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Proposed Regulation
Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-219-10 et seq.
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	

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 effectuate the act, specifically 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, based on the severity of the violation. As the requirement to report prescription drug price information is new, there is no already existing regulatory chapter that would best fit this mandate, so VDH intends to promulgate a new regulatory chapter for these standards. Following the promulgation of emergency regulation, VDH now intends to promulgate a permanent regulation to replace the emergency regulation.

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.

"Commissioner" means the State Health Commissioner.

"NDSO" means the nonprofit organization with which the Commissioner has negotiated and entered into a contract or agreement for the compilation, storage, analysis, and evaluation of data submitted by health care providers pursuant to Code of Virginia § 32.1-276.4.

"PBM" means a pharmacy benefits manager.

"Reporting entity" means a carrier, manufacturer, PBM, or wholesale distributor.

"VDH" means the Virginia Department of Health.

"WAC" means wholesale acquisition cost.

Mandate and Impetus

Identify the mandate for this regulatory change and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, or board decision). For purposes of executive branch review, "mandate" has the same meaning as defined in the ORM procedures, "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

Chapter 304 (2021 Acts of Assembly, Special Session I) amended to the Code of Virginia to enact new prescription drug price transparency reporting requirements and to direct VDH to promulgate regulations to implement these requirements, which included a mandate to promulgate emergency regulations. Emergency promulgation of this new regulatory chapter, pursuant to Code of Virginia § 2.2-4011(B), became effective on January 17, 2022. This emergency regulation is set to expire on July 16, 2023. 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 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 benefits 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, 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.

The rationale or justification for the regulatory change is that the General Assembly enacted Chapter 304 (2021 Acts of Assembly, Special Session I) to require VDH to adopt regulations standards for prescription drug price transparency and reporting. The regulations are essential to protect the health, safety, or welfare of citizens because it requires that reporting entities provide vital information about prescription drug pricing, which is a driver of increased healthcare costs in the Commonwealth. The goals of the regulatory change is to increase transparency of prescription drug pricing and the problem it intends to solve is identify factors that may be leading to increased healthcare costs from prescription drugs.

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, 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 substantive changes have been made from the emergency stage to the proposed stage:

12VAC5-219-10. Definitions.
Removes the definition of "price"; modifies the definitions for "discount" and "launched"; and adds a definition for "National Drug Code" or "NDC."

12VAC5-219-50. Carrier reporting requirements.
Removes "drug code" from the data elements table and replaces it with "NDC" and clarifies that carriers should include data on each drug product of an outpatient prescription drug in their annual reports.

12VAC5-219-60. Pharmacy benefits manager reporting requirements.
Removes "drug code" from the data elements table and replaces it with "NDC" and clarifies that PBMs should include data on each drug product of a prescription drug in their annual reports.

12VAC5-219-70. Manufacturer reporting requirements.
Removes "drug code" from the data elements table and replaces it with "NDC"; clarifies that manufacturers should include data on each drug product of an outpatient prescription drug in its annual report; and clarifies the reporting requirements for manufacturers that do not own the NDC of a prescription drug or who do not control the WAC.

12VAC5-219-80. Wholesale distributor reporting requirements.
Removes "drug code" from the data elements table and replaces it with "NDC" and clarifies that wholesale distributors should include data on each drug product of a prescription drug in their reports if reports are required by VDH.

12VAC5-219-90. Method of report submission.

Amended to reference the updated submission manual, which reflects the changes made to the data elements table for each reporting entity.

12VAC5-219-9999. DOCUMENTS INCORPORATED BY REFERENCE.
Amended to reference the updated submission manual.

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.

Other 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 NDSO is in the process of analyzing 2022 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.

Requirements More Restrictive than Federal

Identify and describe any requirement of the regulatory change which is more restrictive than applicable federal requirements. Include a specific citation for each applicable federal requirement, and a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements, or no requirements that exceed applicable federal requirements, include a specific statement to that effect.

There are no applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

Consistent with § 2.2-4007.04 of the Code of Virginia, identify any other state agencies, localities, or other entities particularly affected by the regulatory change. Other entities could include local partners such as tribal governments, school boards, community services boards, and similar regional organizations. “Particularly affected” are those that are likely to bear any identified disproportionate material impact which would not be experienced by other agencies, localities, or entities. “Locality” can refer to either local

governments or the locations in the Commonwealth where the activities relevant to the regulation or regulatory change are most likely to occur. If no agency, locality, or entity is particularly affected, include a specific statement to that effect.

Other State Agencies Particularly Affected

There are no other state agencies particularly affected.

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.

Economic Impact

Consistent with § 2.2-4007.04 of the Code of Virginia, identify all specific economic impacts (costs and/or benefits) anticipated to result from the regulatory change. When describing a particular economic impact, specify which new requirement or change in requirement creates the anticipated economic impact. Keep in mind that this is the proposed change versus the status quo.

Impact on State Agencies

For your agency: projected costs, savings, fees, or revenues resulting from the regulatory change, including: a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources.	Fund source is general funds and is a fixed, on-going cost to the agency. The FIS published by DPB for Chapter 304 (2021 Acts of Assembly, Special Session I) is accurate as written compared to the agency's internal estimates. <u>Fiscal Year & Cost</u> 2022 - $393,801 2023 - $318,801 2024 - $318,801 2025 - $318,801 2026 - $318,801 2027 - $318,801 The costs of the statutory mandate that this regulatory chapter is responsive to cannot be absorbed within existing resources, which prompted the General Assembly to amend the Appropriations Act to provide the above identified amounts.
For other state agencies: projected costs, savings, fees, or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.	N/A
For all agencies: Benefits the regulatory change is designed to produce.	The benefits the regulatory change is designed to produce is increased knowledge of and

	transparency for prescription drug pricing and the factors that influence consumer healthcare costs.

Impact on Localities

If this analysis has been reported on the ORM Economic Impact form, indicate the tables (1a or 2) on which it was reported. Information provided on that form need not be repeated here.

