The Board of Health will hold its next quarterly meeting on September 2. This will be a hybrid in-person/virtual meeting. Physical attendees will assemble in Boardroom 2 of the Perimeter Center located at 9960 Mayland Drive in Richmond. Virtual participants should register through the electronic process described in the following pages. The meeting will begin at 9:00 a.m.

Agency staff and attendees should comply with the latest CDC guidance dated July 27, 2021 for the in-person location. As such, all attendees at the in-person location shall:

- Wear a mask inside the Perimeter Center, including in Boardroom 2. If you are not able to, or do not wish to, wear a mask, you may attend and participate virtually instead.
- Maintain physical distancing. To aid in this, seats will be spaced out in the meeting room. This spacing will allow for a maximum of 15 members of the public to sit in the room. This seating will be available on a first come, first serve basis.

Any individual who cannot or does not wish to comply with these requirements for medical, religious, or other reasons, can participate through the virtual option.

Any member of the press who would like to attend should contact Maria Reppas, Director of the Office of Communications, at maria.reppas@vdh.virginia.gov or by phone at 804-652-5997.

As a reminder, the public comment period at each Board meeting is to allow the public to share their concerns to the Board members. The public comment period is not a conversation or question and answer between members of the Board and the public. All public comments are limited to 2 minutes per person. Individuals may not sign up for multiple spots in order to speak longer. If you have additional comments or feel you may not be able to speak only in 2 minutes, you may submit written comment to the Board. These written comments will be shared with the Board members and included in the minutes for the meeting provided they are received before the meeting.

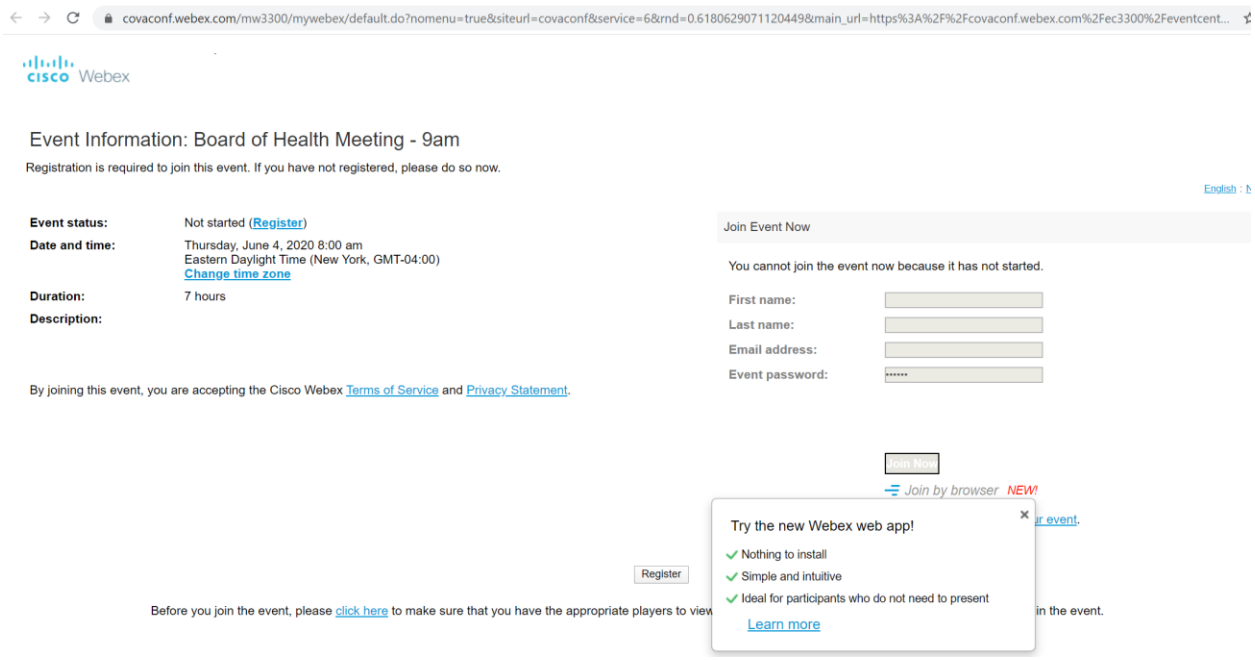
There will be a public comment signup sheet in the room at the Perimeter Center. For those who are attending virtually, as part of the registration process you will be asked if you would like to offer public comment. The list of public speakers will be generated by pulling the physical and virtual sign up lists at 11:00am on the morning of the meeting. The public comment period is limited to 20 minutes maximum, but may be extended by the Board. If you are not able to sign up by this deadline, you may still submit written comment to the Board.

To Register for the Board of Health Meeting on September 2, 2021

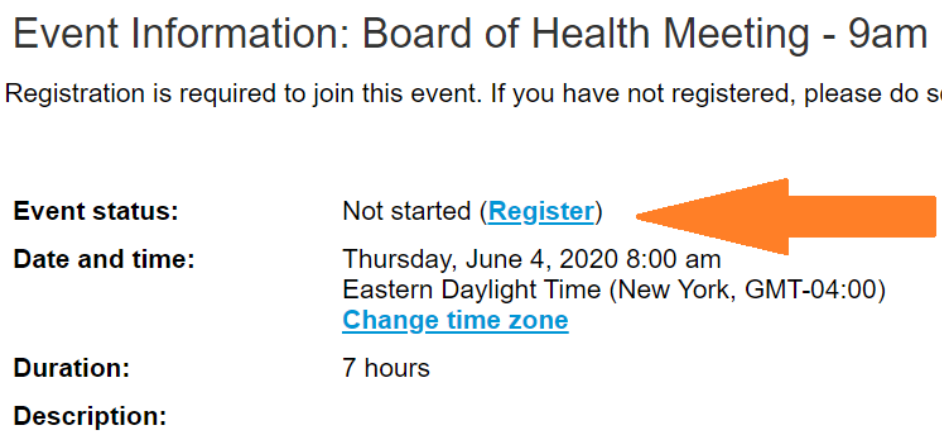
(Either to attend and view the meeting or to speak during the Public Comment Period)

The purpose of these instructions is to help any member of the public who wishes to observe or participate in the Board of Health meeting virtually on September 2 to understand how to do so.

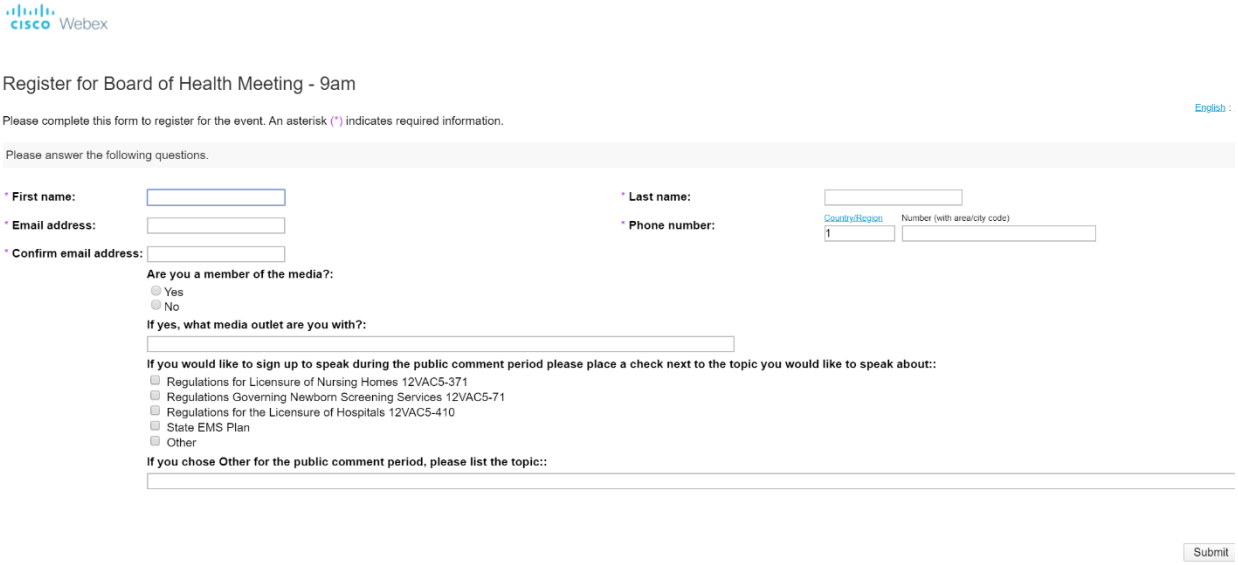
1) Open the link the Online meeting registration: https://covaconf.webex.com/covaconf/onstage/g.php?MTID=e832d5e84c06f3b31cb7076a9b93c5316.



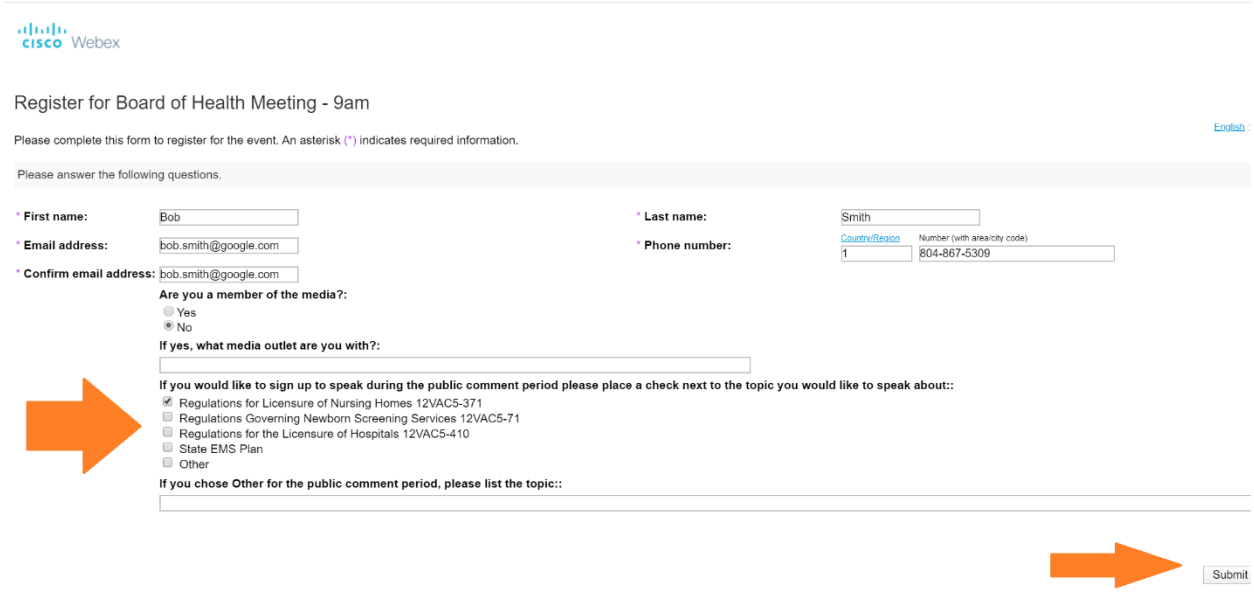
2) Click on the link that says, “Register” It is in blue and on the line that starts with “Event Status”.



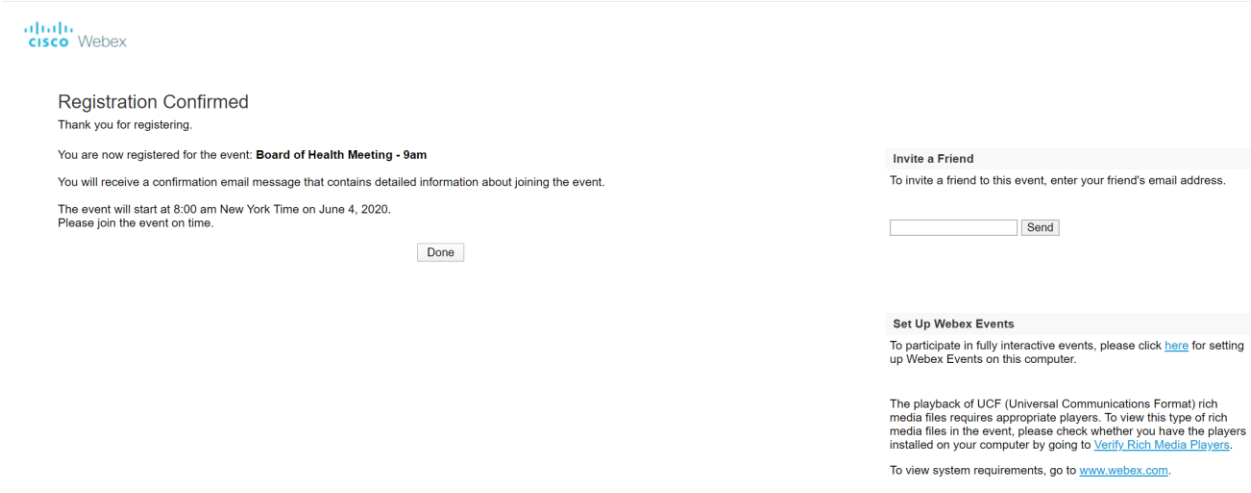
3) This will prompt you to register for the event. Please enter your name and email address on the registration form. (Note: this information will not be retained after the meeting and will only be used for purposes of making sure people who want to connect to the meeting or speak at the meeting can do so.)



