

**State of Board of Health
Agenda
September 22, 2022 – 9:00 a.m.
Perimeter Center, Boardroom 2**

Call to Order and Welcome	Gary Critzer, Chair
Introductions	Mr. Critzer
Review of Agenda	Alexandra Jansson, MPP
Approval of June 23, 2022 Minutes	Mr. Critzer
Commissioner’s Report	Colin Greene, MD, MPH State Health Commissioner
Regulatory Action Update	Michael Capps, MPH Legislative and Regulatory Coordinator
Break	
Public Comment Period	
<u>Regulatory Action Items</u>	
Regulations for the Immunization of School Children 12VAC5-110 (Final Exempt Amendments)	Lilian Peake State Epidemiologist Office of Epidemiology
Sexual Assault Survivor Treatment and Transfer 12VAC5-416 (Proposed Regulations)	Rebekah Allen, JD Senior Policy Analyst Office of Licensure and Certification
Prescription Drug Price Transparency 12VAC5-219 (Proposed Regulations)	Ms. Allen
Break	
Private Well Regulations 12VAC5-630 (Final Amendments)	Julie Henderson Director Office of Environmental Health Services
Regulations for the Licensure of Home Care Organizations 12VAC5-381 (Fast Track Amendments)	Ms. Allen
Regulations for Disease Reporting and Control 12VAC5-90 (Final Amendments)	Dr. Peake

2023 Meeting Dates

Mr. Critzer

Other Business

Adjourn

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State Board of Health: Nominating Committee
June 23, 2022 - 8:30am
Perimeter Center, Boardroom 2

Members Present: Jim Edmondson; Maribel Ramos.
VDH Staff Present: Alexandra Jansson, Senior Policy Analyst.

Call to Order

Ms. Ramos called the meeting to order at 8:31am.

Public Comment

There was no one signed up for the public comment period.

Nomination of Officers

Mr. Edmondson made a motion to nominate Gary Critzer as Chair, Dr. Wendy Klein as Vice Chair, and Dr. Anna Jeng and Dr. Jim Shuler as the two members of the Executive Committee. Ms. Ramos seconded the motion. The motion was carried by a unanimous roll call vote.

Other Business

There was no other business before the committee.

Adjourn

The meeting was adjourned at 8:36am.

State Board of Health
June 23, 2022 - 9:00am
Perimeter Center, Boardroom 2

Members Present: Gary Critzer;; Jim Edmondson; Melissa Green; Linda Hines; Anna Jeng; Patricia Kinser, MD; Wendy Klein, MD, Vice Chair; Benita Miller, DDS; Faye Prichard, Chair; Holly Puritz, MD; Maribel Ramos; and Mary Margaret Whipple.

Members Absent: Stacey Swartz, PharmD; Elizabeth Harrison; Jim Shuler, DVM.

VDH Staff Present: Kathryn Crosby, Chief Diversity, Equity, and Inclusion Officer; Tiffany Ford, Deputy Commissioner for Administration; Dr. Colin Greene, State Health Commissioner; Joe Hilbert, Deputy Commissioner for Governmental and Regulatory Affairs; Parham Jaber, Deputy Commissioner for Community Health Services; Alexandra Jansson, Senior Policy Analyst; Maria Reppas, Director, Office of Communications; Whitney Rickman, Administrative Assistant for Governmental and Regulatory Affairs, Diversity, Equity and Inclusion, and Community Health Services; and Tammie Smith, Public Relations Coordinator.

Other Staff Present: Robin Kurz, JD, Senior Assistant Attorney General; Allyson Tysinger, JD, Senior Assistant Attorney General/Section Chief

Call to Order

Ms. Prichard called the meeting to order at 9:01am.

Introductions

Ms. Prichard welcomed those in attendance to the meeting. Ms. Prichard then started the introductions of the Board members and VDH staff present.

Review of Agenda

Ms. Jansson reviewed the agenda and the items contained in the Board's binder. Ms. Prichard suggested an amendment to the agenda by adding a Q&A section with Dr. Greene regarding a recent Washington Post article. Dr. Kinser made the motion to approve the amendment to the agenda with Dr. Puritz seconding the motion. The motion passed unanimously.

Approval of March 31, 2022 Minutes

Mr. Critzer made the motion to approve the minutes from the March 31, 2022 meeting with Dr. Puritz seconding the motion. The minutes were approved unanimously by voice vote.

Q&A Section with Dr. Greene

Dr. Kinser, Dr. Klein, Mr. Edmondson, Dr. Puritz, Ms. Ramos, Ms. Prichard, Ms. Hines, and Dr. Miller each posed questions to Dr. Greene regarding a recent article in the Washington Post.

Topics discussed included:

- Structural racism and health disparities;
- Board of Health as an apolitical entity;
- Removal of certain links from VDH website;
- Gun violence, including suicide, homicide, accidents, and active shooter incidents
- Regional and urban/rural health disparities;
- Extent to which Dr. Greene believes he was misquoted in the Washington Post article, and any efforts he made to request that corrections be made to the article;
- Dr. Greene's communications with his staff; and
- The importance of choosing the right words when delivering public health messages.

Mr. Edmondson presented, and read aloud to the Board, a resolution pertaining to Dr. Greene. Mr. Edmondson made the motion to approve the recommended resolution with Mr. Critzer seconding the motion. Ms. Tysinger stated the resolution can serve as a guide and recommendation to Dr. Greene but cannot be enforced by the Board. The resolution was approved unanimously by voice vote. The resolution is attached at the end of the minutes.