Projected costs, savings, fees, or revenues resulting from the regulatory change.	N/A
Benefits the regulatory change is designed to produce.	The benefits the regulatory change is designed to produce is increased knowledge of and transparency for prescription drug pricing and the factors that influence consumer healthcare costs.

Impact on Other Entities

If this analysis has been reported on the ORM Economic Impact form, indicate the tables (1a, 3, or 4) on which it was reported. Information provided on that form need not be repeated here.

Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect.	Pharmaceutical Manufacturers, Health Carriers, Pharmacy Benefit Managers, and Pharmaceutical Wholesalers.
Agency's best estimate of the number of such entities that will be affected. Include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated, and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	Pharmaceutical Manufacturers – 231 Health Carriers – 100 Pharmacy Benefit Managers – 36 Pharmaceutical Wholesalers – 300 Less than 50 small businesses, possibly none.
All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Be specific and include all costs including, but not limited to: a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change; c) fees; d) purchases of equipment or services; and e) time required to comply with the requirements.	Costs from implementation of the statutorily mandated program will be limited to the costs of projected reporting, recordkeeping and other administrative costs required for compliance and are not likely to exceed $2,500 per year. Adoption of the proposed regulations will not result in incremental costs to any business in the State of Virginia because the regulations proposed act to specify the form and manner by which business are required to implement the statutorily mandated program and do not expand the scope of the information required to be reported under the statute. Any economic impact of the program is the result of the statutory mandate, not the regulations.
Benefits the regulatory change is designed to produce.	The benefits the regulatory change is designed to produce is increased knowledge of and transparency for prescription drug pricing and the factors that influence consumer healthcare costs. It also enables the state to collect statutorily required information in a consistent form and

	manner, specifies the means of data validation, notice, and response related to review and approval of data submitted to the state, and sets forth the means of disciplinary action, civil penalties, and available appellate procedures for entities that fail to meet the requirements of the statute.

Alternatives to Regulation

Describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the regulatory change. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulatory change.

Creating a permanent regulation to replace the emergency regulation is the least burdensome or intrusive alternative that that meets the essential purpose of the regulatory change because the General Assembly requires VDH to adopt regulations governing the reporting of prescription drug price information. There are no less intrusive or less costly alternatives for small businesses of achieving the purpose of the regulatory change because the reporting interval and the information to be reported is prescribed in statute.

If this analysis has been reported on the ORM Economic Impact form, indicate the tables on which it was reported. Information provided on that form need not be repeated here.

Regulatory Flexibility Analysis

Consistent with § 2.2-4007.1 B of the Code of Virginia, describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) establishing less stringent compliance or reporting requirements; 2) establishing less stringent schedules or deadlines for compliance or reporting requirements; 3) consolidation or simplification of compliance or reporting requirements; 4) establishing performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the regulatory change.

No alternative was considered because the General Assembly requires VDH to adopt regulations governing the reporting of prescription drug price information. VDH is unable to establish less stringent reporting requirements, compliance standards, or deadlines because these are set in the Code of Virginia and the Code of Virginia does not give VDH the authority to exempt small businesses from the statutory requirements.

If this analysis has been reported on the ORM Economic Impact form, indicate the tables on which it was reported. Information provided on that form need not be repeated here.

Periodic Review and Small Business Impact Review Report of Findings

If you are using this form to report the result of a periodic review/small business impact review that is being conducted as part of this regulatory action, and was announced during the NOIRA stage, indicate whether the regulatory change meets the criteria set out in EO 19 and the ORM procedures, e.g., is necessary for the protection of public health, safety, and welfare; minimizes the economic impact on small businesses consistent with the stated objectives of applicable law; and is clearly written and easily understandable. In addition, as required by § 2.2-4007.1 E and F of the Code of Virginia, discuss the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation; (3) the complexity of the regulation; (4) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation. Also, discuss why the agency's decision, consistent with applicable law, will minimize the economic impact of regulations on small businesses.

VDH is not using this form to report the result of a periodic review/small business impact review, as no such review was announced during the NOIRA stage.

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
Catalent Pharma Solutions, Inc.; Gil Roth for Pharma and Biophama Outsourcing Association (PBOA); Sumeet Singh, CEO, and Deneen Fumich, Director, for Pharma Solutions USA, Inc.	A contract manufacturing organization (CMO) is a meets the definition of "manufacturer" in the emergency regulation; CMOs' business operations include manufacturing, labeling, packaging, and analytical testing but it does not participate in distribution, marketing, or price-setting of prescription drugs. 12VAC5-219-70 requires manufacturers to report certain information that CMOs do not readily have available because only its customer or co-licensed partner possesses it. The definition of "manufacturer" found in § 54.1-3401 of the Code of Virginia does not match the definition found in the federal Drug Supply Chain Security Act (21 USC 360eee(10)) (aka DSCSA). Commenters request that CMOs be exclude from the reporting	VDH notes these comments and suggestions. VDH does not have the legal authority to alter the definition of "manufacturer" as it is set by the Code of Virginia nor does it have the legal authority to exempt a subset of manufacturers from reporting; however, VDH has proposed regulatory language in 12VAC5-219-70 that it believes will address the concerns the commenters raised.