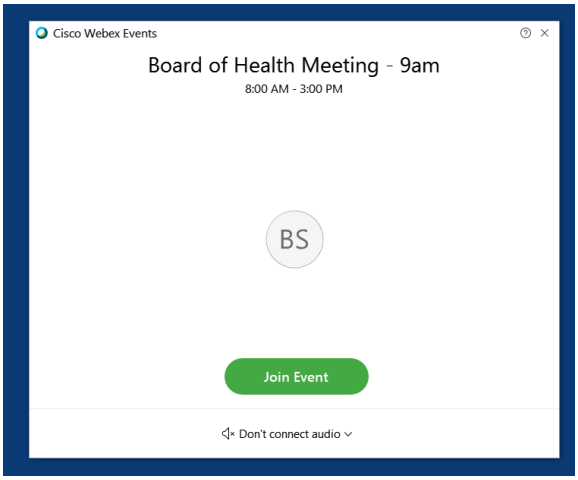
4) If you want to speak during the public comment, choose one of the items on the list in the bottom center of the screen and check the box for the topic you want to speak on. If you do not want to speak during the meeting, but just watch, do not check any of those boxes. When you are finished entering registration information and choosing a topic to speak on (if appropriate) click the "Submit" button in the bottom right.



5) Once you have clicked "Submit" that will lead you to the final screen and then you are finished.

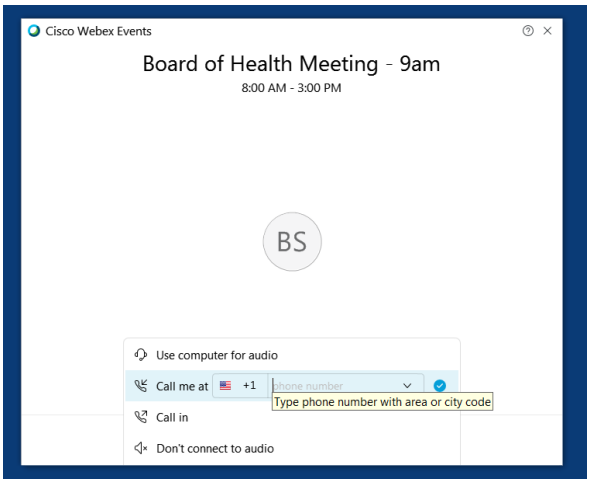


JOINING THE MEETING



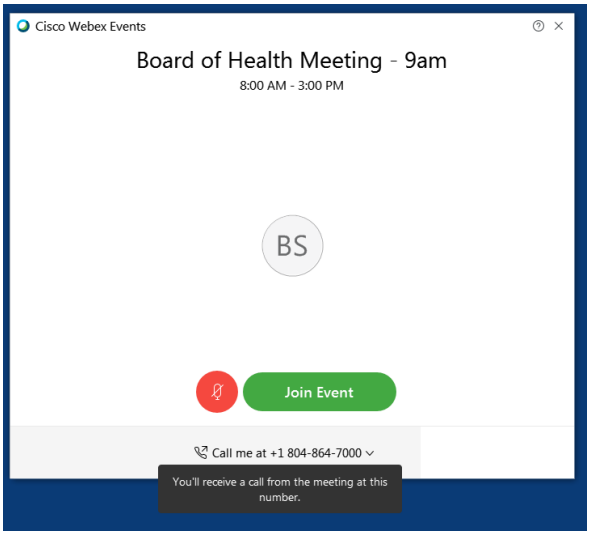
On the day of the meeting, you will click in the email to join the meeting.

You will need to enter your name as it appeared on the registration in order to join.



You should select the “CALL ME AT” option to connect for audio. DO NOT select the call in nor use computer audio options.

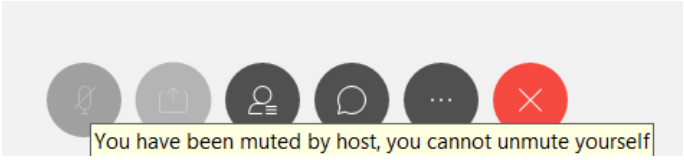
Enter your 10 digit phone number and click the blue check mark.



Click Join Event.

You will receive a phone call from the meeting platform.

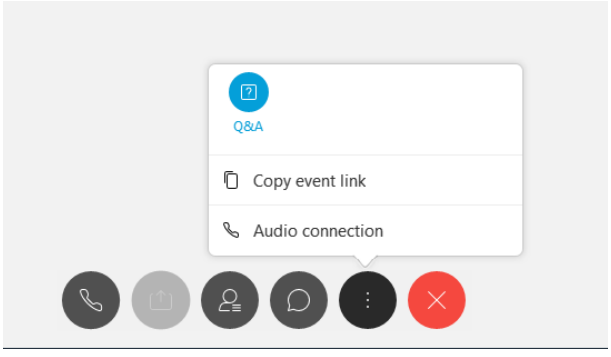
You will be prompted to press 1 when you answer the phone to connect.



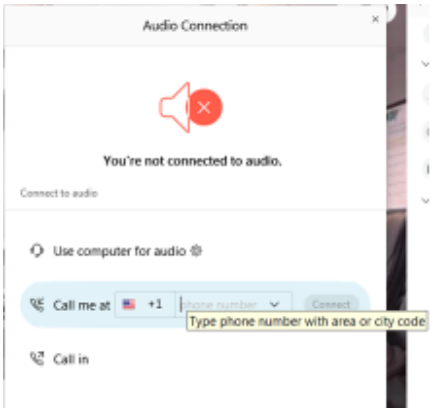
Note that you will be automatically muted when you join the meeting. You cannot unmute yourself to be heard during the meeting until the host unmutes you. This will occur during the public comment period for those who have signed up to do so.

Audio settings:

In order to facilitate public comment, you will need to use your phone to dial in. It is very important that you follow these instructions to merge your phone and computer identification. This will allow you to be unmuted to speak during public comment if you have signed up.



If you have joined the meeting without having WebEx call you, you will need to change the audio settings. Click on the "MORE" control button and select audio connection. **DO NOT** use the call-in option nor the computer audio option.



You will change the type of connection and select “CALL ME AT”. Enter your 10 digit phone number and click CONNECT. Press 1 when prompted on the incoming phone call.

State of Board of Health
Agenda
September 2, 2021 – 9:00 a.m.
Hybrid Meeting
Perimeter Center – Boardroom 2 & WebEx

Call to Order and Welcome	Faye Prichard, Chair
Introductions	Ms. Prichard
Review of Agenda	Alexandra Jansson, MPP Senior Policy Analyst
Approval of June 18, 2021 Minutes	Ms. Prichard
Commissioner's Report	M. Norman Oliver, MD, MA State Health Commissioner
Virginia Center for Public Health Informatics	Tim Powell Director Center for Public Health Informatics
Regulatory Action Update	Ms. Jansson
Break	
Special Lunch Presentation Housing and Health	Pamela Kestner Chief Deputy Department of Housing and Community Development
Public Comment Period	
Regulatory Action Items Regulations of the Patient Level Data System 12VAC5-217 (Emergency Amendments/NOIRA)	Michael Sarkissian Director, Data and Quality Office of Information Management
Prescription Drug Price Transparency Regulation 12VAC5-219 (Emergency Regulations/NOIRA)	Rebekah E. Allen, JD Senior Policy Analyst Office of Licensure and Certification
Break	

Regulatory Action Items	
Disease Reporting and Control Regulations 12VAC5-90 (Proposed Amendments)	Laura Forlano, DO, MPH Deputy Director Office of Epidemiology
Non-Regulatory Action Items	
Cremation Fee Increase	William Gormley, MD, PhD Chief Medical Examiner Office of the Chief Medical Examiner
Presentations	
Legislative and Budget Presentation *Special Session II*	Joe Hilbert Deputy Commissioner for Governmental and Regulatory Affairs and Stephanie Gilliam Deputy Direction for Budget Office of Financial Management
Legislative Update *Development of Proposals for 2022*	Mr. Hilbert
Meeting Dates for 2022	Ms. Prichard
Other Business	
Adjourn	

COMMONWEALTH of VIRGINIA
Department of Health
M. NORMAN OLIVER, MD, MA
STATE HEALTH COMMISSIONER
P O BOX 2448
RICHMOND, VA 23218
TTY 7-1-1 OR
1-800-828-1120

MEMORANDUM

DATE: September 2, 2021

TO: Virginia State Board of Health

FROM: Suresh Soundararajan
Chief Information Officer, Office of Information Management

SUBJECT: Emergency Regulation/Notice of Intended Regulatory Action (NOIRA) – Regulations of the Patient Level Data System (12VAC5-217) – Admission source of any individuals meeting the criteria for voluntary or involuntary psychiatric commitment

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Enclosed for your review is an Emergency Regulatory action/NOIRA to conform the Regulations of the Patient Level Data System (12VAC5-217) to the requirements of Chapter 552 of the 2021 Special Session I Acts of Assembly Item 307(D1-2). This chapter requires inpatient hospitals to report the admission source of any individuals meeting the criteria for voluntary or involuntary psychiatric commitment as outlined in §§ 16.1-338, 16.1-339, 16.1-340.1, 16.1-345, 37.2-805, 37.2-809, or 37.2-904, Code of Virginia, to the Board of Health. The Board shall collect and share any and all data regarding the admission source of individuals admitted to inpatient hospitals as a psychiatric patient, pursuant to Va. Code § 32.1-276.6, with the Department of Behavioral Health and Developmental Services.

Information reported by inpatient hospitals to the Patient Level Data System does not currently include criteria for assessing the voluntary or involuntary psychiatric commitment of minors or adults. After consultation with stakeholders, the recommendation is to amend the regulations by expanding the existing list of required information to include a new section focused on the legal status of the admission as applied to voluntary or involuntary psychiatric admissions. This recommendation conforms to the requirements in Item 307 (D1-2).

The State Board of Health is requested to approve this combined emergency regulatory action and NOIRA. Should the State Board of Health approve this regulatory package, it will be submitted to the Office of the Attorney General to begin the Executive Branch review process, as specified by the Administrative Process Act. Following Executive Branch review and approval, the combined emergency regulatory action and NOIRA will be submitted to The Virginia Register of Regulations via Regulatory Town Hall. The emergency regulatory action will become effective immediately upon submission. This combined emergency regulatory action and

NOIRA will be published in The Virginia Register of Regulations for a 30-day comment period to begin upon publication. The emergency regulation will remain in effect for 18 months while a permanent replacement regulation is being developed. In the event VDH needs additional time, VDH can seek written approval from the Governor to extend the duration of the emergency regulation for up to 6 additional months, for a total duration of 24 months or 2 years.

townhall.virginia.gov

Emergency Regulation and Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12 VAC 5 - 217
VAC Chapter title(s)	Regulations of the Patient Level Data System
Action title	Amend Regulation to conform to Chapter 552 Item 307(D1) of the 2021 Acts of Assembly Special Session I
Date this document prepared	July 22, 2021

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1VAC7-10), 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 the subject matter, intent, and goals of this 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 or changes. If applicable, generally describe the existing regulation.

Chapter 552 of the 2021 Acts of Assembly Special Session I Item 307(D1) requires inpatient hospitals to report the admission source of any individuals meeting the criteria for voluntary or involuntary psychiatric commitment as outlined in § 16.1-338, 16.1-339, 16.1-340.1, 16.1-345, 37.2-805, 37.2-809, or 37.2-904, Code of Virginia, to the Board of Health ("the Board"). The Board shall collect and share any and all data regarding the admission source of individuals admitted to inpatient hospitals as a psychiatric patient, pursuant to Va.Code § 32.1-276.6, with the Department of Behavioral Health and Developmental Services (DBHDS) through the addition of a new legal status field. The new field will be included in the patient-level data that DBHDS receives from Virginia Health Information (VHI.) The existing list of information from that Code section does not include criteria for voluntary or involuntary psychiatric

commitment, accordingly the creation of a new legal status field is required. The Board is using this action to conform to the requirements in Item 307 (D1).

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.

DBHDS – Department of Behavioral Health and Developmental Services
VHI – Virginia Health Information

Mandate and Impetus (Necessity for Emergency)

Explain why this rulemaking is an emergency situation in accordance with § 2.2-4011 A and B of the Code of Virginia. In doing so, either:

a) *Indicate whether the Governor's Office has already approved the use of emergency regulatory authority for this regulatory change.*
b) *Provide specific citations to Virginia statutory law, the appropriation act, federal law, or federal regulation that require that a regulation be effective in 280 days or less from its enactment.*

As required by § 2.2-4011, also describe the nature of the emergency and of the necessity for this regulatory change. In addition, delineate any potential issues that may need to be addressed as part of this regulatory change

Ch. 552 of the 2021 Acts of Assembly Special Session I Item 307(D1) requires inpatient hospitals to report the admission source of any individuals meeting the criteria for voluntary or involuntary psychiatric commitment as outlined in § 16.1-338, 16.1-339, 16.1-340.1, 16.1-345, 37.2-805, 37.2-809, or 37.2-904, Code of Virginia, to the Board of Health. The Board shall collect and share any and all data regarding the admission source of individuals admitted to inpatient hospitals as a psychiatric patient, pursuant to § 32.1-276.6, Code of Virginia, with the Department of Behavioral Health and Developmental Services through the addition of a new legal status field. The new field will be included in the patient-level data that DBHDS receives from VHI. The existing list of information from that Code section does not include criteria for voluntary or involuntary psychiatric commitment, accordingly the creation of a new legal status field is required. The Board is using this action to conform to the requirements of Item 307(D1).

Item 307(D2) requires the Department of Health to promulgate regulations within 280 days from enactment of Chapter 552 of 2021 Special Session I. Use of an emegency regulatory action is required in order to meet that legislatively-mandated deadline..