Commissioner's Report

Dr. Greene provided the Commissioner's Report to the Board. He updated the Board on key issues and projects VDH is engaged in including:

- Agency Stars
- Infant Formula Shortage
- COVID-19 Update
- Monkeypox Update
- Infant and Maternal Mortality
- Suicide and Substance Use Disorder
- ARPA Project: Drinking Water
- Lyme Disease
- Extreme Heat
- Hurricane Season

Non-Regulatory Item: EMS Regional Council Designation

Ron Passmore presented a memo regarding designation of regional emergency medical Mr. Critzer made the motion to approve the amendments with Ms. Hines seconding the motion. The designation of regional councils was approved unanimously by voice vote.

Public Comment Period

There were three persons who signed up for public comment at the meeting. Brent Rawlings recommended approval of the Fast Track Amendments for Hospitals. Doris Knick provided comment on her concerns about the COVID-19 vaccine and safety (see additional written comments at the end of the minutes document). Lindsey Lockwood provided comments regarding a recent Washington Post article pertaining to Dr. Greene. Additional public comment was received via email and is included at the end of the minutes.

Regulatory Action Update

Mr. Hilbert reviewed the summary of all pending VDH regulatory actions.

Since the March 2022 meeting, the Commissioner approved two regulatory actions on behalf of the Board while the Board was not in session. First, the NOIRA for the Regulations for Summer Camps (12VAC5-440) which followed a periodic review and will update the Regulations with modern standards for health and safety at summer camps. Second, the Commissioner approved a NOIRA for the Regulations Governing Virginia Newborn Screening Services (12VAC5-71). This regulatory action follows a periodic review and will update the Regulations to remove outdated information and reflect recommended national best practices.

Since the March 2022 meeting the Commissioner has taken no non-regulatory action on behalf of the Board while the Board was not in session.

Mr. Hilbert advised the Board that there are 20 periodic reviews in progress:

- 12 VAC 5-20 Regulations for the Conduct of Human Research
- 12 VAC 5-66 Regulations Governing Durable Do Not Resuscitate Orders
- 12 VAC 5-191 State plan for the Children with Special Health Care Needs Program
- 12 VAC 5-195 Virginia Women Infants and Children Program Regulations
- 12 VAC 5-200 Regulations Governing Eligibility Standards and Charges for Health Care Services to Individuals
- 12 VAC 5-215 Rules and Regulations Governing Health Data Reporting
- 12 VAC 5-216 Methodology to Measure Efficiency and Productivity of Health Care Institutions
- 12 VAC 5-217 Regulations of the Patient Level Data System
- 12 VAC 5-218 Rules and Regulations Governing Outpatient Data Reporting
- 12 VAC 5-220 Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations
- 12 VAC 5-407 Regulations for the Submission of Health Maintenance Organization Quality of Care Performance Information
- 12 VAC 5-408 Regulation for the Certificate of Quality Assurance of Managed Care Health Insurance Plan (MCHIP) Licensees
- 12 VAC 5-410 Regulations for the Licensure of Hospitals in Virginia
- 12 VAC 5-431 Sanitary Regulations for Hotels
- 12 VAC 5-481 Virginia Radiation Protection Regulations
- 12 VAC 5-490 Virginia Radiation Protection Regulations: Fee Schedule
- 12 VAC 5-501 Rules and Regulations Governing the Construction of Migrant Labor Camps

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- 12 VAC 5-508 Regulations Governing the Virginia Physician Loan Repayment Program
- 12 VAC 5-510 Guidelines for General Assembly Nursing Scholarships
- 12 VAC 5-540 Rules and Regulations for the Identification of Medically Underserved Areas in Virginia

Since the March 2022 meeting, the Executive Branch completed the review of two regulatory actions while the Board was not in session – a NOIRA for the Regulations Governing Virginia Newborn Screening Services (12 VAC 5-71) and a NOIRA for the Regulations for Summer Camps (12VAC 5-440).

Since the March 2022 meeting, there were two Fast Track items withdrawn that were previously approved by the Board – Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations (12 VAC 5-220) and Regulations Governing Vital Records (12 VAC 5-550).

Public Health History in Virginia

Mr. Stover presented information on the Public Health History in Virginia.

Budget Update

Ms. Gilliam presented an update on the status of the budget from the 2022 General Assembly Session. The governor has now signed the biennial budget. The COVID-19 portion of the budget is still very large.

Amendments that the General Assembly made to the Budget Bill introduced by the Governor include:

- Drinking Water
 - Created a phase-in to implementation of the Water Sampling Verification Program
- Epidemiology
 - Level funded comprehensive harm reduction services
- Family Health Services
 - Reduced the amount of new funding for marijuana prevention and education
 - Maintained Temporary Assistance for Needy Families as a funding source for the Virginia Resource Mothers program
- Administration
 - Reduced the amount of funding for an integrated e-referral system
- Pass through payments
 - Increased funding for Pediatric Hospice and Palliative Care

Proposed Rainwater Harvesting Regulations

Julie Henderson presented the proposed Regulations to the Board. The proposed Regulations will promote the use of rainwater as means to reduce fresh water consumption, ease demands on public treatment works and water supply systems, and promote conservation. Mr. Critzer made the motion to approve the proposed regulations with Dr. Puritz seconding the motion. The proposed regulation was approved unanimously by voice vote.