	requirements of 12VAC5-219-70 and only require manufacturers that set or change the WAC to report. Commenters request that the definition of "manufacturer" be modified to match DSCSA language.	
Pharmaceutical Research and Manufacturers of America (PhRMA)	Commenter requested changes to: • 12VAC5-219-10 (Definitions) to remove "coupons, out-of-pocket cost assistance, premium assistance, or copay assistance" from the definition of "Discount"; clarify "launched" to reflect the date a product is first made available for sale in Virginia; remove the term "acquired" from the definition of "launch"; and strike the term "price" from the list of definitions • 12VAC5-219-40 (Allowable Variances) to include "…Nothing in this section will be interpreted to impose greater requirements on reporting entities than those set forth in statute." • 12VAC5-219-70 (Manufacturer Reporting Requirements; Data Element Chart) to remove from final regulations due to not being items that manufacturers are required to report per Code, thereby exceeding VDH authority to include: ○ WAC Unit ○ Drug group: Medi-Span© Generic Product Identifier (GPI): Medi-Span© GPI is a proprietary data element of Medi-Span's drug pricing compendium, and manufacturers may not have access to this information. ○ Date of initial generic competition ○ WAC at market introduction ○ WAC on January 1 of prior calendar year ○ WAC on December 31 of the prior calendar year	VDH notes these comments and suggestions and responds that: • VDH has modified 12VAC5-219-10 in response to the comments. • VDH has not modified 12VAC5-219-40 because the variance process requires the reporting entity to identify proposed alternatives to meet the purpose of the standard or requirement, which is why the regulatory texts states that the Commissioner "[m]ay attach conditions to a variance that, in the sole judgment of the commissioner, satisfies, supports, or furthers the purpose of the standard or requirement"; the language proposed by the commenter may conflict with the essential function of a variance, i.e., to provide individualized flexibility while meeting the purpose of the requirement. • VDH disagrees with the commenter's contention that the data elements specified in 12VAC5-219-70 exceeds VDH's authority to include. Subsection D of Code of Virginia § 32.1-23.4 requires that VDH be able to audit the data submitted; the data elements listed for each reporting entity are intended to enable VDH (through the NDSO) to conduct such audits. VDH has removed "drug code" from the data elements listed and replaced it with "NDC" as the NDC is not proprietary data. • VDH believes that the language proposed subsection F (previously subsection D in the emergency 12VAC5-219-70) already achieves the same purpose that the commenter's language would.

	• 12VAC5-219-70 (Manufacturer Reporting Requirements; Subsection D) to read: "A manufacturer's obligations pursuant to the section shall be fully satisfied by the submission to the nonprofit data services organization with which the Department of Health has entered into a contract pursuant to Section 32.1-23.3 of information and data that a manufacturer includes in the manufacturer's annual consolidation report on Securities and Exchange Commission Form 10-K or any other public disclosure."	

Public Participation

Indicate how the public should contact the agency to submit comments on this regulation, and whether a public hearing will be held, by completing the text below.

VDH is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal, (ii) any alternative approaches, (iii) the potential impacts of the regulation, and (iv) the agency's regulatory flexibility analysis stated in that section of this background document.

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall web site at: https://townhall.virginia.gov. Comments may also be submitted by mail, email or fax to Michael Sarkissian, Director, Data and Quality, Virginia Department of Health, Office of Information Management, 109 Governor Street, Richmond, VA 23219; email: vdh_oim_regulsations@vdh.virginia.gov; fax: (804) 864-7022. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will not be held following the publication of this stage of this regulatory action.

Detail of Changes

List all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. 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. Use all tables that apply, but delete inapplicable tables.

Table 2: Promulgating New VAC Chapter(s) without Repeal and Replace

New chapter-section number	New requirements to be added to VAC	Other regulations and laws that apply	Change, intent, rationale, and likely impact of new requirements
219-20	**12VAC5-219-20. Registration.** A. Each reporting entity shall furnish to and maintain with the NDSO: 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. B. The reporting entity shall notify the NDSO 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 the NDSO of its business closing, discontinuation of business as a carrier, PBM, manufacturer, or wholesale distributor, 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 anticipates that between January 1 and April 1: a. Its business will close; b. Its business as a carrier, PBM, manufacturer, or wholesale distributor will be discontinued; or c. Its acquisition will result in the discontinuation of its business as a carrier,		**CHANGE:** VDH is proposing to promulgate these new requirements and make them permanent. **INTENT:** The intent of these new requirements is for reporting entities to have upto-date contact information on file with the NDSO and for reporting entities to file information about prescription drug pricing even if their business is ending or closing. **RATIONALE:** The rationale for these new requirements is that the NDSO and the department need to have the most accurate contact information available in the event it needs to contact a reporting entity and that a reporting entity should not be able to skirt or avoid the obligation to report by closing or discontinuing its business. **LIKELY IMPACT:** The likely impact of these new requirements is reduced likelihood that a reporting entity will miss important communication from the NDSO and VDH and that the Commonwealth will have the most complete prescription drug pricing information possible.

	PBM, manufacturer, or wholesale distributor. 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.		
219-40	**12VAC5-219-40. Allowable variances.** 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, the NDSO, or a reporting entity may request a variance at any time by filing the request in writing with the commissioner. 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		**CHANGE:** VDH is proposing to promulgate these new requirements. **INTENT:** The intent of these new requirements is to permit the commissioner to grant variances if warranted, to create a clear process by which variances may be requested or modified. **RATIONALE:** The rationale for these new requirements is to permit the commissioner to address unforeseen circumstances that complicate a regulant's compliance with a requirement in this chapter. **LIKELY IMPACT:** The likely impact of these new requirements is reduced likelihood of confusion on how a regulant may request a variance and clarity on what the commissioner's authority is in regards to granting or modifying a variance.

	the standard or requirement; and 6. Other information, if any, believed by the requester to be pertinent to the request. D. The requester shall provide additional information as may be requested or required 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 requester shall comply with the standard or requirement to which a variance has been requested unless a variance has been granted. H. 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. I. If a variance is denied, expires, or is rescinded, the commissioner, the department, or the NDSO, as applicable, shall enforce the standard or requirement to which the variance was granted.		
219-100	Part III Enforcement Article 1 Data Validation and Audits **12VAC5-219-100. Data validation; notification; response.** A. The NDSO 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 the NDSO 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		**CHANGE:** VDH is proposing to promulgate these new requirements. **INTENT:** The intent of these new requirements is to provide for a process by which the NDSO can validate the data reported is complete and by which a reporting entity can correct incomplete data. **RATIONALE:** The rationale for these new requirements is that the NDSO should ensure that the data it receives is complete so as to meet the spirit of the legislative mandate and that reporting entities should have the opportunity to cure incomplete data reports. **LIKELY IMPACT:** The likely impact of these new requirements is improved clarity for reporting entities and the NDSO on what happens to data reports after they are filed.