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 or Acts and 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.

The Code of Virginia § 32.1-12 gives the Board the responsibility to make, adopt, promulgate, and enforce such regulations as may be necessary to carry out the provisions of Va. Code § 32.1. Va. Code § 32.1- 276.6(A) requires the Board to establish and administer an integrated system for collection and analysis of data which is used by consumers, employers, providers, purchasers of health care and state government. Section 32.1-276.6(B) of the Code of Virginia requires that every inpatient hospital shall submit to the Board patient level data where applicable and included on the standard claim forms: (1) hospital identifier; (2) attending physician identifier; (3) operative physician or oral and maxillofacial. surgeon identifier; (4) payor identifier; (5) Employer identifier as required on standard claims forms; (6) Patient identifier (all submissions); (7) Patient sex, race (inpatient only), date of birth (including century indicator), street address, city or county, zip code, employment status code, status at discharge, and birth weight for infants (inpatient only); (8) Admission type, source (inpatient only), date and hour, and diagnosis; (9) Discharge date (inpatient only) and status; (10) Principal and secondary diagnoses; (11) External cause of injury; (12) Co-morbid conditions existing but not treated; (13) Procedures and procedure dates; (14) Revenue center codes, units, and charges as required on standard claims forms; and (15) Total charges.

Purpose

Describe the specific reasons why the agency has determined that this regulation is essential to protect the health, safety, or welfare of citizens. In addition, explain any potential issues that may need to be addressed as the regulation is developed.

The Board is required by Va. Code § 32.1-276.2 to establish effective health care data analysis and reporting initiatives to improve the quality and efficiency of health care, foster competition among health care providers, and increase consumer choice with regard to health care services in the Commonwealth, and that accurate and valuable health care data can best be identified by representatives of state government and the consumer, provider, insurance, and business communities.

The goal of the regulatory change is to conform the provisions of 12VAC5-217-20 to the requirements in Chapter 552 Item 307(D1) of the 2021 Acts of Assembly Special Session I.

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.

12VAC5-217-10: A new legal status field is added to include the provision of information required by Chapter 552 Item 307(D1) of the 2021 Acts of Assembly Special Session I. This is defined to include codes for the legal status of voluntary or involuntary psychiatric admissions.

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.

This action is being used to conform the regulations to the provision of Chapter 552 of the 2021 Special Session I 307(D1). The advantage to the public and the Commonwealth is that the regulations are in compliance with legislative changes enacted by the 2021 General Assembly and will provide helpful information regarding inpatient psychiatric admissions. There are no disadvantages to individual private citizens or businesses not subject to the regulation, the agency, or the Commonwealth. The primary disadvantages to the regulated community are the projected costs of implementing the requirements of the regulations and additional workflows required to complete the new field.

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.

Initiation of this regulatory action is the least burdensome method identified to conform to the Regulations for Inpatient Data Reporting to Chapter 552 Item 307(D1) of the 2021 Acts of Assembly Special Session I.

Periodic Review and Small Business Impact Review Announcement

If you wish to use this regulatory action to conduct, and this Emergency/NOIRA to announce, a periodic review (pursuant to § 2.2-4017 of the Code of Virginia and Executive Order 14 (as amended, July 16, 2018)), and a small business impact review (§ 2.2-4007.1 of the Code of Virginia) of this regulation, keep the following text. Modify as necessary for your agency. Otherwise, delete the paragraph below and insert "This NOIRA is not being used to announce a periodic review or a small business impact review."

This NOIRA is not being used to announce a periodic review or a small business impact review.

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. In addition, as required by § 2.2-4007.02 of the Code of Virginia describe any other means that will be used to identify and notify interested parties and seek their input, such as regulatory advisory panels or general notices.

The Virginia Department of Health 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, and (iii) the potential impacts of the regulation.

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 Mike Sarkissian, 109 Governor Street, 4th Floor, Richmond VA 23219, (804) 229-0517, michael.sarkissian@vdh.virginia.gov. 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 the proposed 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.

If an existing VAC Chapter(s) is being amended or repealed, use Table 1 to describe the changes between existing VAC Chapter(s) and the emergency regulation. If existing VAC Chapter(s) or sections are being repealed and replaced, ensure Table 1 clearly shows both the current number and the new number for each repealed section and the replacement section.

Table 1: Changes to Existing VAC Chapter(s)

Current chapter-section number	New chapter-section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
20			**Change:** 16. Legal Status. Enter the legal status of the admission. Legal status applies to voluntary or involuntary psychiatric admissions of minors and adults. 1= §16.1-338 Parental admission of minors < 14 and nonobjecting minors 14 years of age or older 2=§16.1-339 Parental admission of objecting minor 14 years of age or older 3=§16.1-340.1 Involuntary TDO (minor) 4=§16.1-345 Involuntary commitment (minor) 5=§37.2-805 Voluntary admission (adult) 6=§37.2-809 Involuntary TDO (adult) 7=§37.2-904 Sexually violent predators (prisoners or defendants) **Intent:** The intent of these changes is to conform to Chapter 552 of 2021 Special Session I Item 307(D1). **Rationale:** The patient-level discharge data submitted to VHI do not currently include the patient's legal status. Collecting this information will DHBDS to study the distribution of involuntary psychiatric admissions throughout the community hospital system, with the goal of developing strategies to

			alleviate the high census at state psychiatric hospitals. **Likely Impact:** It is expected that inpatient hospitals will implement operational changes and develop new workflows to enter the legal status for a voluntary or involuntary psychiatric admission through the legal status field.

If a new VAC Chapter(s) is being promulgated and is not replacing an existing Chapter(s), use Table 2.

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

Project 6605 - Emergency/NOIRA

Department Of Health

Amend Regulation to conform to Chapter 552 Item 307(D1) of the 2021 Acts of Assembly Special Session I

12VAC5-217-20. Reporting requirements for patient level data elements.

Every inpatient hospital shall submit a complete filing of each patient level data element listed in the table in this section for each hospital inpatient, including a separate record for each infant, if applicable. Most of these data elements are currently collected from a Uniform Billing Form located in the latest publication of the Uniform Billing Manual prepared by the National Uniform Billing Committee. The Uniform Billing Form and the Uniform Billing Manual are located on the National Uniform Billing Committee's website at www.nubc.org. The Uniform Billing Manual provides a detailed field description and any special instruction pertaining to that element. An asterisk (*) indicates when the required data element is either not on the billing form or in the Uniform Billing Manual. The instructions provided under that particular data element should then be followed. Inpatient hospitals that submit patient level data directly to the board or the nonprofit organization shall submit it in an electronic data format.

Data Element
1. Hospital identifier.* Enter the six-digit Medicare provider number or a number assigned by the board or its designee.
2. Attending physician identifier. Enter the nationally assigned physician identification number, either the Uniform Physician Identification Number (UPIN) or National Provider Identifier (NPI) as approved by the board for the physician assigned as the attending physician for an inpatient.
3. Other physician identifier. Enter the nationally assigned physician identification number, either the Uniform Physician Identification Number (UPIN) or National Provider Identifier (NPI) as approved by the board for the physician identified as the operating physician for the principal procedure reported.
4. Payor identifier.
5. Employer identifier.
6. Patient identifier.* Enter the nine-digit social security number of the patient. If a social security number has not been assigned, leave blank. The nine-digit social security number is not required for patients under four years of age.
7a. Patient sex.
7b. Race code.* If an inpatient hospital collects information regarding the choices listed below, the appropriate one-digit code reflecting the race of the patient should be entered. If a hospital only collects information for categories 0, 1, or 2, then the appropriate code should be entered from those three selections.
0 = White

1 = Black
2 = Other
3 = Asian
4 = American Indian
5 = White Hispanic
6 = Black Hispanic
7c. Date of birth.
7d. Street address, city or county, and zip code.
7e. Employment status code.
7f. Patient status (i.e., discharge). Inpatient codes only.
7g. Birth weight (for infants).* Enter the birth weight of newborns in grams.
8a. Admission type.
8b. Admission source.
8c. Admission date.
8d. Admission hour.
8e. Admission diagnosis code.
9a. Discharge date. Only enter date of discharge.
10. Principal diagnosis code. Enter secondary diagnoses (up to eight). In addition, include diagnoses recorded in the comments section for DX6-DX9.
11. External cause of injury code (E-code). Record all external cause of injury codes in secondary diagnoses position after recording all treated secondary diagnoses.
12. Co-morbid conditions existing but not treated.
13. Principal procedure code and date. Enter other procedures and dates (up to five). In addition, include procedures recorded in the comments section for PX4-PX6.
14. Revenue code (up to 23). Units of service (up to 23). Units of service charges (up to 23).
15. Total charges (by revenue code category or by HCPCS code). (R.C. Code 001 is for total charges. See page 47-1.)

16. Legal Status.

Enter the legal status of the admission. Legal status applies to voluntary or involuntary psychiatric admissions of minors and adults.

1= §16.1-338 Parental admission of minors < 14 and nonobjecting minors 14 years of age or older

2=§16.1-339 Parental admission of objecting minor 14 years of age or older

3=§16.1-340.1 Involuntary TDO (minor)

4=§16.1-345 Involuntary commitment (minor)

5=§37.2-805 Voluntary admission (adult)

6=§37.2-809 Involuntary TDO (adult)

7=§37.2-904 Sexually violent predators (prisoners or defendants)

COMMONWEALTH of VIRGINIA
Department of Health
M. NORMAN OLIVER, MD, MA
STATE HEALTH COMMISSIONER
P O BOX 2448
RICHMOND, VA 23218
TTY 7-1-1 OR
1-800-828-1120

MEMORANDUM

DATE: August 13, 2021

TO: State Board of Health

FROM: Rebekah E. Allen, JD
Senior Policy Analyst, Office of Licensure and Certification

SUBJECT: Emergency/NOIRA – Prescription Drug Pricing Transparency Regulation – Promulgation of Regulatory Chapter

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Enclosed for your review are a combined emergency regulatory action and Notice of Intended Regulatory Action (NOIRA) to Prescription Drug Pricing Transparency Regulation (12VAC5-219).

Chapter 304 of the 2021 Acts of Assembly, Special Session I created Code of Virginia §§ 32.1-23.4, 38.2-3407.15:6, 38.2-3407.22, 54.1-3436.1, and 54.1-3442.02. Collectively, these new statutory provisions created a new reporting mandate involving prescription drug pricing for health insurance carriers, pharmacy benefit managers, manufacturers, and wholesale distributors. The data collection will be done through Virginia Health Information, which is a nonprofit data services organization that VDH is required by law to use for this task. Any adjudication under the Administrative Process Act for compliance failures will remain the responsibility of VDH. The legislative act also requires the creation of regulations for these reporting requirements within 280 days of enactment, which necessitates the use of a combined emergency regulatory action and NOIRA to meet that deadline.

The State Board of Health is requested to approve this combined emergency regulatory action and NOIRA. Should the State Board of Health approve this regulatory package, it will be submitted to the Office of the Attorney General to begin the Executive Branch review process, as specified by the Administrative Process Act. Following Executive Branch review and approval, the combined emergency regulatory action and NOIRA will be submitted to The Virginia Register of Regulations via Regulatory Town Hall. The emergency regulatory action will become effective immediately upon submission. This combined emergency regulatory action and NOIRA will be published in The Virginia Register of Regulations for a 30-day comment period to begin upon publication. The emergency regulation will remain in effect for 18 months while a permanent replacement regulation is being developed. In the event we need additional time, we can seek written approval from the Governor to extend the duration of the emergency regulation for up to 6 additional months, for a total duration of 24 months or 2 years.

Form: TH-05
April 2020

townhall.virginia.gov

Emergency Regulation and Notice of Intended Regulatory Action (NOIRA) 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	August 13, 2021

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1VAC7-10), 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 the subject matter, intent, and goals of this 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 or changes. If applicable, generally describe the existing regulation.

Chapter 304 (2021 Acts of Assembly, Special Session I) requires 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.

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

"VDH" means the Virginia Department of Health.

Mandate and Impetus (Necessity for Emergency)

Explain why this rulemaking is an emergency situation in accordance with § 2.2-4011 A and B of the Code of Virginia. In doing so, either:

a) *Indicate whether the Governor's Office has already approved the use of emergency regulatory authority for this regulatory change.*
b) *Provide specific citations to Virginia statutory law, the appropriation act, federal law, or federal regulation that require that a regulation be effective in 280 days or less from its enactment.*

As required by § 2.2-4011, also describe the nature of the emergency and of the necessity for this regulatory change. In addition, delineate any potential issues that may need to be addressed as part of this regulatory change

This rulemaking is an emergency situation pursuant to subsection B of § 2.2-4011 of the Code of Virginia, which authorizes agencies to adopt emergency regulations "in situations in which Virginia statutory law...requires that a regulation be effective in 280 days or less from its enactment and the regulation is not exempt under the provisions of subdivision A 4 of § 2.2-4006 [of the Code of Virginia]." The third enactment clause of Chapter 304 (2021 Acts of Assembly, Special Session I) directs VDH to promulgate regulations within 280 days of the enactment date, which is March 24, 2021, so regulations must be promulgated on or before December 29, 2021. The regulatory changes contemplated would not qualify for an exemption under division A 4 of § 2.2-4006 of the Code of Virginia.

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 or Acts and 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

Describe the specific reasons why the agency has determined that this regulation is essential to protect the health, safety, or welfare of citizens. In addition, explain any potential issues that may need to be addressed as the regulation is developed.