Fast Track Amendments to Food Regulations

Ms. Henderson presented the Fast Track Amendments to the Board. The Fast Track Amendments conform the Food Regulations to the provisions of Chapter 853 of the 2020 General Assembly Session, which authorize any employee of a licensed restaurant to possess and administer epinephrine on the premises of a restaurant at which the employee is employed, provided that such employee is authorized by a prescriber, and is trained in the administration of

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epinephrine. Trained employees who provide, administer, or assist in the administration of epinephrine to someone who, in good faith they believe is having an anaphylactic reaction, shall not be liable for certain civil damage. The proposed regulatory change will also allow for the storage of medications for use by children at a daycare center which contains a permitted food establishment.

Dr. Puritz made the motion to approve the proposed regulations with Dr. Jeng seconding the motion. There was discussion around the scope of the changes to the regulations and how training and administration of medications would be tracked. The Fast Track amendments were approved by voice vote, with Dr. Kinser voting no.

Fast Track Amendments to Regulations for the Licensure of Hospitals in Virginia

The Fast Track amendments were presented by Rebekah Allen. Chapters 712 and 722 of the 2022 Acts of Assembly require the State Board of Health to amend its hospital regulations to exempt from licensure temporary increase in the total number of beds in an existing hospital to include “a temporary increase in the total number of beds resulting from the addition of beds at a temporary structure or satellite location operated by the hospital..., provided that the ability remains to safely staff services across the existing hospital...” These acts also amended the exemption to now also be triggered by an emergency order entered pursuant to Va. Code section 32.1-13 or 32.1-20 for the purpose of suppressing a nuisance dangerous to public health or a communicable, contagious or infectious disease or other danger to the public life and health. The duration of this exemption has been amended to be either “a period of no more than the duration of the Commissioner’s determination plus 30 days...when the Commissioner has determined that a natural or man made disaster has caused the evacuation of a hospital or nursing home and that a public health and that a public health emergency exists due to a shortage of hospital or nursing home beds” or “ a period of no more than the duration of the emergency order entered pursuant to” section 32.1-13 or 32.1-20.

Ms. Whipple made the motion to approve the proposed regulations with Ms. Green seconding the motion. The Fast Track amendments were approved unanimously by voice vote.

Fast Track Amendments to the Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations

The Fast Track amendments were presented by Ms. Allen. Chapters 712 and 722 of the 2022 Acts of Assembly require the State Board of Health to amend its regulation about exemptions for certificates of public need for projects that involve a temporary increase in the total number of beds in an existing hospital or nursing home to include “a temporary increase in the total number of beds resulting from the addition of beds at a temporary structure or satellite location operated by the hospital or nursing home, provided that the ability remains to safely staff services across the existing hospital or nursing home.” These acts also amended the exemption to now also be triggered by an emergency order entered pursuant to Va. Code section 32.1-13 or 32.1-20 for the purpose of suppressing a nuisance dangerous to public health or a communicable, contagious or infectious disease or other danger to the public life and health. The duration of this exemption has been amended to be either “a period of no more than the duration of the Commissioner’s determination plus 30 days...when the Commissioner has determined that a natural or man made disaster has caused the evacuation of a hospital or nursing home and that a public health and that a public health emergency exists due to a shortage of hospital or nursing home beds” or “ a period of no more than the duration of the emergency order entered pursuant to” section 32.1-13 or 32.1-20.

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Dr. Kinser made the motion to approve the proposed regulations with Dr. Miller seconding the motion. The Fast Track amendments were approved unanimously by voice vote.

Fast Track Amendments to Regulations for Nursing Facilities

The Fast Track amendments were presented by Ms. Allen. Chapters 712 and 722 of the 2022 Acts of Assembly require the State Board of Health to amend its nursing home regulation to exempt from licensure a temporary increase in the total number of beds in an existing nursing home to include “a temporary increase in the total number of beds resulting from the addition of beds at a temporary structure or satellite location operated by the... nursing home, provided that the ability remains to safely staff services across the existing... nursing home.” These acts also amended the exemption to now also be triggered by an emergency order entered pursuant to Va. Code section 32.1-13 or 32.1-20 for the purpose of suppressing a nuisance dangerous to public health or a communicable, contagious or infectious disease or other danger to the public life and health. The duration of this exemption has been amended to be either “a period of no more than the duration of the Commissioner’s determination plus 30 days...when the Commissioner has determined that a natural or man made disaster has caused the evacuation of a hospital or nursing home and that a public health and that a public health emergency exists due to a shortage of hospital or nursing home beds” or “ a period of no more than the duration of the emergency order entered pursuant to” section 32.1-13 or 32.1-20.

Dr. Puritz made the motion to approve the proposed regulations with Mr. Critzer seconding the motion. The Fast Track amendments were approved unanimously by voice vote.

Fast Track Amendments to the Public Participation Guidelines

The Fast Track amendments were presented by Mr. Hilbert. The fast track amendments will conform the Guidelines to relevant statues and regulations, as well as changes in style to conform to the Form, Style and Procedure Manual for Publication of Virginia Regulations.

Dr. Jeng made the motion to approve the proposed regulations with Ms. Green seconding the motion. The Fast Track amendments were approved unanimously by voice vote.

Report of the Nominating Committee

Ms. Ramos presented the report of the Nominating Committee. The recommended slate of officers for the year beginning July 1, 2022 is Chair - Gary Critzer, Vice Chair - Dr. Wendy Klein, Executive Committee Member - Dr. Jim Shuler, Executive Committee Member - Dr. Anna Jeng. Ms. Ramos made a motion to approve the nominations with Dr. Miller seconding the motion. The nominations were approved unanimously by voice vote.

Other Business

During other business, Ms. Prichard, Mr. Edmondson, and Dr. Miller noted that the June 2022 meeting was the last meeting of their terms, expressed their thanks for their time on the Board, and their appreciation for VDH staff.