	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, the NDSO 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. The NDSO shall provide to the commissioner within 1 business day of the second 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 the NDSO and the reporting entity after the notification sent pursuant to subsection A of this section; and 2. The commissioner shall deem the second failure to correct as a failure to report pursuant to Part II (12VAC5-219-50 et seq.) of this chapter.		
219-110	**12VAC5-219-110. Audit; corrective action plan.** A. When submitting any notification or report to the NDSO, a reporting entity shall include: 1. A signed, written certification of the accuracy of any notification or report filed in a physical format; and 2. Electronic certification of the accuracy of any notification or report filed by email or through the NDSO's online collection tool. B. The NDSO may verify the accuracy of finalized data reported by a reporting entity through an audit conducted by the NDSO, provided that the NDSO 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. The NDSO shall send a copy of the audit findings to the reporting entity no more than 5 business days after the conclusion of the audit		**CHANGE:** VDH is proposing to promulgate these new requirements. **INTENT:** The intent of these new requirements is to comply with the statutory mandate that requires auditing procedures by which the NDSO can audit the data reported for accuracy and to provide a reporting entity the opportunity to correct inaccurate data. **RATIONALE:** The rationale for these new requirements is that the NDSO should ensure that the data it receives is accurate so as to meet the spirit of the legislative mandate and that reporting entities should have the opportunity to cure inaccurate data reports. **LIKELY IMPACT:** The likely impact of these new requirements is improved clarity for reporting entities and the NDSO on what happens to auditing procedures are.

	at its email mailing address of record. D. If any deficiencies are found during the audit: 1. The NDSO 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 the NDSO 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		

	implementation of the corrective action plan signs, dates, and indicates their title on the corrective action plan. G. The NDSO shall: 1. Notify the reporting entity if the NDSO 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 the NDSO initially determines to be unacceptable. If the reporting entity revises and resubmits the corrective action plan, the revision is due to the NDSO and the commissioner no more than 15 business days after the NDSO 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. The NDSO shall provide to the commissioner any correspondence between the NDSO 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.		
219-120	Article 2 Administrative Process **12VAC5-219-120. Sanctions.** A. A reporting entity may not violate the provisions of this chapter.		**CHANGE:** VDH is proposing to promulgate these new requirements. **INTENT:** The intent of these new requirements is to specify

	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 and pursuant to subsection C of § 32.1-23.4 of the Code of Virginia, 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 one or more sanctions. 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.		the consequences for failure to comply and to clarify that knowingly submitting false, inaccurate, or misleading data will be treated as a failure to comply. **RATIONALE:** The rationale for these new requirements is that reporting entities should be made aware of potential consequences for failure to comply and that reporting compliance requires both timely reporting and submission of true and accurate data to the best of the reporting entity's ability. **LIKELY IMPACT:** The likely impact of these new requirements is improved clarity for reporting entities.
219-130	**12VAC5-219-130. Civil penalty.** 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		**CHANGE:** VDH is proposing to promulgate these new requirements. **INTENT:** The intent of these new requirements is to create a schedule of civil penalties based on the severity of the violation. **RATIONALE:** The rationale for these new requirements is that there should be a standardized amount of penalties assessed,

	reporting entity in an amount of: 1. For the first offense: a. $500 for 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 for 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. The commissioner shall assess civil penalties in the aggregate on a per day basis. 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,		that severity is based on how long it takes for reporting entity to come into compliance and how frequently it has violated the reporting requirements, and that reporting entities should be aware of when civil penalties begin to accumulate, how to pay, and the consequences for failing to timely remit payment. **LIKELY IMPACT:** The likely impact of these new requirements is improved clarity for reporting entities on how civil penalties will function for violations of this regulatory chapter.

	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 46th calendar day after the publication of the general notice pursuant to subdivision A 1 of 12VAC5-219-80 for a wholesale distributor that that fails to submit any information or documentation or that knowingly submits false, inaccurate, or misleading data; 3. 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 4. 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.		
219-140	**12VAC5-219-140. Informal fact-finding proceeding.**		**CHANGE:** VDH is proposing to promulgate these new requirements.

	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 pursuant to § 2.2-4019 of the Code of Virginia: 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-		**INTENT:** The intent of these new requirements is outline the procedural steps that a reporting entity must take to request an informal fact-finding proceeding and the effect of an informal fact-finding conference on the accumulation of civil penalties. **RATIONALE:** The rationale for these new requirements is that there should be a standardized process and timeline for requesting an informal fact-finding proceeding and that accumulation or tolling of fees and penalties should be clearly articulated. **LIKELY IMPACT:** The likely impact of these new requirements is improved clarity for reporting entities on the procedural requirements and the effect to the accumulation of civil penalties.

	219-120 shall be final on the 15th calendar day after the date of receipt of the notice of civil penalty imposition. E. If a reporting entity remains aggrieved by a case decision after an informal fact finding proceeding, it may seek review of the case decision in accordance with Article 5 (§ 2.2-4025 et seq.) of Chapter 40 of Title 2.2. of the Code of Virginia.		

Table 3: Changes to the Emergency Regulation

Emergency chapter-section number	New chapter-section number, if applicable	Current emergency requirement	Change, intent, rationale, and likely impact of new or changed requirements since emergency stage
219-10	Same as emergency chapter-section number	Part I General Information and Requirements **12VAC5-219-10. Definitions.** The following words and terms when used in this chapter have the following meanings unless the context clearly indicates otherwise: "Biologic" means 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.	**CHANGE:** VDH is proposing to eliminate the definition of “price” and promulgate these changed requirements since emergency stage requirements: **12VAC5-219-10. Definitions.** The following words and terms when used in this chapter have the following meanings unless the context clearly indicates otherwise: "Biologic" means 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.