By enacting Chapter 304 (2021 Acts of Assembly, Special Session I), the General Assembly required VDH to adopt regulations standards for prescription drug price transparency and reporting. In order to ensure that such regulations protect the health, safety, and welfare of citizens, it is necessary to assess relevant available information about prescription drug prices to determine what should be included or incorporated into the regulatory text. VDH may also address other issues that arise as a result of this Notice.

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 intention of VDH is to ensure the regulatory language fulfills VDH's responsibilities under § 32.1-23.4 of the Code of Virginia. Revisions to the regulation content may be proposed based on public comments received.

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.

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.

No alternative was considered because the General Assembly requires VDH to adopt regulations governing the reporting of prescription drug price information.

Periodic Review and Small Business Impact Review Announcement

If you wish to use this regulatory action to conduct, and this Emergency/NOIRA to announce, a periodic review (pursuant to § 2.2-4017 of the Code of Virginia and Executive Order 14 (as amended, July 16, 2018)), and a small business impact review (§ 2.2-4007.1 of the Code of Virginia) of this regulation, keep the following text. Modify as necessary for your agency. Otherwise, delete the paragraph below and insert "This NOIRA is not being used to announce a periodic review or a small business impact review."

This NOIRA is not being used to announce a periodic review or a small business impact review.

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. In addition, as required by § 2.2-4007.02 of the Code of Virginia describe any other means that will be used to identify and notify interested parties and seek their input, such as regulatory advisory panels or general notices.

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, and (iii) the potential impacts of the regulation.

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 Rebekah E. Allen, Senior Policy Analyst, Virginia Department of Health, Office of Licensure and Certification, 9960 Mayland Drive, Suite 401, Henrico, VA 23233; email: regulatorycomment@vdh.virginia.gov; fax: (804) 527-4502. 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 the proposed 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.

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

219-10	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. "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.	Code of Virginia §§ 32.1-23.4, 38.2-3407.10, 38.2-3407.15:4, 38.2-3407.22, 38.2-3438, 54.1-3401, 54.1-3436.1, 54.1-3442.02	**CHANGE:** VDH is proposing to promulgate these new requirements. **INTENT:** The intent of these new requirements is to provide definitions for terms used in the regulation. **RATIONALE:** The rationale for these new 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 new requirements is improved clarity for regulants.

	"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 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, 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 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. **Statutory Authority** Chapter 304 of the 2021 Acts of Assembly, Special Session I.		
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		**CHANGE:** VDH is proposing to promulgate these new requirements. **INTENT:** The intent of these new requirements is for reporting entities to have up-to-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.

	seq.) of this chapter prior to its closure, discontinuation, or acquisition if the reporting entity plans or anticipated that between January 1 and April 1: a. Its business will close; b. Its business as a carrier, PBM, manufacturer, or wholesale distributor will be discontinued; or c. Its acquisition will result in the discontinuation of its business as a carrier, 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. **Statutory Authority** Chapter 304 of the 2021 Acts of Assembly, Special Session I.		**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.
219-30	**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		**CHANGE:** VDH is proposing to promulgate these new requirements. **INTENT:** The intent of these new requirements is to provide advance notification to reporting entities of the means and method by which to expect important communication and to ensure that VDH has timely access to records involving the reporting entity. **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

	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 days after the request, except as otherwise agreed to between the NDSO and the commissioner or the department. **Statutory Authority** Chapter 304 of the 2021 Acts of Assembly, Special Session I.		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.
219-40	**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;		**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

	2. The nature and duration of the variance requested; 3. A description of how compliance with the current standard or requirement is economically burdensome and constitutes an impractical hardship unique to the requester; 4. Statements or evidence why the purpose of the standard or requirement would not be frustrated if the variance were granted; 5. Proposed alternatives to meet the purpose of the standard or requirement; and 6. Other information, if any, believed by the request to be pertinent to the request. D. The requester shall provide additional information as may be required and requested by the commissioner to evaluate the variance request. E. The requester may withdraw a request for a variance at any time. F. The commissioner shall notify the requester in writing of the commissioner's decision on the variance request. If granted, the commissioner: 1. Shall identify: a. The standard or requirement to which a variance has been granted; b. To whom the variance applies; and c. The effective date and expiration date of the variance; and 2. May attach conditions to a variance that, in the sole judgment of the commissioner, satisfies, supports, or furthers the purpose of the standard or requirement. G. The requester shall comply with the standard or requirement to which a variance has been requested unless a variance has been granted.		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.

	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. **Statutory Authority** Chapter 304 of the 2021 Acts of Assembly, Special Session I.		
219-50	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		**CHANGE:** VDH is proposing to promulgate these new requirements. **INTENT:** The intent of these new 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 the name and definition of the data fields to be completed by the carrier. **RATIONALE:** The rationale for these new requirements is that the regulations should parallel the statutory requirements and that providing required data field names and definitions should result in uniform reporting by carriers.

	drugs covered at the greatest cost, calculated using the total annual spending by such health benefit plan for each outpatient prescription drug covered by the health benefit plan; and c. The names of the 25 outpatient prescription drugs that experienced the greatest year-over-year increase in cost, calculated using the total annual spending by a health benefit plan for each outpatient prescription drug covered by the health benefit plan; 2. The percent increase in annual net spending for prescription drugs after accounting for aggregated discounts; 3. The percent increase in premiums that were attributable to each health care service, including prescription drugs; 4. The percentage of specialty drugs with utilization management requirements; and 5. The premium reductions that were attributable to specialty drug utilization management. B. In determining which outpatient prescription drugs are reportable under subdivision A 1 of this section, the carrier shall: 1. Average the frequency of prescription for all drug products of an outpatient prescription drug for such health benefit plan to determine which outpatient prescription drugs are reportable under subdivision A 1 a; 2. Average the cost, calculated using the total annual spending by such health benefit plan for all drug products of an outpatient prescription drug covered by		**LIKELY IMPACT:** The likely impact of these new requirements is improved clarity for carriers on what data is to be reported and how it should be formatted.

the health benefit plan, to determine which outpatient prescription drugs are reportable under subdivision A 1 b; and

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

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

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

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

Data Element Name	Data Element Definition
Carrier tax identification number	The 9-digit tax Taxpayer Identification Number used by the IRS.
Carrier name	The legal name of the reporting entity.

	Health benefit plan category	The 2-digit health plan category identifier. The first digit corresponds to the insurance line and valid values are D (Medicaid); R (Medicare); C (commercial); and O (other). The second digit corresponds to the insurance policy type and valid values include I (individual); F (fully insured group); S (self insured group); and C (Commonwealth of Virginia employees).		
	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.		
	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 proprietary 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 after accounting for aggregated discounts or other reductions in price.		
	Premium increase	The percent year-over-year increase in premiums that were attributable to each health care service, including prescription drugs.		

	<table><tr><td>Specialty drugs with utilization management</td><td>The percentage of specialty drugs with utilization management requirements.</td></tr><tr><td>Premium reductions</td><td>The percent year-over-year of premium reductions that were attributable to specialty drug utilization management.</td></tr><tr><td>Comments</td><td>A text field for any additional information the carrier wishes to provide.</td></tr></table> **Statutory Authority** Chapter 304 of the 2021 Acts of Assembly, Special Session I.		
219-60	**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		**CHANGE:** VDH is proposing to promulgate these new requirements. **INTENT:** The intent of these new 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 the name and definition of the data fields to be completed by the PBM. **RATIONALE:** The rationale for these new requirements is that the regulations should parallel the statutory requirements and that providing required data field names and definitions should result in uniform reporting by PBMs. **LIKELY IMPACT:** The likely impact of these new requirements is improved clarity for PBMs on what

<table>
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<td>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>PBM tax identification number</td><td>The 9-digit tax Taxpayer Identification Number used by the IRS.</td></tr>
<tr><td>PBM 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>
<tr><td>Drug group</td><td>The first two digits of the Medi-Span© Generic Product Identifier assigned to the proprietary prescription drug</td></tr>
<tr><td>Brand-name or generic</td><td>Whether the prescription drug is brand-name or generic.</td></tr>
<tr><td>Carrier name</td><td>The legal name of the carrier to whom rebates were distributed or passed on.</td></tr>
<tr><td>Total rebates</td><td>Total aggregate rebates received or negotiated directly with the manufacturer in</td></tr>
</table>
</td>
<td></td>
<td>data is to be reported and how it should be formatted.</td>
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</table>

		the last 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.
	Comments	A text field for any additional information the PBM wishes to provide.

Statutory Authority
Chapter 304 of the 2021 Acts of Assembly, Special Session I.

219-70	**12VAC5-219-70. Manufacturer reporting requirements.** A. Every manufacturer shall report annually by April 1 to the NDSO on each of its:		**CHANGE:** VDH is proposing to promulgate these new requirements. **INTENT:** The intent of these new requirements is to incorporate the minimum

	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 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		data required to be reported by manufacturers pursuant to Va. Code § 54.1-3442.02 and to specify the name and definition of the data fields to be completed by the manufacturer. **RATIONALE:** The rationale for these new requirements is that the regulations should parallel the statutory requirements and that providing required data field names and definitions should result in uniform reporting by manufacturers. **LIKELY IMPACT:** The likely impact of these new requirements is improved clarity for manufacturers on what data is to be reported and how it should be formatted.

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 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 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 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.
Effective date of change in WAC	The month and year that the WAC changed.
Justification for current-year WAC increase	The reason or reasons that the manufacturer increased the WAC of the prescription drug compared with last year.
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.
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.

Statutory Authority
Chapter 304 of the 2021 Acts of Assembly, Special Session I.

219-80	**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 health 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 A of this section and no more than 45 calendar days after the publication of the general notice pursuant to subdivision A 1 of this section, a wholesale distributor shall report for the 25 costliest prescription drugs dispensed in the Commonwealth, including each drug product of a reportable prescription drug: 1. The WAC directly negotiated with 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		**CHANGE:** VDH is proposing to promulgate these new requirements. **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 the name and definition of the data fields to be completed by the wholesale distributor if it chooses to not utilize the flexibility provided for in the proposed subsection F. **RATIONALE:** The rationale for these new requirements is that the regulations should parallel the statutory requirements and that providing required data field names and definitions should result in uniform reporting by wholesale distributors if it chooses to not utilize the flexibility provided for in the proposed subsection F. **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 if it chooses to not utilize the flexibility provided for in the proposed subsection F, and how VDH will notify wholesale distributors that data reporting is required.

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:

Data Element Name	Data Element Description
Wholesale distributor tax identification number	The 9-digit tax Taxpayer Identification Number used by the IRS.
Wholesale distributor name	The legal name of the reporting entity.
Proprietary drug name	The brand or trademark name of the prescription drug reported to the FDA.
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.		
	Current year minus one WAC	WAC in U.S. dollars, for each prescription drug for which the wholesale distributor has negotiated with a manufacturer in the last calendar year, related to prescriptions under a health benefit plan issued in the Commonwealth.		
	Current year WAC	WAC in U.S. dollars, for each prescription drug for which the wholesale distributor has negotiated with a manufacturer in the current calendar year, related to prescriptions under a health benefit plan issued in the Commonwealth.		
	Total manufacturer discounts	Total aggregate discounts for each prescription drug directly negotiated with a manufacturer		

	<table><tr><td></td><td>in the last calendar year, for business in the Commonwealth.</td></tr><tr><td>Total pharmacy discounts, dispensing fees, and other fees</td><td>Total aggregate discounts, dispensing fees, and other fees for each prescription drug negotiated in the last calendar year with a pharmacy.</td></tr><tr><td>Comments</td><td>A text field for any additional information the wholesale distributor wishes to provide</td></tr></table> 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. **Statutory Authority** Chapter 304 of the 2021 Acts of Assembly, Special Session I.		
219-90	**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		**CHANGE:** VDH is proposing to promulgate these new requirements. **INTENT:** The intent of these new requirements specify the method of data collection and submission. **RATIONALE:** The rationale for these new requirements is that both the NDSO and

	each report and that comply with the NDSO's Format and File Specifications for Submission of Prescription Drug Reports. C. The NDSO shall notify each reporting entity in writing at least 30 calendar days before any change in the report collection method. **Statutory Authority** Chapter 304 of the 2021 Acts of Assembly, Special Session I.		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 new requirements is improved clarity for reporting entities and the NDSO on how to report data.
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 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.		**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.

	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 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 failure to correct as a failure to report pursuant to Part II (12VAC5-219-50 et seq.) of this chapter.		