Adjourn

The meeting adjourned at 2:49 pm

A RESOLUTION OF THE VIRGINIA BOARD OF HEALTH
ADOPTED AT ITS MEETING OF JUNE 23, 2022

WHEREAS, it has been the policy of the Board of Health and the Department of Health for many years to recognize that health care access and health outcomes have not been comparable across all demographic groups in the Commonwealth; and

WHEREAS, the truth of these observations has been proved by analysis of data over many years by medical scientists in the Commonwealth and across the country, and in particular by previous Commissioners of the Department and staff; and

WHEREAS, the disparities in health care outcomes between minority and low-income households and individuals and the population at large are particularly great, and greatest between African-Americans and the population at large; and

WHEREAS, the differences have been and continue to be most noticeable in maternal care and outcomes, but also in many other health categories; and

WHEREAS, the Commissioner has recently made public statements contrary to the position on these issues of the Board and its individual members to their and our embarrassment; now be it

RESOLVED BY THE BOARD OF HEALTH

That the Board directs the Commissioner and Department staff to acknowledge these differences as demonstrated by scientific and statistical evidence and to direct resources of the Department to the offices within the Department that focus on improving practices and delivery of care that will reduce these disparities over time. Improvements can and must be made in education of both the health care workforce and members of minority and lower-income groups; location of points of access to services; building of staff for new facilities; recruitment of voices within the communities to use such services confidently; continued gathering of statistics that demonstrate progress or lack of progress in achieving these goals.

FURTHER RESOLVED

That the Commissioner and other spokespeople of the Department will make no public statements contrary to the Board's policy or intentions regarding disparities in care and outcomes, nor make statements that carry a message of denial of basic scientific facts regarding disparities.

FURTHER RESOLVED

That the Commissioner and Department should advocate vigorously within the current and future administrations for additional resources to meet specific goals for the reduction and eventual elimination of the disparities.



State Board of Health, rr <boardofhealth@vdh.virginia.gov>

Public Comment - Commissioner Greene

1 message

Jessica Hunt <jessicah1228@gmail.com>

Wed, Jun 22, 2022 at 9:34 PM

To: boardofhealth@vdh.virginia.gov, faye.prichard@gmail.com, lisaruffinharrison@gmail.com, ramosmvaboh@gmail.com, lillian.peake@vdh.virginia.gov

To the Esteemed Members of the Virginia State Board of Health,

Unfortunately, I cannot be there to express my sentiments in person, but I hope that you will share this letter at your meeting tomorrow.

I implore you to remove Colin Greene from the position of State Health Commissioner. He has proven he is unfit for duty by denying, downplaying, and dismissing racism, gun violence, and scientific data. The mission of the Virginia Department of Health is "to protect the health and promote the well-being of all people in Virginia," yet he has hurt his colleagues without remorse. He does not represent the values of the Department of Health nor does he respect their work. Please remove him from this influential position before he causes further harm to the people of Virginia.

We deserve better.

We demand better.



Jansson, Alexandra <alexandra.jansson@vdh.virginia.gov>

Missing Data: Doris Knick's Public Comments at VDH BOH on June 23rd

1 message

Doris Knick <healersporch@yahoo.com>

Fri, Jun 24, 2022 at 8:34 PM

Reply-To: Doris Knick <healersporch@yahoo.com>

To: Alexandra Jansson <alexandra.jansson@vdh.virginia.gov>, "faye.prichard@gmail.com" <faye.prichard@gmail.com>, "critzergp@ci.waynesboro.va.us" <critzergp@ci.waynesboro.va.us>, "jedmondson@eandgggroup.com" <jedmondson@eandgggroup.com>, "Melissa.Green@NevaSeniorCare.com" <Melissa.Green@nevaseniorcare.com>, "lisaruffinharrison@gmail.com" <lisaruffinharrison@gmail.com>, "lhines@vapremier.com" <lhines@vapremier.com>, "hjeng@odu.edu" <hjeng@odu.edu>, "kinserpa.boh@gmail.com" <kinserpa.boh@gmail.com>, "wklein@healthbrigade.org" <wklein@healthbrigade.org>, "benitamiller58@gmail.com" <benitamiller58@gmail.com>, "h.puritz@tgfw.com" <h.puritz@tgfw.com>, "stacey.swartz@gmail.com" <stacey.swartz@gmail.com>, "mmwhipple@erols.com" <mmwhipple@erols.com>, "ramosmvaboh@gmail.com" <ramosmvaboh@gmail.com>, "Dr. Greene's Assistant" <maryanne.wollman@vdh.virginia.gov>

Ms. Jansson, VDH Board of Health Members, and Dr. Greene,

I spoke yesterday at the board of health meeting but forgot to give copies of what I spoke in regard to. I am emailing this to the board members listed on the website but if I missed anyone could you please forward to them?

Would you please add these documents attached to the public record?

One last comment for all members is that **these meetings should be recorded and posted** so the public whom you advocate for can be aware.

It would also be appreciated if there was a **virtual option to speak for those of us with children out of school for the summer**. There are many more parents with similar concerns to mine.

Since Mr. Edmondson alerted me to the fact that this has not been spoken about before it has assured me that only one narrative has primarily been shared with this board of health. I'm confident that he does not know anyone who is fully unvaccinated to be able to ask about their experiences.

As most physicians have only a half day of training on vaccines, none of which includes adverse events, it's not surprising that many physicians aren't aware of the dangers. Feel free to correct me if I am wrong.