		“Discount” means 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” means 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” means 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 benefits plan” has the same meaning as ascribed to the term in § 38.2-3438 of the Code of Virginia. "IRS" means the U.S. Internal Revenue Service. “Launched” means 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. “Nonprofit data services organization” or “NDSO” has the same meaning as ascribed to the term in § 32.1-23.4 of the Code of Virginia. “Outpatient prescription drug” means a prescription drug that may be obtained only by prescription and dispensed by a	"Department" means the Virginia Department of Health. "Discount" means any price concessions, however characterized, offered or provided by a reporting entity for a prescription drug, including rebates and reductions in price, that has the effect of reducing the cost of a prescription drug for a consumer. "Drug product" means 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" means 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" means the U.S. Internal Revenue Service. "Launched" means the month and year on which a manufacturer first marketed a prescription drug for sale in the Commonwealth. "Manufacturer" has the same meaning as ascribed to the term in § 54.1-3401 of the Code of Virginia. “National Drug Code” or “NDC” means a unique numeric code assigned by the FDA for each finished drug product or unfinished drug subject to the listing requirements of 21 CFR Part 207. "New prescription drug" has the same meaning as ascribed to the term in § 54.1-3442.02 of the Code of Virginia. "Nonprofit data services organization" or "NDSO" has the same meaning as ascribed to the term in § 32.1-23.4 of the Code of Virginia.

		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" had the same meaning as ascribed to the term in § 38.2-3407.15:4 of the Code of Virginia. "Pharmacy benefits manager" or "PBM" has the same meaning as ascribed to the term in § 38.2-3407.15:4 of the Code of Virginia. "Premium" means the amount members pay to a carrier or health benefit plan for their medical and prescription drug insurance. "Price" means 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" means carriers, PBMs, wholesale distributors, and manufacturers. "Specialty drug" means 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,	"Outpatient prescription drug" means 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" or "PBM" has the same meaning as ascribed to the term in § 38.2-3407.15:4 of the Code of Virginia. "Premium" means the amount members pay to a carrier or health benefit plan for their medical and prescription drug insurance. "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" means carriers, PBMs, wholesale distributors, and manufacturers. "Specialty drug" means 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;

		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" means the amount of money, expressed in U.S. dollars, expended after discounts. "Therapeutically equivalent" means 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	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. A prescription drug appearing on Medicare Part D's specialty tier is presumed to be a specialty drug. "Spending" means the amount of money, expressed in United States dollars, expended after discounts. "Therapeutically equivalent" means 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: (1) Contains identical amounts of the identical active drug ingredient in the identical dosage form and route of administration; and (2) Meets compendial or other applicable standards of strength, quality, purity, and identity; or b. A bioequivalent to a brand-name drug in that: (1) It does not present a known or potential bioequivalence problem, and they meet an acceptable in vitro standard; or (2) If it does present such a known or potential problem, it is shown to

		ii. If it does present such a known or potential problem, it is shown to meet an appropriate bioequivalence standard. "USAN Council" means the United States Adopted Names Council. "Utilization management" means 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. "Wholesale acquisition cost" or "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" means 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.	meet an appropriate bioequivalence standard. "USAN Council" means the United States Adopted Names Council. "Utilization management" means 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. "Wholesale acquisition cost" or "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" means the total daily dosage units of a prescription drug recommended by its prescribing label as approved by the FDA for 30 days or fewer. 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. **INTENT:** The intent of these changed requirements since emergency stage requirements is to provide definitions for terms used in the regulation. **RATIONALE:** The rationale for these changed requirements since emergency stage requirements is that these terms could have multiple meanings unless defined and that the lack of definitions could lead to confusions among regulants.

			LIKELY IMPACT: The likely impact of these changed requirements since emergency stage requirements is improved clarity for regulants.
219-30	Same as emergency chapter-section number	**12VAC5-219-30. Notice.** A. The NDSO 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 the NDSO 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 the NDSO's determination and the effective date of this determination; and 2. The NDSO shall notify every reporting entity of the NDSO'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. The NDSO 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	**CHANGE:** VDH is proposing to remove subsection B from the emergency stage: **12VAC5-219-30. Notice.** A. The NDSO 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. 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. C. The NDSO 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 the NDSO and the commissioner or the department. **INTENT:** The intent of these new requirements is to specify how reporting entities will be contact by the NDSO and VDH, and to ensure that VDH has timely access to records involving the reporting entity.

		days after the request, except as otherwise agreed to between the NDSO and the commissioner or the department.	**RATIONALE:** The rationale for these new requirements is to set clear expectations on how the NDSO and VDH will contact a reporting entity and on the timeliness of information sharing so that VDH can adjudicate enforcement in an efficient manner. **LIKELY IMPACT:** The likely impact of these new requirements is reduced likelihood of confusion on how the NDSO and VDH should communicate with reporting entities and improved data sharing between the NDSO and VDH on enforcement matters.
219-50	Same as emergency chapter-section number	Part II Reporting Requirements **12VAC5-219-50. Carrier reporting requirements.** A. Every carrier offering a health benefit plan shall report annually by April 1 to the NDSO 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	**CHANGE:** VDH is proposing to remove “drug group” as a data element and promulgate these changed requirements since emergency stage requirements: Part II Reporting Requirements **12VAC5-219-50. Carrier reporting requirements.** A. Every carrier offering a health benefit plan shall report annually by April 1 to the NDSO 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

		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	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. When submitting a report pursuant to this section, a carrier:

<table>
<tr>
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<td>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:

