlined below have been made since the proposed stage. The following sections of the Proposed regulations have substantive changes: **Subsection A – adjusts the timeframe during which a reporting entity may request an IFFC.** This change does not impose a new requirement. **Technical amendments.**	**Change:** Revisions to subdivision 2 of subsection A adjust the timeframe during which a reporting entity may request an IFFC by providing 15 calendar days from the date the commissioner's notice of civil penalty is issued rather than initiating the timeframe from the date the notice is received by the reporting entity. Subsection B has been removed and technical amendments update provisional references in subdivisions 1 and 2 of subsection C to align with the changes to subsection headers in 12VAC5-219-130 that have been made between the Proposed and Final stages of this regulatory action. **Intent:** To ensure timelines for requesting an IFFC are consistent throughout the Final regulations, and to ensure that references to other regulatory provisions are accurate and direct readers to the correct requirements. Changes to subsection A rectify inconsistency in subsections A and D which cite the number of days the reporting entity has to request an IFFC (14 vs 15 calendar days).

			Rationale: The Final regulations should provide a clear and consistent timeframe during which a reporting entity may request an IFFC. **Likely Impact:** Reporting entities will have a better understanding of when to request an IFFC as permitted in § 2.2-4019 of the Code of Virginia. The Final regulations will be easier to read, follow, and understand.