The science is settled, and the evidence points to vaccine injury from this Covid "Vaccine" showing more deaths in the past 2 years than in all 30 years from VAERS combined, that cannot and should not be allowed to continue to be denied!

There has been far too much censorship surrounding this topic. I pray debates and open conversations continue to be welcomed and not discouraged by demeaning, gaslighting comments to the public from board members.

Sincerely,

Doris Knick
healersporch@yahoo.com

[VDH BOH 6/23/2022](#)



VDH BOH 6/23/2022

Board Members and fellow citizens. I know you can't answer questions during this time but I'd like to make this...

Your Advocate for Wellness,
"May your path to healing be natural, safe, pure and JOYfilled."

2 attachments



Pfizer Adverse Events Reported 5.3.6.pdf
984K



Pfizer NonClinical Overview 125742_S1_M2_24_.pdf
1650K

**5.3.6 CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENT
REPORTS OF PF-07302048 (BNT162B2) RECEIVED THROUGH 28-FEB-2021**

Report Prepared by:

Worldwide Safety

Pfizer

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APPENDICES

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LIST OF ABBREVIATIONS

Acronym	Term
AE	adverse event
AESI	adverse event of special interest
BC	Brighton Collaboration
CDC	Centers for Disease Control and Prevention
COVID-19	coronavirus disease 2019
DLP	data lock point
EUA	emergency use authorisation
HLGT	(MedDRA) High Group Level Term
HLT	(MedDRA) High Level Term
MAH	marketing authorisation holder
MedDRA	medical dictionary for regulatory activities
MHRA	Medicines and Healthcare products Regulatory Agency
PCR	Polymerase Chain Reaction
PT	(MedDRA) Preferred Term
PVP	pharmacovigilance plan
RT-PCR	Reverse Transcription-Polymerase Chain Reaction
RSI	reference safety information
TME	targeted medically event
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
SMQ	standardised MedDRA query
SOC	(MedDRA) System Organ Class
UK	United Kingdom
US	United States
VAED	vaccine-associated enhanced disease
VAERD	vaccine-associated enhanced respiratory disease
VAERS	vaccine adverse event reporting system

1. INTRODUCTION

Reference is made to the Request for Comments and Advice submitted 04 February 2021 regarding Pfizer/BioNTech's proposal for the clinical and post-authorization safety data package for the Biologics License Application (BLA) for our investigational COVID-19 Vaccine (BNT162b2). Further reference is made to the Agency's 09 March 2021 response to this request, and specifically, the following request from the Agency.

“Monthly safety reports primarily focus on events that occurred during the reporting interval and include information not relevant to a BLA submission such as line lists of adverse events by country. We are most interested in a cumulative analysis of post-authorization safety data to support your future BLA submission. Please submit an integrated analysis of your cumulative post-authorization safety data, including U.S. and foreign post-authorization experience, in your upcoming BLA submission. Please include a cumulative analysis of the Important Identified Risks, Important Potential Risks, and areas of Important Missing Information identified in your Pharmacovigilance Plan, as well as adverse events of special interest and vaccine administration errors (whether or not associated with an adverse event). Please also include distribution data and an analysis of the most common adverse events. In addition, please submit your updated Pharmacovigilance Plan with your BLA submission.”

This document provides an integrated analysis of the cumulative post-authorization safety data, including U.S. and foreign post-authorization adverse event reports received through 28 February 2021.

2. METHODOLOGY

Pfizer is responsible for the management post-authorization safety data on behalf of the MAH BioNTech according to the Pharmacovigilance Agreement in place. Data from BioNTech are included in the report when applicable.

Pfizer's safety database contains cases of AEs reported spontaneously to Pfizer, cases reported by the health authorities, cases published in the medical literature, cases from Pfizer-sponsored marketing programs, non-interventional studies, and cases of serious AEs reported from clinical studies regardless of causality assessment.

The limitations of post-marketing adverse drug event reporting should be considered when interpreting these data:

- Reports are submitted voluntarily, and the magnitude of underreporting is unknown. Some of the factors that may influence whether an event is reported include: length of time since marketing, market share of the drug, publicity about a drug or an AE, seriousness of the reaction, regulatory actions, awareness by health professionals and consumers of adverse drug event reporting, and litigation.
- Because many external factors influence whether or not an AE is reported, the spontaneous reporting system yields reporting proportions not incidence rates. As a result, it is generally not appropriate to make between-drug comparisons using these

proportions; the spontaneous reporting system should be used for signal detection rather than hypothesis testing.

- In some reports, clinical information (such as medical history, validation of diagnosis, time from drug use to onset of illness, dose, and use of concomitant drugs) is missing or incomplete, and follow-up information may not be available.
- An accumulation of adverse event reports (AERs) does not necessarily indicate that a particular AE was caused by the drug; rather, the event may be due to an underlying disease or some other factor(s) such as past medical history or concomitant medication.
- Among adverse event reports received into the Pfizer safety database during the cumulative period, only those having a complete workflow cycle in the safety database (meaning they progressed to Distribution or Closed workflow status) are included in the monthly SMSR. This approach prevents the inclusion of cases that are not fully processed hence not accurately reflecting final information. Due to the large numbers of spontaneous adverse event reports received for the product, the MAH has prioritised the processing of serious cases, in order to meet expedited regulatory reporting timelines and ensure these reports are available for signal detection and evaluation activity. The increased volume of reports has not impacted case processing for serious reports, and compliance metrics continue to be monitored weekly with prompt action taken as needed to maintain compliance with expedited reporting obligations. Non-serious cases are entered into the safety database no later than 4 calendar days from receipt. Entrance into the database includes the coding of all adverse events; this allow for a manual review of events being received but may not include immediate case processing to completion. Non-serious cases are processed as soon as possible and no later than 90 days from receipt. Pfizer has also taken a multiple actions to help alleviate the large increase of adverse event reports. This includes significant technology enhancements, and process and workflow solutions, as well as increasing the number of data entry and case processing colleagues. To date, Pfizer has onboarded approximately (b) (4) additional full-time employees (FTEs). More are joining each month with an expected total of more than (b) (4) additional resources by the end of June 2021.