<table>
<tr><td>Data Element Name</td><td>Data Element Definition</td></tr>
<tr><td>Carrier tax identification number</td><td>The 9-digit tax Taxpayer Identification Number used by the IRS.</td></tr>
<tr><td>Carrier name</td><td>The legal name of the reporting entity.</td></tr>
<tr><td>Health benefit plan category</td><td>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</td></tr>
</table>
</td>
<td>1. 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;
2. 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;
3. Shall report on all drug products of an outpatient prescription drug determined to be reportable pursuant to subsections A and B 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 subsections A and B of this section on a form prescribed by the department that includes the following data elements:

<table>
<tr><td>Data Element Name</td><td>Data Element Definition</td></tr>
<tr><td>Carrier tax identification number</td><td>The 9-digit tax Taxpayer Identification Number used by the IRS.</td></tr>
<tr><td>Carrier name</td><td>The legal name of the reporting entity.</td></tr>
<tr><td>Health benefit plan category</td><td>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</td></tr>
</table>
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</tr>
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			(fully insured group); S (self insured group); and C (Commonwealth of Virginia employees).		(individual); F (fully insured group); S (self insured group); and C (Commonwealth of Virginia employees).
			Health benefit plan unique identifier	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.	Health benefit plan unique identifier	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.
			Proprietary drug name	The brand or trademark name of the prescription drug reported to the FDA.	Proprietary drug name	The brand or trademark name of the prescription drug reported to the FDA.
			Non-proprietary drug name	The generic name of the prescription drug assigned by the USAN Council.	Non-proprietary 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.	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.
			Drug group	The first two digits of the Medi-Span© Generic Product Identifier	NDC	The NDC assigned to each drug product of an outpatient prescription drug.
					Brand-name or generic	Whether the prescription drug is brand-name or generic.
					Net spending increase	The percent year-over-year increase in annual net spending for prescription drugs

			assigned to the proprietary prescription drug.		after accounting for aggregated discounts or other reductions in price.
			Brand-name or generic	Whether the prescription drug is brand-name or generic.	Premium increase	The percent year-over-year increase in premiums that were attributable to each health care service, including prescription drugs.
			Net spending increase	The percent year-over-year increase in annual net spending for prescription drugs after accounting for aggregated discounts or other reductions in price.	Specialty drugs with utilization management	The percentage of specialty drugs with utilization management requirements.
			Premium increase	The percent year-over-year increase in premiums that were attributable to each health care service, including prescription drugs.	Premium reductions	The percent year-over-year of premium reductions that were attributable to specialty drug utilization management.
			Specialty drugs with utilization management	The percentage of specialty drugs with utilization management requirements.	Comments	A text field for any additional information the carrier wishes to provide.
			Premium reductions	The percent year-over-year of premium reductions that were attributable to specialty drug utilization management.		
			Comments	A text field for any additional information the		
					INTENT: The intent of these changed requirements since emergency stage requirements is to incorporate the minimum data required to be reported by carriers pursuant to Va. Code § 38.2-3407.15:6 and to specify and define the data fields to be completed by the carrier so that compliance may be determined and so that the NDSO can validate and audit the data. **RATIONALE:** The rationale for these changed requirements since emergency stage requirements is that the regulations should parallel the statutory requirements, that the minimum data to be reported must facilitate the validation and auditing

		carrier wishes to provide.	of data, and that providing required data field names and definitions should result in uniform reporting by carriers. **LIKELY IMPACT:** The likely impact of these changed requirements since emergency stage requirements is improved clarity for carriers on what data is to be reported and how it should be formatted.
219-60	Same as emergency chapter-section number	**12VAC5-219-60. Pharmacy benefits manager reporting requirements.** A. Every PBM providing pharmacy benefits management under contract to a carrier shall report annually by April 1 to the NDSO 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: Data Element Name: Data Element Definition PBM tax identification number: The 9-digit tax Taxpayer Identification Number used by the IRS.	**CHANGE:** VDH is proposing to remove “drug group” as a data element and promulgate these changed requirements since emergency stage requirements: **12VAC5-219-60. Pharmacy benefits manager reporting requirements.** A. Every PBM providing pharmacy benefits management under contract to a carrier shall report annually by April 1 to the NDSO 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. A PBM shall report on all drug products of a prescription drug determined to be reportable pursuant to subsection A of this section. C. 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:

		PBM name	The legal name of the reporting entity.	Data Element Name	Data Element Definition
		Proprietary drug name	The brand or trademark name of the prescription drug reported to the FDA.	PBM tax identification number	The 9-digit tax Taxpayer Identification Number used by the IRS.
		Non-proprietary drug name	The generic name of the prescription drug assigned by the USAN Council.	PBM name	The legal name of the reporting entity.
		Drug group	The first two digits of the Medi-Span© Generic Product Identifier assigned to the proprietary prescription drug	Proprietary drug name	The brand or trademark name of the prescription drug reported to the FDA.
		Brand-name or generic	Whether the prescription drug is brand-name or generic.	Non-proprietary drug name	The generic name of the prescription drug assigned by the USAN Council.
		Carrier name	The legal name of the carrier to whom rebates were distributed or passed on.	NDC	The NDC assigned to each drug product of a prescription drug.
		Total rebates	Total aggregate rebates received or negotiated directly with the manufacturer in the last calendar year, for business in the Commonwealth.	Brand-name or generic	Whether the prescription drug is brand-name or generic.
		Total rebates distributed	Total aggregate rebates distributed to the relevant health benefit plan in the last	Carrier name	The legal name of the carrier to whom rebates were distributed or passed on.
				Total rebates	Total aggregate rebates received or negotiated directly with the manufacturer in the last calendar year, for business in the Commonwealth.