	Statutory Authority Chapter 304 of the 2021 Acts of Assembly, Special Session I.		
219-110	**12VAC5-219-110. Audit; corrective action plan.** A. A reporting entity shall include: 1. A signed, written certification of the accuracy of any notification or report to the NDSO; or 2. Electronic certification of their notification or report 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 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		**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.

	commissioner a corrective action plan no more than 10 business days after receipt of the audit findings, and shall include in the corrective action plan: 1. A description of the corrective action or actions to be taken for each deficiency and the position title of the employees to implement the corrective action; 2. The deadline for completion of all corrective action, not to exceed 45 business days from the receipt of the audit findings; and 3. A description of the measures implemented to prevent a recurrence of the deficiency. F. The reporting entity shall ensure that the person responsible for the validity of the corrective action plan signs, dates, and indicates their title on the corrective action plan. G. 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 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. **Statutory Authority** Chapter 304 of the 2021 Acts of Assembly, Special Session I.		
219-120	Article 2 Administrative Process **12VAC5-219-120. Disciplinary action.** A. A reporting entity may not violate the provisions of this chapter. B. The commissioner may: 1. For each violation of this chapter, petition an appropriate court for an injunction, mandamus, or other appropriate remedy or imposition of a civil penalty against the reporting entity pursuant to subsection B or C of § 32.1-27 of the Code of Virginia: and 2. For each violation of Part II (12VAC5-219-50 et seq.) of this chapter, levy a civil penalty upon the reporting entity as specified in subsection B of 12VAC5-219-130, in accordance with the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia). C. Each day that a reporting entity fails to report in violation of this chapter is a sufficient cause for imposition of disciplinary action. If a reporting entity knowingly submits false, inaccurate, or misleading data pursuant to the reporting requirements of this chapter, the commissioner shall deem that submission as a failure to report. **Statutory Authority** Chapter 304 of the 2021 Acts of Assembly, Special Session I.		**CHANGE:** VDH is proposing to promulgate these new requirements. **INTENT:** The intent of these new requirements is to specify 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 reporting entity in an amount of: 1. For the first offense: a. $500 the first day in which the reporting entity fails to report; b. $1,000 for the second day in which the reporting entity fails to report; c. $1,500 for the third day in which the reporting entity fails to report; d. $2,000 for the fourth day in which the reporting entity fails to report; and e. $2,500 for the fifth day and each subsequent day in which the reporting entity fails to report; and 2. For the second offense: a. $1,000 the first day in which the reporting entity fails to report; b. $1,750 for the second day in which the reporting entity fails to report; and c. $2,500 for the third and each subsequent day in which the reporting entity fails to report; and 3. For the third and all subsequent offenses, $2,500 for each day in which the reporting entity fails to report. C. The commissioner shall deem the first day in which the reporting entity fails to report as: 1. April 2 for a reporting entity that fails to submit any information or documentation pursuant to 12VAC5-219-50, 12VAC5-219-60, or 12VAC5-219-70 or for a reporting entity that knowingly submits		**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, 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.

	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. **Statutory Authority** Chapter 304 of the 2021 Acts of Assembly, Special Session I; § 2.2-4805 of the Code of Virginia.		
219-140	**12VAC5-219-140. Informal fact-finding proceeding.** A. A reporting entity may dispute the imposition of a civil penalty pursuant to subdivision B 2 of 12VAC5-219-120 by requesting an informal fact finding proceeding: 1. In writing to the commissioner; and 2. No more than 14 calendar days after the date of receipt		**CHANGE:** VDH is proposing to promulgate these new requirements. **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

	of the notice of civil penalty imposition. B. In requesting an informal fact finding proceeding pursuant to subsection A of this section, a reporting entity: 1. Shall identify with specificity the reason or alleged good cause for its failure to report; and 2. May present factual data, argument, information, or proof in support of its reason or alleged good cause for its failure to report. C. The request for an informal fact finding proceeding: 1. May not toll the imposition of a civil penalty on a per day basis, as specified in subsection B of 12VAC5-219-130; 2. Shall toll all assessments and charges under subdivision F 1 of 12VAC5-219-130 until a case decision after an informal fact finding proceeding has been served. D. If a reporting entity does not request an informal fact finding proceeding pursuant to subsection A of this section, the civil penalty imposed pursuant to subdivision B 2 of 12VAC5-219-120 shall be final on the 15th calendar day after the date of receipt of the notice of civil penalty imposition. **Statutory Authority** Chapter 304 of the 2021 Acts of Assembly, Special Session I.		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.
DIBR (219-9999)	**Documents Incorporated By Reference (12VAC5-219)** Format and File Specifications for Submission of Prescription Drug Reports, 2021, Virginia Health Information.		**CHANGE:** VDH is proposing to promulgate these new requirements. **INTENT:** The intent of these new requirements is to incorporate by reference the format and file standards for data reports. **RATIONALE:** The rationale for these new requirements

			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 new requirements is improved clarity for reporting entities on the format and file standards when filing data reports.

Project 6828 - Emergency/NOIRA

Department Of Health

Promulgation of New Regulation to Implement Chapter 304 of the 2021 Acts of Assembly, Special Session I

Chapter 219

Prescription Drug Price Transparency Regulation

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.

"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 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, 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

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.

Statutory Authority

Chapter 304 of the 2021 Acts of Assembly, Special Session I.

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 anticipated 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, 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.

Statutory Authority

Chapter 304 of the 2021 Acts of Assembly, Special Session I.

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 days after the request, except as otherwise agreed to between the NDSO and the commissioner or the department.

Statutory Authority

Chapter 304 of the 2021 Acts of Assembly, Special Session I.

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 the standard or requirement; and

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

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

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

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

1. Shall identify:

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

b. To whom the variance applies; and

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

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

G. The 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.

Statutory Authority

Chapter 304 of the 2021 Acts of Assembly, Special Session I.

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 benefit plan for each outpatient prescription drug covered by the health benefit plan;

2. The percent increase in annual net spending for prescription drugs after accounting for aggregated discounts;

3. The percent increase in premiums that were attributable to each health care service, including prescription drugs;

4. The percentage of specialty drugs with utilization management requirements; and

5. The premium reductions that were attributable to specialty drug utilization management.

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

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

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

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

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

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

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

Data Element Name	Data Element Definition
Carrier tax identification number	The 9-digit tax Taxpayer Identification Number used by the IRS.
Carrier name	The legal name of the reporting entity.
Health benefit plan category	The 2-digit health plan category identifier. The first digit corresponds to the insurance line and valid values are D (Medicaid); R (Medicare); C (commercial); and O (other). The second digit corresponds to the insurance policy type and valid values include I (individual); F (fully insured group); S (self insured group); and C (Commonwealth of Virginia employees).
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.
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 proprietary 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 after accounting for aggregated discounts or other reductions in price.
Premium increase	The percent year-over-year increase in premiums that were attributable to each health care service, including prescription drugs.
Specialty drugs with utilization management	The percentage of specialty drugs with utilization management requirements.
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 carrier wishes to provide.

Statutory Authority

Chapter 304 of the 2021 Acts of Assembly, Special Session I.

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.
PBM 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.
Drug group	The first two digits of the Medi-Span© Generic Product Identifier assigned to the proprietary prescription drug
Brand-name or	Whether the prescription drug is brand-name or generic.

generic	
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.
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.
Comments	A text field for any additional information the PBM wishes to provide.

Statutory Authority

Chapter 304 of the 2021 Acts of Assembly, Special Session I.

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 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 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 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 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.
Effective date of change in WAC	The month and year that the WAC changed.
Justification for current-year WAC increase	The reason or reasons that the manufacturer increased the WAC of the prescription drug compared with last year.
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.
Year of research and	The year in which final audit data is available.

development costs	
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.

Statutory Authority

Chapter 304 of the 2021 Acts of Assembly, Special Session I.

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 health 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 A of this section and no more than 45 calendar days after the publication of the general notice pursuant to subdivision A 1 of this section, a wholesale distributor shall report for the 25 costliest prescription drugs dispensed in the Commonwealth, including each drug product of a reportable prescription drug:

1. The WAC directly negotiated with 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:

Data Element Name	Data Element Description
Wholesale distributor tax identification number	The 9-digit tax Taxpayer Identification Number used by the IRS.
Wholesale distributor name	The legal name of the reporting entity.
Proprietary drug name	The brand or trademark name of the prescription drug reported to the FDA.
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.
Current year minus one WAC	WAC in U.S. dollars, for each prescription drug for which the wholesale distributor has negotiated with a manufacturer in the last calendar year, related to prescriptions under a health benefit plan issued in the Commonwealth.
Current year WAC	WAC in U.S. dollars, for each prescription drug for which the wholesale distributor has negotiated with a manufacturer in the current calendar year, related to prescriptions under a health benefit plan issued in the Commonwealth.
Total manufacturer discounts	Total aggregate discounts for each prescription drug directly negotiated with a manufacturer in the last calendar year, for business in the Commonwealth.
Total pharmacy discounts, dispensing fees, and other fees	Total aggregate discounts, dispensing fees, and other fees for each prescription drug negotiated in the last calendar year with a pharmacy.
Comments	A text field for any additional information the wholesale distributor wishes to provide

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.

Statutory Authority

Chapter 304 of the 2021 Acts of Assembly, Special Session I.

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 Format and File Specifications for Submission of Prescription Drug Reports.

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

Statutory Authority

Chapter 304 of the 2021 Acts of Assembly, Special Session I.

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 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 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 failure to correct as a failure to report pursuant to Part II (12VAC5-219-50 et seq.) of this chapter.

Statutory Authority

Chapter 304 of the 2021 Acts of Assembly, Special Session I.

12VAC5-219-110. Audit; corrective action plan.

A. A reporting entity shall include:

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

2. Electronic certification of their notification or report 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 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 validity 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 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.

Statutory Authority

Chapter 304 of the 2021 Acts of Assembly, Special Session I.

Article 2

Administrative Process

12VAC5-219-120. Disciplinary action.

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

B. The commissioner may:

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

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

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

Statutory Authority

Chapter 304 of the 2021 Acts of Assembly, Special Session I.

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 reporting entity in an amount of:

1. For the first offense:

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

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

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

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

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

2. For the second offense:

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

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

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

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

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

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

2. The 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.

Statutory Authority

Chapter 304 of the 2021 Acts of Assembly, Special Session I; § 2.2-4805 of the Code of Virginia.

12VAC5-219-140. Informal fact-finding proceeding.

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

1. In writing to the commissioner; and

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

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

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

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

C. The request for an informal fact finding proceeding:

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

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

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

Statutory Authority

Chapter 304 of the 2021 Acts of Assembly, Special Session I.

DIBRS (12VAC5-219)

Format and File Specifications for Submission of Prescription Drug Reports, 2021, Virginia Health Information.

COMMONWEALTH of VIRGINIA
Department of Health
M. NORMAN OLIVER, MD, MA
STATE HEALTH COMMISSIONER
P O BOX 2448
RICHMOND, VA 23218
TTY 7-1-1 OR
1-800-828-1120

MEMORANDUM

DATE: July 22, 2021

TO: Virginia State Board of Health

FROM: Lilian Peake, MD, MPH – State Epidemiologist and Director of Epidemiology

SUBJECT: Proposed Stage for Regulations Governing COVID-19 Reporting

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The Regulations for Disease Reporting and Control provide information about the process and procedures for reporting diseases to the Virginia Department of Health (VDH), including what diseases must be reported, who must report them and other details related to reporting and disease control. During the Governor's Declared Emergency, VDH implemented Emergency Regulations related to COVID-19 and is now pursuing the Proposed Stage to make some of those emergency amendments permanent.

Consistent with the Emergency Regulations, this regulatory action requires physicians' and directors of medical care facilities' to report hospitalizations and ICU admissions related to COVID-19; requires COVID-19 case report forms be submitted electronically; clarifies that the category "laboratory directors" includes any entity that holds CLIA Certificates of Waiver; adds ethnicity to the fields required to be reported by all parties related to COVID-19; and adds "coronavirus, severe" to the list of infectious disease that shall be reported to persons practicing funeral services.

If this regulatory action is approved by the Board of Health, the regulatory package will be submitted to Town Hall and proceed to executive branch review. This review includes the Office of the Attorney General, the Division of Planning and Budget, the Office of the Secretary of Health and Human Resources, and the Office of the Governor.

townhall.virginia.gov

Proposed Regulation
Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-90
VAC Chapter title(s)	Disease Reporting and Control Regulations
Action title	Amendments Governing COVID-19 Reporting
Date this document prepared	July 1, 2021

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1VAC7-10), 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.

The Regulations for Disease Reporting and Control provide information about the process and procedures for reporting diseases to the Virginia Department of Health (VDH), including what diseases must be reported, who must report them and other details related to reporting and disease control. VDH is proposing an amendment to the regulations to ensure all health providers report necessary public health information.

This regulatory action requires COVID-19 case and laboratory report forms be submitted electronically; clarifies that the category “laboratory directors” includes any entity that holds CLIA Certificates of Waiver; adds ethnicity to the fields required to be reported by all parties related to COVID-19; and adds “coronavirus, severe” to the list of infectious disease that shall be reported to persons practicing funeral services.

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.

No acronyms are used that are not defined in context.

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 Executive Order 14 (as amended, July 16, 2018), "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."

Emergency amendments to these regulations became effective on January 20, 2021. Those emergency amendments are set to expire on July 19, 2022. The impetus for this regulatory action is to make several of those amendments permanent. The proposed changes are essential to protect the health and safety of citizens because they will improve the ability of VDH to conduct surveillance and investigations, including collection of necessary public health information. Further, the proposed changes are essential to continue to implement disease control measures for COVID-19. The changes will position the agency to better detect and respond to these illnesses to protect the health of the public..

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.

Chapter 2 of Title 32.1 of the Code of Virginia, §§ 32.1-12 and 32.1-35 through 32.1-73, contain mandatory language authorizing the State Board of Health to promulgate the proposed regulations.

Specifically, § 32.1-35 directs the Board of Health to promulgate regulations specifying which diseases occurring in the Commonwealth are to be reportable and the method by which they are to be reported.

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's intended to solve.

The proposed changes are essential to protect the health and safety of citizens because they will improve the ability of VDH to conduct surveillance and investigations, collect necessary public health information,

and continue to implement disease control measures for COVID-19. The changes will position the agency to better detect and respond to these illnesses to protect the health of the public.

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.