3. RESULTS

3.1. Safety Database

3.1.1. General Overview

It is estimated that approximately (b) (4) doses of BNT162b2 were shipped worldwide from the receipt of the first temporary authorisation for emergency supply on 01 December 2020 through 28 February 2021.

Cumulatively, through 28 February 2021, there was a total of 42,086 case reports (25,379 medically confirmed and 16,707 non-medically confirmed) containing 158,893 events. Most cases (34,762) were received from United States (13,739), United Kingdom (13,404) Italy (2,578), Germany (1913), France (1506), Portugal (866) and Spain (756); the remaining 7,324 were distributed among 56 other countries.

Table 1 below presents the main characteristics of the overall cases.

Table 1. General Overview: Selected Characteristics of All Cases Received During the Reporting Interval

	Characteristics	Relevant cases (N=42086)
Gender:	Female	29914
	Male	9182
	No Data	2990
Age range (years): 0.01 -107 years Mean = 50.9 years n = 34952	≤ 17	175 ^a
	18-30	4953
	31-50	13886
	51-64	7884
	65-74	3098
	≥ 75	5214
	Unknown	6876
Case outcome:	Recovered/Recovering	19582
	Recovered with sequelae	520
	Not recovered at the time of report	11361
	Fatal	1223
	Unknown	9400

a. in 46 cases reported age was <16-year-old and in 34 cases <12-year-old.

As shown in [Figure 1](#), the System Organ Classes (SOCs) that contained the greatest number ($\geq 2\%$) of events, in the overall dataset, were General disorders and administration site conditions (51,335 AEs), Nervous system disorders (25,957), Musculoskeletal and connective tissue disorders (17,283), Gastrointestinal disorders (14,096), Skin and subcutaneous tissue disorders (8,476), Respiratory, thoracic and mediastinal disorders (8,848), Infections and infestations (4,610), Injury, poisoning and procedural complications (5,590), and Investigations (3,693).

Figure 1. Total Number of BNT162b2 AEs by System Organ Classes and Event Seriousness

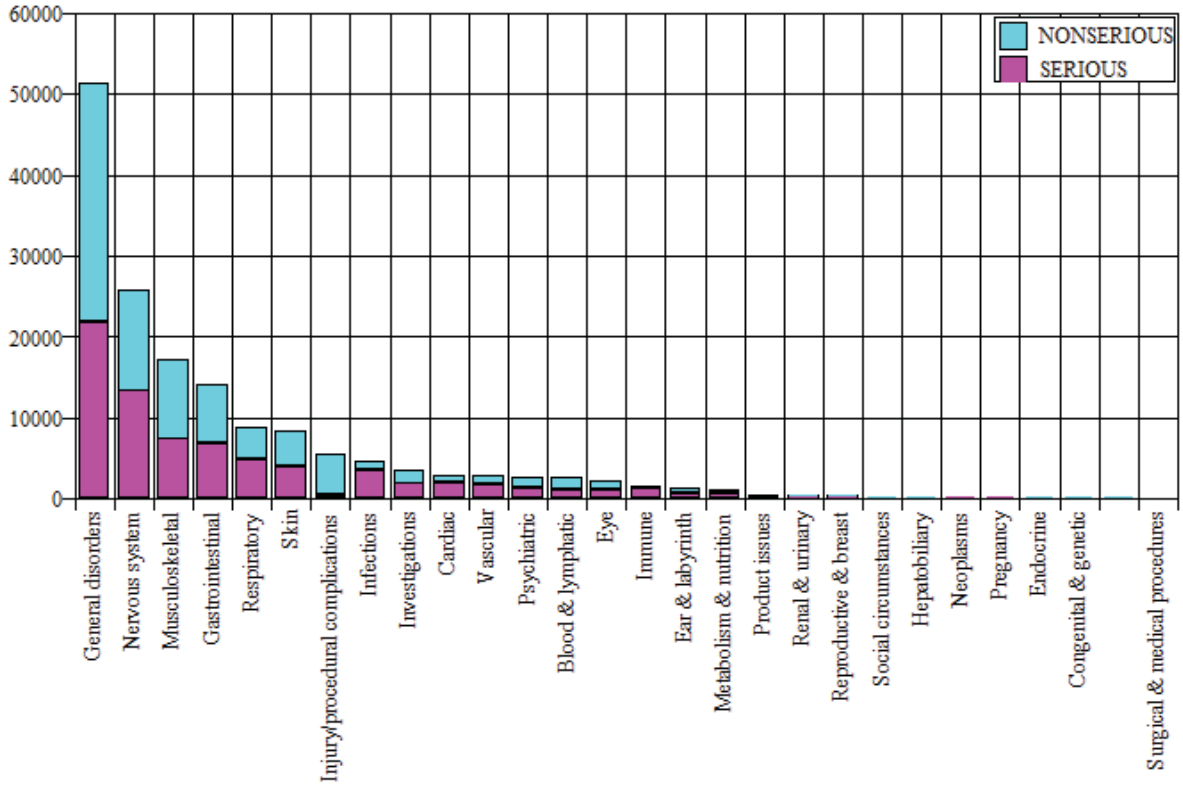


Table 2 shows the most commonly ($\geq 2\%$) reported MedDRA (v. 23.1) PTs in the overall dataset (through 28 February 2021),