		calendar year, for business in the Commonwealth.	Total rebates distributed: Total aggregate rebates distributed to the relevant health benefit plan in the last calendar year, for business in the Commonwealth.
		Total rebates passed on: 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.	Total rebates passed on: 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.
		Comments: A text field for any additional information the PBM wishes to provide.	Comments: A text field for any additional information the PBM wishes to provide.
			INTENT: The intent of these changed requirements since emergency stage requirements is to incorporate the minimum data required to be reported by PBMs pursuant to Va. Code § 38.2-3407.15:6 and to specify and define the data fields to be completed by the PBM so that compliance may be determined and so that the NDSO can validate and audit the data. **RATIONALE:** The rationale for these changed requirements since emergency stage requirements is that the regulations should parallel

			the statutory requirements, that the minimum data to be reported must facilitate the validation and auditing of data, and that providing required data field names and definitions should result in uniform reporting by PBMs. **LIKELY IMPACT:** The likely impact of these changed requirements since emergency stage requirements is improved clarity for PBMs on what data is to be reported and how it should be formatted.
219-70	Same as emergency chapter-section number	**12VAC5-219-70. Manufacturer reporting requirements.** A. Every manufacturer shall report annually by April 1 to the NDSO 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 the NDSO; 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	**CHANGE:** VDH is proposing to remove “drug group” as a data element and promulgate these changed requirements since emergency stage requirements: **12VAC5-219-70. Manufacturer reporting requirements.** A. Except as provided in subsection D of this section, every manufacturer shall report annually by April 1 to the NDSO 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 the NDSO; 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

		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: Data Element Name / Data Element Definition Manufacturer tax identification number / The 9-digit tax Taxpayer Identification Number (TIN) used by the IRS. Manufacturer name / The legal name of the	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. A manufacturer shall report on all drug products of a prescription drug determined to be reportable pursuant to subsection A of this section. D. A manufacturer that does not own the NDC of a prescription drug or does not control the WAC of a prescription drug shall report annually by April 1 to the NDSO that it has no data responsive to the requirements of this section. E. Except as provided in subsection D of this section, every manufacturer shall provide the information specified in subsections A and B of this section on a form

		reporting entity.	
		Proprietary drug name	The brand or trademark name of the prescription drug reported to the FDA.
		Non-proprietary 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.
		Drug group	The first two digits of the Medi-Span© Generic Product Identifier assigned to the prescription drug.
		Brand-name drug or generic drug	Whether the report is about a brand-name drug or generic drug.
		Subject to generic competition	The month and year of initial generic competition.
		Date of initial generic competition	The year of market introduction of the
		prescribed by the department that includes the following data elements:	
		Data Element Name	Data Element Definition
		Manufacturer tax identification number	The 9-digit tax Taxpayer Identification Number (TIN) used by the IRS.
		Manufacturer name	The legal name of the reporting entity.
		Proprietary drug name	The brand or trademark name of the prescription drug reported to the FDA.
		Non-proprietary 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.
		Brand-name drug or generic drug	Whether the report is about a brand-name

			prescription drug.		drug or generic drug.
		WAC at market introduction	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.	Subject to generic competition	The month and year of initial generic competition.
				Date of initial generic competition	The year of market introduction of the prescription drug.
				WAC at market introduction	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.
		WAC on January 1 of the prior calendar year	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.	WAC on January 1 of the prior calendar year	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
		WAC on December 31 of the prior	The manufacturer's list price in U.S. dollars per unit, to		

		calendar year	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.		prescription drug pricing data; it does not include discounts.
		Effective date of change in WAC	The month and year that the WAC changed.	WAC on December 31 of the prior calendar year	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.
		Justification for current-year WAC increase	The reason or reasons that the manufacturer increased the WAC of the prescription drug compared with last year.	Effective date of change in WAC	The month and year that the WAC changed.
		Research and development costs	Aggregate, company-level research and development costs in U.S. dollars for the most recent year for which final audit data is available.	Justification for current-year WAC increase	The reason or reasons that the manufacturer increased the WAC of the prescription drug compared with last year.
		Year of research and development costs	The year in which final audit data is available.	Research and development costs	Aggregate, company-level research and development costs in U.S. dollars for the most recent year for which final audit data is available.
		Comments	A text field for any additional information the manufacturer		

		wishes to provide.	Year of research and development costs: The year in which final audit data is available. Comments: A text field for any additional information the manufacturer wishes to provide. D. To satisfy the reporting requirements of this section, a manufacturer may submit information and data that a manufacturer includes in its annual consolidation report on the U.S. Securities and Exchange Commission Form 10-K or any other public disclosure. F. To satisfy the reporting requirements of this section, a manufacturer may submit information and data that a manufacturer includes in its annual consolidation report on the U.S. Securities and Exchange Commission Form 10-K or any other public disclosure. **INTENT:** The intent of these changed requirements since emergency stage requirements is to incorporate the minimum data required to be reported by manufacturers pursuant to Va. Code § 54.1-3442.02; to specify and define the data fields to be completed by the manufacturer so that compliance may be determined and so that the NDSO can validate and audit the data, if the manufacturer chooses to not utilize the flexibility provided for in the proposed subsection F; and to address concerns from commenters about manufacturers who do not have data to report because they do not control the WAC. **RATIONALE:** The rationale for these changed requirements since emergency stage requirements is that the regulations should parallel the statutory requirements; that providing required data field names and definitions should result in uniform reporting by manufacturers, if the manufacturer chooses to not utilize the flexibility provided for in the proposed subsection F; that the minimum data to be reported must

			facilitate the validation and auditing of data; and that regulatory flexibility should be afforded to the extent permitted under law. **LIKELY IMPACT:** The likely impact of these changed requirements since emergency stage requirements is improved clarity for manufacturers on what data is to be reported and how it should be formatted.
219-80	Same as emergency chapter-section number	**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 specific in subsection B of this section. 1. The department shall publish a general notice in the Virginia Register that contains its determination, the request for wholesale distributors reporting, and the deadline for wholesale distributors to report pursuant to subsection B of this section. 2. The NDSO shall notify every wholesale distributor of the department's determination and request by electronic mail at its electronic mailing 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	**CHANGE:** VDH is proposing to remove "drug group" as a data element and promulgate these changed requirements since emergency stage requirements: **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 specific in subsection B of this section. 1. The department shall publish a general notice in the Virginia Register that contains its determination, the request for wholesale distributors reporting, and the deadline for wholesale distributors to report pursuant to subsection B of this section. 2. The NDSO shall notify every wholesale distributor of the department's determination and request by electronic mail at its electronic mailing 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