Amendments to current regulations will:

- For COVID-19 specifically:
  - Require all suspect or confirmed COVID-19 case report forms be submitted electronically to VDH;
  - Clarify that the category "laboratory directors" includes all entities that hold CLIA Certificates of Waiver so that entities testing for COVID-19 are required to report to VDH;
  - Require all COVID-19 laboratory reports be submitted electronically to VDH;
  - Add the requirement that patient phone number, email address, and ethnicity be included in the list of fields that are reported by physicians, laboratory directors, and directors of medical care facilities.
  - Add "coronavirus, severe" to the list of infectious diseases that shall be reported to persons practicing funeral services.

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 advantages to the public are the improved ability of the agency to control the risk of disease in the community based on timelier reporting through VDHs online morbidity reporting portal and the improved ability to accurately report COVID-19 data. No disadvantages have been identified.

The primary advantage to the agency is that the proposed changes improve the focus of surveillance and ability of VDH to conduct surveillance and implement disease control for conditions of public health concern in a timely manner. The changes will position the agency to better detect and respond to these illnesses to protect the health of the public. No disadvantages have been identified.

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.

The Coronavirus Aid, Relief, and Economic Security (CARES) Act is the applicable federal law related to COVID-19 reporting. None of the changes in this document would make this regulation more restrictive than requirements specified in the CARES Act.

Agencies, Localities, and Other Entities Particularly Affected

Identify any other state agencies, localities, or other entities particularly affected by the regulatory change. "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

No particular agency is affected by these amendments.

Localities Particularly Affected

No particular locality is affected by these amendments.

Other Entities Particularly Affected

Persons responsible for reporting, particularly laboratories, and persons in charge of funeral homes are particularly affected by these amendments.

Economic Impact

Pursuant to § 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 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	Potential non-general fund cost savings for VDH are expected with the elimination of COVID-19 paper reports.
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.	No economic impacts expected.
For all agencies: Benefits the regulatory change is designed to produce.	More efficient and accurate reporting of data by the VDH.

Impact on Localities

Projected costs, savings, fees or revenues resulting from the regulatory change.	No economic impacts expected.

Benefits the regulatory change is designed to produce.	More efficient and accurate reporting of data by the VDH.

Impact on Other Entities

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.	This regulatory change impacts persons who are required to report (i.e. physicians, medical directories, laboratories, and persons with COVID-19 related CLIA waivers).
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.	20,000 physicians 125 laboratories 100 hospitals 250 nursing homes Some of these may be small businesses.
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.	No additional costs are expected based on changes proposed to the existing regulations.
Benefits the regulatory change is designed to produce.	Benefits include more timely and complete reporting of COVID-19 to VDH so that actions can be taken to minimize the spread of disease in Virginia's communities and a better understanding of the magnitude of these health problems in Virginia will be gained.

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.

In light of the clear, specific and mandatory authority of the State Board of Health to promulgate the proposed amendments to the regulations, no alternatives are available that are advisable.

Regulatory Flexibility Analysis

Pursuant to § 2.2-4007.1B 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.

The agency has found that there are no alternative regulatory methods that will accomplish the objectives of these amendments. The agency has put forth thoughtful consideration about the burdens of additional reporting and has limited these amendments to those necessary to protect the health and safety of Virginians.

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 Executive Order 14 (as amended, July 16, 2018), 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.

This Proposed Stage is not being used to announce a periodic review or a small business impact review.

The agency has assessed the need for the Disease Reporting and Control regulations and has found that they are critical to containing and mitigating communicable disease spread throughout the Commonwealth. VDH did not receive any comments following publication of the emergency amendments, which went into effect on January 20, 2021.

Public Comment

Summarize all comments received during the public comment period following the publication of the previous stage, and provide the agency 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

No comments were received during the Emergency/NOIRA stage.

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.

The Virginia Department of Health 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 Kristin Collins, 109 Governor St., Richmond, VA 23219, 804-864-7298, Kristin.collins@vdh.virginia.gov. 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.

If an existing VAC Chapter(s) is being amended or repealed, use Table 1 to describe the changes between existing VAC Chapter(s) and the proposed regulation. If existing VAC Chapter(s) or sections are being repealed and replaced, ensure Table 1 clearly shows both the current number and the new number for each repealed section and the replacement section.

Table 1: Changes to Existing VAC Chapter(s)

Current chapter-section number	New chapter-section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
12VAC5-90-80		Reportable Disease List	Change: ● Add that COVID-19 (SARS-CoV-2) shall be reported as specified in subsection I of the section Intent:

			● to create regulatory requirements specific to COVID-19 Rationale: ● COVID-19 requires different reporting requirements than other reportable diseases Likely Impact: ● clarify responsibilities for persons reporting COVID-19 and ensure VDH gets necessary public health data
12VAC5-90-80		COVID-19 (SARS-CoV-2)	Change: ● Add subsection I: ● Require all suspect or confirmed COVID-19 case report forms be submitted electronically to VDH; ● Require all COVID-19 laboratory reports be submitted electronically to VDH; ● Clarify that the category “laboratory directors” includes all entities that hold CLIA Certificates of Waiver so that all entities testing for COVID-19 are required to report to VDH; ● Add the requirement that patient phone number, email address, and ethnicity be included in the list of fields that are reported by physicians, laboratory directors, and directors of medical care facilities. Intent: ● to clarify information required and methods of reporting for COVID-19 Rationale: ● COVID-19 requires different reporting requirements than other reportable diseases Likely Impact: ● clarify responsibilities for persons reporting COVID-19 and ensure VDH gets necessary public health data
12VAC5-90-90		Persons in charge of a medical care facility.	Change: ● Replace “hospital chart number” with “medical record number” Intent: ● to update a field to the current terminology Rationale:

			● clarify the term so that reporters know what information VDH is requiring Likely Impact: ● clarify responsibilities for persons reporting COVID-19 and ensure VDH gets necessary public health data
12VAC5-90-90		Persons in charge of hospitals, nursing facilities or nursing homes, assisted living facilities, and correctional facilities.	Change: ● Add "coronavirus, severe" to the list of infectious diseases that shall be reported to persons practicing funeral services Intent: ● to ensure persons practicing funeral services are informed about a potential exposure to COVID-19 Rationale: ● a dead body with COVID-19 could potentially expose a person performing funeral services and so additional precautions are necessary Likely Impact: ● Persons performing funeral services have necessary information to take necessary public health precautions to prevent the spread of an infectious disease

If a <u>new</u> VAC Chapter(s) is being promulgated and is <u>not</u> replacing an existing Chapter(s), use Table 2.

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

*If the regulatory change is replacing an **emergency regulation**, and the proposed regulation is <u>identical</u> to the emergency regulation, complete Table 1 and/or Table 2, as described above.*

*If the regulatory change is replacing an **emergency regulation**, but <u>changes have been made</u> since the emergency regulation became effective, <u>also</u> complete Table 3 to describe the changes made <u>since</u> the emergency regulation.*

Table 3: Changes to the Emergency Regulation

Emergency chapter-	New chapter-section	Current <u>emergency</u> requirement	Change, intent, rationale, and likely impact of new or changed requirements since emergency stage

section number	number, if applicable		
12VAC5-90-80		All SARS-CoV-2 tests, positive and negative, shall be reported by directors of laboratories, including pharmacies that hold CLIA Certificates of Waiver.	Change: ● Remove the requirement to report negative COVID-19 tests ● Remove the requirement to report hospitalizations and ICU admissions through the Emergency Department Care Coordination program. Intent: ● To ensure the requirement to get negative tests does not become permanent as the emergency has ended and this data will only be needed temporarily. ● To remove unnecessary language. Rationale: ● VDH will continue to collect this information for the CDC as it is still a requirement in the CARES Act and is used to report percent positivity. VDH does not require that negative tests are reported for any other communicable disease and believes that reporting percent positivity will be temporary. ● This has not been developed as a useful tool for this information and VDH has alternative means for collecting this data. Likely Impact: ● The workload for labs and VDH staff will decrease due to reporting of information that is no longer necessary. ● No other impact expected.

Project 6359 - Emergency/NOIRA

Department Of Health

COVID-19 Emergency Update

12VAC5-90-80. Lists of diseases that shall be reported.

~~Part III~~
~~Reporting of Disease~~

A. Reportable disease list. The board declares suspected or confirmed cases of the following named diseases, toxic effects, and conditions to be reportable by the persons enumerated in 12VAC5-90-90. Conditions identified by an asterisk (*) require immediate communication to the local health department by the most rapid means available upon suspicion or confirmation, as defined in subsection C of this section. Other conditions should be reported within three days of suspected or confirmed diagnosis, unless otherwise specified in this section. Neonatal Abstinence Syndrome shall be reported as specified in subsection E of this section. COVID-19 (SARS-CoV-2) shall be reported as specified in subsection I of the section.

Amebiasis (Entamoeba histolytica)
*Anthrax (Bacillus anthracis)
Arboviral infections (e.g., CHIK, dengue, EEE, LAC, SLE, WNV, Zika)
Babesiosis (Babesia spp.)
*Botulism (Clostridium botulinum)
*Brucellosis (Brucella spp.)
Campylobacteriosis (Campylobacter spp.)
Candida auris, infection or colonization
Carbapenemase-producing organism, infection or colonization
Chancroid (Haemophilus ducreyi)
Chickenpox (Varicella virus)
Chlamydia trachomatis infection
*Cholera (Vibrio cholerae O1 or O139)
*Coronavirus infection, severe
Cryptosporidiosis (Cryptosporidium spp.)
Cyclosporiasis (Cyclospora spp.)
*Diphtheria (Corynebacterium diphtheriae)
*Disease caused by an agent that may have been used as a weapon
Ehrlichiosis/Anaplasmosis (Ehrlichia spp., Anaplasma phagocytophilum)
Giardiasis (Giardia spp.)
Gonorrhea (Neisseria gonorrhoeae)
Granuloma inguinale (Calymmatobacterium granulomatis)
*Haemophilus influenzae infection, invasive
Hantavirus pulmonary syndrome
Hemolytic uremic syndrome (HUS)
*Hepatitis A
Hepatitis B (acute and chronic)

Hepatitis C (acute and chronic)
Hepatitis, other acute viral
Human immunodeficiency virus (HIV) infection
Influenza, confirmed
*Influenza-associated deaths if younger than 18 years of age
Lead, blood levels
Legionellosis (Legionella spp.)
Leprosy (Hansen's disease) (Mycobacterium leprae)
Leptospirosis (Leptospira interrogans)
Listeriosis (Listeria monocytogenes)
Lyme disease (Borrelia spp.)
Lymphogranuloma venereum (Chlamydia trachomatis)
Malaria (Plasmodium spp.)
*Measles (Rubeola)
*Meningococcal disease (Neisseria meningitidis)
Mumps
Neonatal abstinence syndrome (NAS)
Ophthalmia neonatorum
*Outbreaks, all (including foodborne, health care-associated, occupational, toxic substance-related, waterborne, and any other outbreak)
*Pertussis (Bordetella pertussis)
*Plague (Yersinia pestis)
*Poliovirus infection, including poliomyelitis
*Psittacosis (Chlamydophila psittaci)
*Q fever (Coxiella burnetii)
*Rabies, human and animal
Rabies treatment, post-exposure
*Rubella, including congenital rubella syndrome
Salmonellosis (Salmonella spp.)
Shiga toxin-producing Escherichia coli infection
Shigellosis (Shigella spp.)
*Smallpox (Variola virus)
Spotted fever rickettsiosis (Rickettsia spp.)
Streptococcal disease, Group A, invasive or toxic shock
Streptococcus pneumoniae infection, invasive if younger than five years of age
Syphilis (Treponema pallidum) report *congenital, *primary, *secondary, and other
Tetanus (Clostridium tetani)
Toxic substance-related illness
Trichinosis (Trichinellosis) (Trichinella spiralis)
*Tuberculosis, active disease (Mycobacterium tuberculosis complex)
Tuberculosis infection

*Tularemia (Francisella tularensis)

*Typhoid/Paratyphoid infection (Salmonella Typhi, Salmonella Paratyphi)

*Unusual occurrence of disease of public health concern

*Vaccinia, disease or adverse event

Vancomycin-intermediate or vancomycin-resistant Staphylococcus aureus infection

*Vibriosis (Vibrio spp.)

*Viral hemorrhagic fever

*Yellow fever

Yersiniosis (Yersinia spp.)

B. Conditions reportable by directors of laboratories. Laboratories shall report all test results indicative of and specific for the diseases, infections, microorganisms, conditions, and toxic effects specified in this subsection for humans. Such tests include microbiological culture, isolation, or identification; assays for specific antibodies; and identification of specific antigens, toxins, or nucleic acid sequences. Additional condition-specific requirements are noted in this subsection and subsection D of this section. Conditions identified by an asterisk (*) require immediate communication to the local health department by the most rapid means available upon suspicion or confirmation, as defined in subsection C of this section. Other conditions should be reported within three days of suspected or confirmed diagnosis.

Amebiasis (Entamoeba histolytica)

*Anthrax (Bacillus anthracis)

Arboviral infection, for example, CHIK, dengue, EEE, LAC, SLE, WNV, or Zika

Babesiosis (Babesia spp.)

*Botulism (Clostridium botulinum)

*Brucellosis (Brucella spp.)

Campylobacteriosis (Campylobacter spp.)

Candida auris - Include available antimicrobial susceptibility findings in report.

Carbapenemase-producing organism - Include available antimicrobial susceptibility findings in report.

Chancroid (Haemophilus ducreyi)

Chickenpox (Varicella virus)

Chlamydia trachomatis infection

*Cholera (Vibrio cholerae O1 or O139)

*Coronavirus infection, severe (e.g., SARS-CoV, MERS-CoV)

Cryptosporidiosis (Cryptosporidium spp.)