Table 2. Events Reported in $\geq 2\%$ Cases

MedDRA SOC	MedDRA PT	Cumulatively Through 28 February 2021 AEs (AERP%) N = 42086
Blood and lymphatic system disorders		
	Lymphadenopathy	1972 (4.7%)
Cardiac disorders		
	Tachycardia	1098 (2.6%)
Gastrointestinal disorders		
	Nausea	5182 (12.3%)
	Diarrhoea	1880 (4.5%)
	Vomiting	1698 (4.0%)
General disorders and administration site conditions		
	Pyrexia	7666 (18.2%)
	Fatigue	7338 (17.4%)
	Chills	5514 (13.1%)
	Vaccination site pain	5181 (12.3%)

Table 2. Events Reported in $\geq 2\%$ Cases

		Cumulatively Through 28 February 2021
MedDRA SOC	MedDRA PT	AEs (AERP%) N = 42086
	Pain	3691 (8.8%)
	Malaise	2897 (6.9%)
	Asthenia	2285 (5.4%)
	Drug ineffective	2201 (5.2%)
	Vaccination site erythema	930 (2.2%)
	Vaccination site swelling	913 (2.2%)
	Influenza like illness	835 (2%)
Infections and infestations		
	COVID-19	1927 (4.6%)
Injury, poisoning and procedural complications		
	Off label use	880 (2.1%)
	Product use issue	828 (2.0%)
Musculoskeletal and connective tissue disorders		
	Myalgia	4915 (11.7%)
	Pain in extremity	3959 (9.4%)
	Arthralgia	3525 (8.4%)
Nervous system disorders		
	Headache	10131 (24.1%)
	Dizziness	3720 (8.8%)
	Paraesthesia	1500 (3.6%)
	Hypoaesthesia	999 (2.4%)
Respiratory, thoracic and mediastinal disorders		
	Dyspnoea	2057 (4.9%)
	Cough	1146 (2.7%)
	Oropharyngeal pain	948 (2.3%)
Skin and subcutaneous tissue disorders		
	Pruritus	1447 (3.4%)
	Rash	1404 (3.3%)
	Erythema	1044 (2.5%)
	Hyperhidrosis	900 (2.1%)
	Urticaria	862 (2.1%)
Total number of events		93473

3.1.2. Summary of Safety Concerns in the US Pharmacovigilance Plan**Table 3. Safety concerns**

Important identified risks	Anaphylaxis
Important potential risks	Vaccine-Associated Enhanced Disease (VAED), Including Vaccine-associated Enhanced Respiratory Disease (VAERD)
Missing information	Use in Pregnancy and lactation Use in Paediatric Individuals <12 Years of Age Vaccine Effectiveness

Table 4. Important Identified Risk

Topic	Description														
Important Identified Risk	Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)														
Anaphylaxis	<p>Since the first temporary authorization for emergency supply under Regulation 174 in the UK (01 December 2020) and through 28 February 2021, 1833 potentially relevant cases were retrieved from the Anaphylactic reaction SMQ (Narrow and Broad) search strategy, applying the MedDRA algorithm. These cases were individually reviewed and assessed according to Brighton Collaboration (BC) definition and level of diagnostic certainty as shown in the Table below:</p> <table border="1" data-bbox="423 569 1276 768"> <thead> <tr> <th>Brighton Collaboration Level</th> <th>Number of cases</th> </tr> </thead> <tbody> <tr> <td>BC 1</td> <td>290</td> </tr> <tr> <td>BC 2</td> <td>311</td> </tr> <tr> <td>BC 3</td> <td>10</td> </tr> <tr> <td>BC 4</td> <td>391</td> </tr> <tr> <td>BC 5</td> <td>831</td> </tr> <tr> <td><i>Total</i></td> <td>1833</td> </tr> </tbody> </table> <p>Level 1 indicates a case with the highest level of diagnostic certainty of anaphylaxis, whereas the diagnostic certainty is lowest for Level 3. Level 4 is defined as “reported event of anaphylaxis with insufficient evidence to meet the case definition” and Level 5 as not a case of anaphylaxis.</p> <p>There were 1002 cases (54.0% of the potentially relevant cases retrieved), 2958 potentially relevant events, from the Anaphylactic reaction SMQ (Broad and Narrow) search strategy, meeting BC Level 1 to 4:</p> <p>Country of incidence: UK (261), US (184), Mexico (99), Italy (82), Germany (67), Spain (38), France (36), Portugal (22), Denmark (20), Finland, Greece (19 each), Sweden (17), Czech Republic , Netherlands (16 each), Belgium, Ireland (13 each), Poland (12), Austria (11); the remaining 57 cases originated from 15 different countries.</p> <p>Relevant event seriousness: Serious (2341), Non-Serious (617);</p> <p>Gender: Females (876), Males (106), Unknown (20);</p> <p>Age (n=961) ranged from 16 to 98 years (mean = 54.8 years, median = 42.5 years);</p> <p>Relevant even outcome^a: fatal (9)^b, resolved/resolving (1922), not resolved (229), resolved with sequelae (48), unknown (754);</p> <p>Most frequently reported relevant PTs (≥2%), from the Anaphylactic reaction SMQ (Broad and Narrow) search strategy: Anaphylactic reaction (435), Dyspnoea (356), Rash (190), Pruritus (175), Erythema (159), Urticaria (133), Cough (115), Respiratory distress, Throat tightness (97 each), Swollen tongue (93), Anaphylactic shock (80), Hypotension (72), Chest discomfort (71), Swelling face (70), Pharyngeal swelling (68), and Lip swelling (64).</p> <p>Conclusion: Evaluation of BC cases Level 1 - 4 did not reveal any significant new safety information. Anaphylaxis is appropriately described in the product labeling as are non-anaphylactic hypersensitivity events. Surveillance will continue.</p>	Brighton Collaboration Level	Number of cases	BC 1	290	BC 2	311	BC 3	10	BC 4	391	BC 5	831	<i>Total</i>	1833
Brighton Collaboration Level	Number of cases														
BC 1	290														
BC 2	311														
BC 3	10														
BC 4	391														
BC 5	831														
<i>Total</i>	1833														