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<td>drug product of a reportable prescription drug:
1. The WAC directly negotiated with a manufacturer in the last calendar year;
2. The WAC directly negotiated with 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, in total; and
4. Aggregate total discounts, dispensing fees, and other fees negotiated in the last calendar year with pharmacies, in total.
D. In determining which prescription drugs are reportable under subsection B of this section, the wholesale distributor shall average the cost for all drug products of a dispensed prescription drug.
E. Every wholesale distributor shall provide the information specified in subsection B of this section on a form prescribed by the department that includes the following data elements:
<table>
<tr><th>Data Element Name</th><th>Data Element Description</th></tr>
<tr><td>Wholesale distributor tax identification number</td><td>The 9-digit tax Taxpayer Identification Number used by the IRS.</td></tr>
<tr><td>Wholesale distributor name</td><td>The legal name of the reporting entity.</td></tr>
<tr><td>Proprietary drug name</td><td>The brand or trademark name of the prescription drug reported to the FDA.</td></tr>
<tr><td>Non-proprietary drug name</td><td>The generic name of the prescription drug assigned by the USAN Council.</td></tr>
</table>
</td>
<td>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 a manufacturer in the last calendar year;
2. The WAC directly negotiated with 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, in total; and
4. Aggregate total discounts, dispensing fees, and other fees negotiated in the last calendar year with pharmacies, in total.
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 manufacturer shall report on all drug products of a prescription drug determined to be reportable pursuant to subsections C and D of this section.
F. Every 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:
<table>
<tr><th>Data Element Name</th><th>Data Element Description</th></tr>
<tr><td>Wholesale distributor tax identification number</td><td>The 9-digit tax Taxpayer Identification Number used by the IRS.</td></tr>
<tr><td>Wholesale distributor name</td><td>The legal name of the reporting entity.</td></tr>
<tr><td>Proprietary drug name</td><td>The brand or trademark name of the prescription</td></tr>
</table>
</td>
</tr>
</table>

		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.		drug reported to the FDA.
		Drug group	The first two digits of the Medi-Span© Generic Product Identifier assigned to the prescription drug.	Non-proprietary drug name	The generic name of the prescription drug assigned by the USAN Council.
		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.	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.
		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	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

		issued in the Commonwealth.	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 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.	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	Comments: A text field for any additional information the wholesale distributor wishes to provide
		F. 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.	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.

			INTENT: The intent of these new requirements is to incorporate the minimum data required to be reported by wholesale distributors pursuant to Va. Code § 54.1-3436.1 if required and to specify and define the data fields to be completed by the wholesale distributers so that compliance may be determined and so that the NDSO can validate and audit the data by the wholesale distributor. **RATIONALE:** The rationale for these new requirements is that the regulations should parallel the statutory requirements, that the minimum data to be reported must facilitate the validation and auditing of data, and that providing required data field names and definitions should result in uniform reporting by wholesale distributors. **LIKELY IMPACT:** The likely impact of these new requirements is improved clarity for wholesale distributors on what data is to be reported, how it should be formatted, and how VDH will notify wholesale distributors that data reporting is required.
219-90	Same as emergency chapter-section number	**12VAC5-219-90. Method of report submission.** A. A reporting entity shall submit any report required by Part II (12VAC5-219-50 et seq.) of this chapter to the NDSO through the NDSO's online collection tool. B. A reporting entity shall submit any required report by uploading electronic spreadsheet files, or other methods as determined by the NDSO, that include all required information for each report and that comply with the NDSO's Prescription Drug Price Transparency Regulation (12VAC5-219-10) Submission Manual, Version 1.0. C. The NDSO shall notify each reporting entity in writing at least 30 calendar days before any change in the report collection method.	**CHANGE:** VDH is proposing to promulgate these changed requirements since emergency stage: **12VAC5-219-90. Method of report submission.** A. A reporting entity shall submit any report required by Part II (12VAC5-219-50 et seq.) of this chapter to the NDSO through the NDSO's online collection tool. B. A reporting entity shall submit any required report by uploading electronic spreadsheet files, or other methods as determined by the NDSO, that include all required information for each report and that comply with the NDSO's Prescription Drug Price Transparency Regulation (12VAC5-219-10) Submission Manual, Version 1.1.

			C. The NDSO shall notify each reporting entity in writing at least 30 calendar days before any change in the report collection method. **INTENT:** The intent of these changed requirements since emergency stage is to specify the updated method of data collection and submission. **RATIONALE:** The rationale for these changed requirements since emergency stage is that both the NDSO and the reporting entity should have a mutual understanding of how to file reports and what format they should be in. **LIKELY IMPACT:** The likely impact of these changed requirements since emergency stage is improved clarity for reporting entities and the NDSO on how to report data.
DIBR (219-9999)	Same as emergency chapter-section number	**Documents Incorporated By Reference (12VAC5-219)** Prescription Drug Price Transparency Regulation Submission Manual, Version 1.0, 2021, Virginia Health Information (eff. 8/2021).	**CHANGE:** VDH is proposing to promulgate these changed requirements since emergency stage requirements: **Documents Incorporated By Reference (12VAC5-219)** Prescription Drug Price Transparency Regulation Submission Manual, Version 1.1, 2022, Virginia Health Information (rev. 9/2022). **INTENT:** The intent of these changed requirements since emergency stage is to incorporate by reference the most up-to-date format and file standards for data reports. **RATIONALE:** The rationale for these changed requirements since emergency stage is that there should be a standardized format and file for all reports as that increase the likelihood that the data received is uniform and reduces the amount of time the NDSO spends to validate the data.

			LIKELY IMPACT: The likely impact of these changed requirements since emergency stage is improved clarity for reporting entities on the format and file standards when filing data reports.