Cyclosporiasis (Cyclospora spp.)

*Diphtheria (Corynebacterium diphtheriae)

Ehrlichiosis/Anaplasmosis (Ehrlichia spp., Anaplasma phagocytophilum)

Giardiasis (Giardia spp.)

Gonorrhea (Neisseria gonorrhoeae) - Include available antimicrobial susceptibility findings in report.

*Haemophilus influenzae infection, invasive

Hantavirus pulmonary syndrome

*Hepatitis A

Hepatitis B (acute and chronic) - For All hepatitis B patients, also report available results of serum alanine aminotransferase (ALT) and all available results from the hepatitis panel.

Hepatitis C (acute and chronic) - For all patients with any positive HCV test, also report all results of HCV viral load tests, including undetectable viral loads and report available results of serum alanine aminotransferase (ALT) and all available results from the hepatitis panel.

Hepatitis, other acute viral - Any finding indicative of acute infection with hepatitis D, E, or other cause of viral hepatitis. For any reportable hepatitis finding, submit all available results from the hepatitis panel.

Human immunodeficiency virus (HIV) infection - For HIV-infected patients, report all results of CD4 and HIV viral load tests, including undetectable viral loads. For HIV-infected patients, report all HIV genetic nucleotide sequence data associated with HIV drug resistance tests by electronic submission. For children younger than three years of age, report all tests regardless of the test findings (e.g., negative or positive).

Influenza, confirmed - By culture, antigen detection by direct fluorescent antibody (DFA), or nucleic acid detection.

Lead, blood levels - All lead results from tests of venous or capillary blood performed by a laboratory certified by the Centers for Medicare and Medicaid Services in accordance with 42 USC § 263a, the Clinical Laboratory Improvement Amendment of 1988 (CLIA-certified).

Legionellosis (Legionella spp.)

Leptospirosis (Leptospira interrogans)

Listeriosis (Listeria monocytogenes), invasive or if associated with miscarriage or stillbirth from placental or fetal tissue

Lyme disease (Borrelia spp.)

Malaria (Plasmodium spp.)

*Measles (Rubeola)

*Meningococcal disease (Neisseria meningitidis), invasive - Include identification of gram-negative diplococci.

Mumps

*Mycobacterial diseases - (See 12VAC5-90-225 B) Report any of the following:

1. Acid fast bacilli;
2. M. tuberculosis complex or any other mycobacteria;
3. Antimicrobial susceptibility results for M. tuberculosis complex.

*Pertussis (Bordetella pertussis)

*Plague (Yersinia pestis)

*Poliovirus infection

*Psittacosis (Chlamydophila psittaci)

*Q fever (Coxiella burnetii)

*Rabies, human and animal

*Rubella

Salmonellosis (Salmonella spp.)

Shiga toxin-producing Escherichia coli infection

Shigellosis (Shigella spp.)

*Smallpox (Variola virus)

Spotted fever rickettsiosis (Rickettsia spp.)

Streptococcal disease, Group A, invasive or toxic shock

Streptococcus pneumoniae infection, invasive if younger than five years of age

*Syphilis (Treponema pallidum)

Toxic substance-related illness - By blood or urine laboratory findings above the normal range, including heavy metals, pesticides, and industrial-type solvents and gases. When applicable and available, report speciation of metals when blood or urine levels are elevated in order to differentiate the chemical species (elemental, organic, or inorganic).

Trichinosis (Trichinellosis) (Trichinella spiralis)

Tuberculosis infection

*Tularemia (Francisella tularensis)

*Typhoid/Paratyphoid infection (Salmonella Typhi, Salmonella Paratyphi A, Salmonella Paratyphi B, Salmonella Paratyphi C)

*Vaccinia, disease or adverse event

Vancomycin-intermediate or vancomycin-resistant Staphylococcus aureus infection - Include available antimicrobial susceptibility findings in report.

*Vibriosis (Vibrio spp., Photobacterium damselae, Grimontia hollisae), other than toxigenic Vibrio cholera O1 or O139, which are reportable as cholera

*Viral hemorrhagic fever

*Yellow fever

Yersiniosis (Yersinia spp.)

C. Reportable diseases requiring rapid communication. Certain of the diseases in the list of reportable diseases because of their extremely contagious nature, potential for greater harm, or availability of a specific intervention that must be administered in a timely manner require immediate identification and control. Reporting of persons confirmed or suspected of having these diseases, listed in this subsection, shall be made immediately by the most rapid means available, preferably by telephone to the local health department. (These same diseases are also identified by an asterisk (*) in subsections A and B, where applicable, of this section.)

Anthrax (Bacillus anthracis)

Botulism (Clostridium botulinum)

Brucellosis (Brucella spp.)

Cholera (Vibrio cholerae O1 or O139)

Coronavirus infection, severe

Diphtheria (Corynebacterium diphtheriae)

Disease caused by an agent that may have been used as a weapon

Haemophilus influenzae infection, invasive

Hepatitis A

Influenza-associated deaths if younger than 18 years of age

Influenza A, novel virus

Measles (Rubeola virus)

Meningococcal disease (Neisseria meningitidis)

Outbreaks, all

Pertussis (Bordetella pertussis)
Plague (Yersinia pestis)
Poliovirus infection, including poliomyelitis
Psittacosis (Chlamydophila psittaci)
Q fever (Coxiella burnetii)
Rabies, human and animal
Rubella, including congenital rubella syndrome
Smallpox (Variola virus)
Syphilis, congenital, primary, and secondary (Treponema pallidum)
Tuberculosis, active disease (Mycobacterium tuberculosis complex)
Tularemia (Francisella tularensis)
Typhoid/Paratyphoid infection (Salmonella Typhi, Salmonella Paratyphi (all types))
Unusual occurrence of disease of public health concern
Vaccinia, disease or adverse event
Vibriosis (Vibrio spp., Photobacterium damselae, Grimontia hollisae), other than toxigenic Vibrio cholerae O1 or O139, which are reportable as cholera
Viral hemorrhagic fever
Yellow fever

D. Submission of initial isolate or other specimen for further public health testing. A laboratory identifying evidence of any of the conditions in this subsection shall notify the local health department of the positive culture or other positive test result within the timeframes specified in subsection B of this section and submit the initial isolate (preferred) or other initial specimen to the Division of Consolidated Laboratory Services or other public health laboratory where specified in this subsection within seven days of identification. All specimens must be identified with the patient and physician information required in 12VAC5-90-90 B.

Anthrax (Bacillus anthracis)
Botulism (Clostridium botulinum)
Brucellosis (Brucella sp.)
Candida auris
Candida haemulonii
Carbapenem-resistant Enterobacteriaceae
Carbapenem-resistant Pseudomonas aeruginosa
Cholera (Vibrio cholerae O1 or O139)
Coronavirus infection, severe (e.g., SARS-CoV, MERS-CoV)
Diphtheria (Corynebacterium diphtheriae)
Haemophilus influenzae infection, invasive
Influenza, unsubtypeable
Listeriosis (Listeria monocytogenes)
Meningococcal disease (Neisseria meningitidis)
Plague (Yersinia pestis)
Poliovirus infection
Q fever (Coxiella burnetii)

Salmonellosis (Salmonella spp.)

Shiga toxin-producing E. coli infection (Laboratories that identify a Shiga toxin but do not perform simultaneous culture for Shiga toxin-producing E. coli should forward all positive stool specimens or positive enrichment broths to the Division of Consolidated Laboratory Services for confirmation and further characterization.)

Shigellosis (Shigella spp.)

Streptococcal disease, Group A, invasive

Tuberculosis (A laboratory identifying Mycobacterium tuberculosis complex (see 12VAC5-90-225) shall submit a representative and viable sample of the initial culture to the Division of Consolidated Laboratory Services or other laboratory designated by the board to receive such specimen.)

Tularemia (Francisella tularensis)

Typhoid/Paratyphoid infection (Salmonella Typhi, Salmonella Paratyphi (all types))

Vancomycin-intermediate or vancomycin-resistant Staphylococcus aureus infection

Vibriosis (Vibrio spp., Photobacterium damselae, Grimontia hollisae)

Yersiniosis (Yersinia spp.)

Other diseases as may be requested by the health department.

E. Neonatal abstinence syndrome. Neonatal abstinence syndrome shall be reported by physicians and directors of medical care facilities when a newborn has been diagnosed with neonatal abstinence syndrome, a condition characterized by clinical signs of withdrawal from exposure to prescribed or illicit drugs. Reports shall be submitted within one month of diagnosis by entering the information into the Department of Health's online Confidential Morbidity Report portal (http://www.vdh.virginia.gov/clinicians).

F. Outbreaks. The occurrence of outbreaks or clusters of any illness that may represent a group expression of an illness that may be of public health concern shall be reported to the local health department immediately by the most rapid means available, preferably by telephone.

G. Toxic substance-related illnesses. All toxic substance-related illnesses, including pesticide and heavy metal poisoning or illness resulting from exposure to an occupational dust or fiber or radioactive substance, shall be reported.

If such illness is verified or suspected and presents an emergency or a serious threat to public health or safety, the report of such illness shall be made immediately by the most rapid means available, preferably by telephone.

H. Unusual occurrence of disease of public health concern. Unusual or emerging conditions of public health concern shall be reported to the local health department immediately by the most rapid means available, preferably by telephone. In addition, the commissioner or the commissioner's designee may establish surveillance systems for diseases or conditions that are not on the list of reportable diseases. Such surveillance may be established to identify cases (delineate the magnitude of the situation), to identify the mode of transmission and risk factors for the disease, and to identify and implement appropriate action to protect public health. Any person reporting information at the request of the department for special surveillance or other epidemiological studies shall be immune from liability as provided by § 32.1-38 of the Code of Virginia.

I. COVID-19 (SARS-CoV-2). COVID-19 shall be reported by physicians and directors of medical care facilities when a person who is infected with or who is suspected of having COVID-19 is treated or examined, hospitalized, or admitted into the intensive care unit. Physicians and directors of medical care facilities shall report that person's name, telephone number, email address, address, age, date of birth, race, ethnicity, sex, and pregnancy status; name of disease

diagnosed or suspected; the medical record number (if applicable); the date of onset of illness; available laboratory tests and results; and the name, address, and telephone number of the physician and medical facility where the examination was made. Case reports shall be submitted immediately or within 24 hours by entering the information into the Department of Health online Confidential Morbidity Report portal at http://www.vdh.virginia.gov/clinicians or via electronic case reporting (https://www.vdh.virginia.gov/meaningful-use/meaningful-use-submissions-of-electronic-case-reports/).

Positive SARS-CoV-2 tests shall be reported by directors of laboratories, including other entities that hold Clinical Laboratory Improvement Amendments Certificates of Waiver. Each report shall give the source of the specimen and the laboratory method and result; the name, telephone number, email address, address, age, date of birth, race, ethnicity, sex, and pregnancy status (if known) of the person from whom the specimen was obtained; and the name, address, and telephone number of the physician at whose request and medical facility at which the examination was made. Reports shall be submitted immediately or within 24 hours to the department. Reports shall be made by entering information into the Department's available portal(s) for laboratory reporting at http://www.vdh.virginia.gov/clinicians or via electronic laboratory reporting (http://www.vdh.virginia.gov/meaningful-use/submissionofreportablelabresults).

12VAC5-90-90. Those required to report.

A. Physicians. Each physician who treats or examines any person who is suffering from or who is suspected of having a reportable disease or condition shall report that person's name, address, age, date of birth, race, sex, and pregnancy status for females; name of disease diagnosed or suspected; the date of onset of illness; available laboratory tests and results; and the name, address, and telephone number of the physician and medical facility where the examination was made, except that influenza should be reported by number of cases only (and type of influenza, if available). Reports are to be made to the local health department serving the jurisdiction where the physician practices. A physician may designate someone to report on his behalf, but the physician remains responsible for ensuring that the appropriate report is made. Any physician, designee, or organization making such report as authorized herein shall be immune from liability as provided by § 32.1-38 of the Code of Virginia.

Such reports shall be made on a Form Epi-1, a computer generated printout containing the data items requested on Form Epi-1, or a CDC or VDH surveillance form that provides the same information and shall be made within three days of the suspicion or confirmation of disease except that those identified in 12VAC5-90-80 C shall be reported immediately by the most rapid means available, preferably by telephone, to the local health department serving the jurisdiction in which the facility is located. Reporting may be done by means of secure electronic transmission upon agreement of the physician and the department.

Additional elements are required to be reported for individuals with confirmed or suspected active tuberculosis disease. Refer to Part X (12VAC5-90-225 et seq.) for details on these requirements.

B. Directors of laboratories. Laboratory directors shall report any laboratory examination of any clinical specimen, whether performed in-house or referred to an out-of-state laboratory, which yields evidence, by the laboratory method(s) indicated or any other confirmatory test, of a disease listed in 12VAC5-90-80 B.

Each report shall give the source of the specimen and the laboratory method and result; the name, address, age, date of birth, race, sex, and pregnancy status for females (if known) of the person from whom the specimen was obtained; and the name, address, and telephone number of the physician at whose request and medical facility at which the examination was made. When the influenza virus is isolated, the type should be reported, if available. Reports shall be made

within three days of identification of evidence of disease, except that those identified in 12VAC5-90-80 C shall be reported immediately by the most rapid means available, preferably by telephone, to the local health department serving the jurisdiction in which the laboratory is located. Reports shall be made on Form Epi-1 or on the laboratory's own form if it includes the required information. Computer generated reports containing the required information may be submitted. Reporting may be done by means of secure electronic transmission upon agreement of the laboratory director and the department. Reports of HIV genetic nucleotide sequence data associated with HIV drug resistance tests must be submitted electronically. Any person making such report as authorized herein shall be immune from liability as provided by § 32.1-38 of the Code of Virginia.

A laboratory identifying evidence of any of the following conditions shall notify the local health department of the positive culture or other positive test result within the timeframes specified in 12VAC5-90-80 and submit the initial isolate or other initial specimen to the Division of Consolidated Laboratory Services within seven days of identification. All specimens must be identified with the patient and physician information required in this subsection.

Anthrax

Botulism

Brucellosis

Cholera

Diphtheria

E. coli infection, Shiga toxin-producing. (Laboratories that use a Shiga toxin EIA methodology but do not perform simultaneous culture for Shiga toxin-producing E. coli should forward all positive stool specimens or positive enrichment broths to the Division of Consolidated Laboratory Services for confirmation and further characterization.)

Haemophilus influenzae infection, invasive

Influenza A, novel virus

Listeriosis

Meningococcal disease

Pertussis

Plague

Poliovirus infection

Q fever

Salmonellosis

Shigellosis

Streptococcal disease, Group A, invasive

Tuberculosis (A laboratory identifying Mycobacterium tuberculosis complex (see 12VAC5-90-225) shall submit a representative and viable sample of the initial culture to the Division of Consolidated Laboratory Services or other laboratory designated by the board to receive such specimen.)

Tularemia

Typhoid/Paratyphoid fever

Vancomycin-intermediate or vancomycin-resistant Staphylococcus aureus infection

Vibrio infection, including infections due to Photobacterium damselae and Grimontia hollisae

Yersiniosis

Other diseases as may be requested by the health department

When a clinical specimen yields evidence indicating the presence of a select agent or toxin as defined by federal regulations in 42 CFR Part 73, the person in charge of the laboratory shall contact the Division of Consolidated Laboratory Services and arrange to forward an isolate for confirmation. If a select agent or toxin has been confirmed in a clinical specimen, the laboratory director shall consult with Division of Consolidated Laboratory Services or CDC regarding isolate transport or destruction.

Laboratories operating within a medical care facility shall be considered to be in compliance with the requirement to notify the local health department when the director of that medical care facility assumes the reporting responsibility; however, laboratories are still required to submit isolates to the Division of Consolidated Laboratory Services or other designated laboratory as noted in this subsection.

C. Persons in charge of a medical care facility. Any person in charge of a medical care facility shall make a report to the local health department serving the jurisdiction where the facility is located of the occurrence in or admission to the facility of a patient with a reportable disease listed in 12VAC5-90-80 A unless he has evidence that the occurrence has been reported by a physician. Any person making such report as authorized herein shall be immune from liability as provided by § 32.1-38 of the Code of Virginia. The requirement to report shall include all inpatient, outpatient, and emergency care departments within the medical care facility. Such report shall contain the patient's name, address, age, date of birth, race, sex, and pregnancy status for females; name of disease being reported; available laboratory tests and results; the date of admission; ~~hospital chart~~ medical record number; date expired (when applicable); and attending physician. Influenza should be reported by number of cases only (and type of influenza, if available). Reports shall be made within three days of the suspicion or confirmation of disease except that those identified in 12VAC5-90-80 C shall be reported immediately by the most rapid means available, preferably by telephone, to the local health department serving the jurisdiction in which the facility is located. Reports shall be made on Form Epi-1, a computer generated printout containing the data items requested on Form Epi-1, or a CDC or VDH surveillance form that provides the same information. Reporting may be done by means of secure electronic transmission upon agreement of the medical care facility and the department.

A person in charge of a medical care facility may assume the reporting responsibility on behalf of the director of the laboratory operating within the facility.

D. Persons in charge of a residential or day program, service, or facility licensed or operated by any agency of the Commonwealth, or a school, child care center, or summer camp. Any person in charge of a residential or day program, service, or facility licensed or operated by any agency of the Commonwealth, or a school, child care center, or summer camp as defined in § 35.1-1 of the Code of Virginia shall report immediately to the local health department the presence or suspected presence in his program, service, facility, school, child care center, or summer camp of persons who have common symptoms suggesting an outbreak situation. Such persons may report additional information, including identifying and contact information for individuals with communicable diseases of public health concern or individuals who are involved in outbreaks that occur in their facilities, as necessary to facilitate public health investigation and disease control. Any person so reporting shall be immune from liability as provided by § 32.1-38 of the Code of Virginia.

E. Local health directors. The local health director shall forward any report of a disease or report of evidence of a disease which has been made on a resident of his jurisdiction to the Office of Epidemiology within three days of receipt. This report shall be submitted immediately by the most rapid means available if the disease is one requiring rapid communication, as required in 12VAC5-90-80 C. All such rapid reporting shall be confirmed in writing and submitted to the Office

of Epidemiology, by either a paper report or entry into a shared secure electronic disease surveillance system, within three days. Furthermore, the local health director shall immediately forward to the appropriate local health director any disease reports on individuals residing in the latter's jurisdiction or to the Office of Epidemiology on individuals residing outside Virginia. The Office of Epidemiology shall be responsible for notifying other state health departments of reported illnesses in their residents and for notifying CDC as necessary and appropriate.

F. Persons in charge of hospitals, nursing facilities or nursing homes, assisted living facilities, and correctional facilities. In accordance with § 32.1-37.1 of the Code of Virginia, any person in charge of a hospital, nursing facility or nursing home, assisted living facility, or correctional facility shall, at the time of transferring custody of any dead body to any person practicing funeral services, notify the person practicing funeral services or his agent if the dead person was known to have had, immediately prior to death, an infectious disease which may be transmitted through exposure to any bodily fluids. These include any of the following infectious diseases:

<u>Coronavirus, severe</u>

Creutzfeldt-Jakob disease

Human immunodeficiency virus infection

Hepatitis B

Hepatitis C

Rabies

Smallpox

Syphilis, infectious

Tuberculosis, active disease

Vaccinia, disease or adverse event

Viral hemorrhagic fever

G. Employees, conditional employees, and persons in charge of food establishments. 12VAC5-421-80 of the Food Regulations requires a food employee or conditional employee to notify the person in charge of the food establishment when diagnosed with certain diseases that are transmissible through food and requires the person in charge of the food establishment to notify the regulatory authority. Refer to 12VAC5-421-80 for further guidance and clarification regarding these reporting requirements.

COMMONWEALTH of VIRGINIA

Department of Health

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July 27, 2021

DECISION MEMORANDUM

TO: Virginia State Board of Health

THROUGH: M. Norman Oliver, MD, MA
State Health Commissioner

Robert Hicks
Deputy Commissioner, Public Health and Preparedness

FROM: William T. Gormley, MD
Chief Medical Examiner

SUBJECT: Cremation Fee

PURPOSE

To recommend approval to increase the cremation fee assessed by the Office of the Chief Medical Examiner (OCME) from $50.00 to $100.00.

BACKGROUND

Section 32.1-309.3 of the Code of Virginia mandates that no decedent whose death occurred in Virginia can be cremated or buried at sea unless a medical examiner has determined that there is no further need for medicolegal inquiry into the death. The medical examiner must certify that no further investigation is needed by completing the cremation certificate and the medical examiner shall be entitled to a fee. This fee, which has been $50 since 1974, is established by the State Board of Health and cannot exceed the $150 fee that medical examiners receive for each death investigation they handle. The cremation fee is paid by the funeral home to the medical examiner and the OCME assumes that the decedent's next-of-kin reimburses the funeral home.

The cremation fee has always been viewed as a way to compensate medical examiners appointed in accordance with § 32.1-282 of the Code of Virginia, who are private physicians, physician assistants, or nurse practitioners, for taking the time from their private practices to complete the necessary examination and documents. Additionally, it allows for these examinations to be completed in a timely manner within the community; thus, the decedents do not have to be brought to an OCME district office to have the cremation examination performed which could cause a significant delay in the cremation view being performed and additional costs (e.g., travel to and from OCME) for the funeral home and/or grieving family. Furthermore, current OCME

staffing levels could not handle the additional workload, especially as the number of cremations continue to increase in Virginia:

Year	Number of Deaths	Number of Cremations	% of Deaths Cremated
2016	65,578	27,911	43%
2017	67,786	28,903	43%
2018	68,473	29,892	44%
2019	69,455	31,364	45%
2020	79,513	37,579	47%

Source: Virginia Department of Health, Office of Vital Records

The National Funeral Directors Association (NFDA) reported that 2015 was the first year that the national cremation rate surpassed the burial rate. The NFDA projects that in 2025 the national cremation rate will be 63.3% and in 2030 the rate will be 69.5%. They attribute this increase in cremations to its lower cost, religions that previously frowned upon cremation are now accepting of it, and the COVID-19 pandemic. According to the NFDA, more than half of funeral directors experienced an increase in cremation rate during the pandemic; therefore, solidifying cremation as the popular choice for final disposition.

Before a decedent is cremated, the medical examiner must perform an examination of the body. This examination requires the medical examiner to undress the decedent and examine the body for markings, trauma, injuries, and medical therapies. The medical examiner must also review the death certificate to ensure that the cause of death is appropriate and that the death should not have been investigated by the OCME. In some cases, the medical examiner will have to conduct follow-up with the physician who signed the death certificate and/or review the decedent's medical records if the cause of death listed on the death certificate is inappropriate and/or their findings do not match what is listed on the death certificate. These required tasks can be cumbersome and time consuming, especially considering that the local medical examiners have full-time jobs and are performing these tasks after work and in their free time.

Many medical examiners have expressed dissatisfaction with the $50 fee. They express that the fee is not reflective of the work involved. They feel that they are often asked to leave their full-time employment to perform a cremation examination due to the lack of planning of the funeral home and/or the grieving family changed their minds about final disposition. Additionally, it is more lucrative for them to remain at their office seeing their patients. When a local medical examiner is unavailable to perform a cremation examination, then the funeral home must make arrangements to bring it to OCME district office for an Assistant Chief Medical Examiner (ACME) to examine. Due to the performance of autopsies and other duties (e.g., testifying in court), these visits have to be scheduled to ensure there is an ACME available. As the OCME continues to see an increase in its caseload, it is becoming more difficult for the ACMEs to perform these cremation exams in a timely manner. If an ACME is unavailable, then OCME staff will assist the funeral home with reaching out to a nearby medical examiner; however, in these situations many of the medical examiners are reluctant to travel to the funeral home to perform the examination, especially as we continue to see an increase in the price of gasoline.

JUSTIFICATION

This fee increase will assist with the retention and recruitment of medical examiners and provide a fee that is commensurate for the work performed. This fee increase will also ensure that

families do not encounter a significant delay with the final arrangements for their loved ones, especially as cremations are projected to be the most popular choice of families for final disposition.

Increasing the cremation fee will aid the OCME with the recruitment and retention of medical examiners. Recruiting and retaining medical examiners has become difficult over the years as fewer physicians value community service and are becoming increasingly burdened with maintaining their private practices. Currently, there are 143 local medical examiners compared to 320 in 2015. The number of medical examiners continues to decrease, even after amending the Code of Virginia in 2015 to allow nurse practitioners and physician assistants to become local medical examiners. A fee increase to help reimburse physicians for their community service will help recruit and retain medical examiners and ensure medical examiners services are available to Virginia communities. Also, the increased fee would be more enticing for neighboring medical examiners to perform these examinations in surrounding localities; therefore, lessening the workload on the already understaffed OCME offices.

Pursuant to § 32.1-283 of the Code of Virginia, the OCME is responsible for the scientific medicolegal death investigations of all violent, suspicious, unnatural, and unusual deaths in Virginia. The requirement for medical examiners to conduct cremation examinations before a decedent is cremated is a mechanism to ensure that OCME is investigating those deaths as defined by law. It is not uncommon for a medical examiner, while performing a cremation examination, to discover a death that should have been investigated by the OCME. Some of the common discoveries include, but are not limited to, decedents who have hip fractures, falling, or may have been a victim of a previous violent act several years prior to death; however, the violent act contributed to the death. The discovery of these cases ensures that families know the correct reason for a loved one's death and that justice can be served if the death is due to violence.

An increased fee in the amount of $100 would be more reflective of the work required for completing a cremation examination. In most medical examiner systems, the medical examiner is only required to review the death certificate and/or medical records before authorizing the cremation. The fee for these reviews range from $50 - $200. For example, in Washington, D.C. the fee is $75 and in Utah the fee is $200. Both jurisdictions have an electronic cremation authorization process and their medical examiners are not required to perform a physical examination of the decedent. However, the Milwaukee, WI medical examiner has a similar process to Virginia's in which the medical examiner reviews the death certificate, travels to a funeral home to perform an examination of the body, and conducts all needed follow-up (e.g., review medical records). The Milwaukee medical examiner fee for this service is $357. Although we cannot implement a fee similar to Milwaukee because of Virginia law, it is important to increase the fee to $100 in an effort to have a fee reflective of the amount of work required. An increase of this fee will also demonstrate to medical examiners that we recognize and value their personal sacrifice to ensure these services remain available in their communities.

RECOMMENDATION
The State Board of Health should approve an increase in the cremation fee from $50 to $100.

APPROVAL

☐ Recommend ☐ Recommend with Modification ☐ Deny

M. Norman Oliver MD 8/17/21

M. Norman Oliver, MD, MA Date

REFERENCES

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