a Different clinical outcome may be reported for an event that occurred more than once to the same individual.

b There were 4 individuals in the anaphylaxis evaluation who died on the same day they were vaccinated. Although these patients experienced adverse events (9) that are potential symptoms of anaphylaxis, they all had serious underlying medical conditions, and one individual appeared to also have COVID-19 pneumonia, that likely contributed to their deaths

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Table 5. Important Potential Risk

Topic	Description
Important Potential Risk	Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)
Vaccine-Associated Enhanced Disease (VAED), including Vaccine-Associated Enhanced Respiratory Disease (VAERD)	<p>No post-authorized AE reports have been identified as cases of VAED/VAERD, therefore, there is no observed data at this time. An expected rate of VAED is difficult to establish so a meaningful observed/expected analysis cannot be conducted at this point based on available data. The feasibility of conducting such an analysis will be re-evaluated on an ongoing basis as data on the virus grows and the vaccine safety data continues to accrue.</p> <p>The search criteria utilised to identify potential cases of VAED for this report includes PTs indicating a lack of effect of the vaccine and PTs potentially indicative of severe or atypical COVID-19^a.</p> <p>Since the first temporary authorization for emergency supply under Regulation 174 in the UK (01 December 2020) and through 28 February 2021, 138 cases [0.33% of the total PM dataset], reporting 317 potentially relevant events were retrieved:</p> <p>Country of incidence: UK (71), US (25), Germany (14), France, Italy, Mexico, Spain, (4 each), Denmark (3); the remaining 9 cases originated from 9 different countries; Cases Seriousness: 138; Seriousness criteria for the total 138 cases: Medically significant (71, of which 8 also serious for disability), Hospitalization required (non-fatal/non-life threatening) (16, of which 1 also serious for disability), Life threatening (13, of which 7 were also serious for hospitalization), Death (38). Gender: Females (73), Males (57), Unknown (8); Age (n=132) ranged from 21 to 100 years (mean = 57.2 years, median = 59.5); Case outcome: fatal (38), resolved/resolving (26), not resolved (65), resolved with sequelae (1), unknown (8); Of the 317 relevant events, the most frequently reported PTs (≥2%) were: Drug ineffective (135), Dyspnoea (53), Diarrhoea (30), COVID-19 pneumonia (23), Vomiting (20), Respiratory failure (8), and Seizure (7).</p> <p>Conclusion: VAED may present as severe or unusual clinical manifestations of COVID-19. Overall, there were 37 subjects with suspected COVID-19 and 101 subjects with confirmed COVID-19 following one or both doses of the vaccine; 75 of the 101 cases were severe, resulting in hospitalisation, disability, life-threatening consequences or death. None of the 75 cases could be definitively considered as VAED/VAERD.</p> <p>In this review of subjects with COVID-19 following vaccination, based on the current evidence, VAED/VAERD remains a theoretical risk for the vaccine. Surveillance will continue.</p>

a. Search criteria: Standard Decreased Therapeutic Response Search AND PTs Dyspnoea; Tachypnoea; Hypoxia; COVID 19 pneumonia; Respiratory Failure; Acute Respiratory Distress Syndrome; Cardiac Failure; Cardiogenic shock; Acute myocardial infarction; Arrhythmia; Myocarditis; Vomiting; Diarrhoea; Abdominal pain; Jaundice; Acute hepatic failure; Deep vein thrombosis; Pulmonary embolism; Peripheral Ischaemia; Vasculitis; Shock; Acute kidney injury; Renal failure; Altered state of consciousness; Seizure; Encephalopathy; Meningitis; Cerebrovascular accident; Thrombocytopenia; Disseminated intravascular coagulation; Chillblains; Erythema multiforme; Multiple organ dysfunction syndrome; Multisystem inflammatory syndrome in children.

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Table 6. Description of Missing Information

Topic	Description
Missing Information	Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)
Use in Pregnancy and lactation	<ul style="list-style-type: none"> • Number of cases: 413^a (0.98% of the total PM dataset); 84 serious and 329 non-serious; • Country of incidence: US (205), UK (64), Canada (31), Germany (30), Poland (13), Israel (11); Italy (9), Portugal (8), Mexico (6), Estonia, Hungary and Ireland, (5 each), Romania (4), Spain (3), Czech Republic and France (2 each), the remaining 10 cases were distributed among 10 other countries. <p>Pregnancy cases: 274 cases including:</p> <ul style="list-style-type: none"> • 270 mother cases and 4 foetus/baby cases representing 270 unique pregnancies (the 4 foetus/baby cases were linked to 3 mother cases; 1 mother case involved twins). • Pregnancy outcomes for the 270 pregnancies were reported as spontaneous abortion (23), outcome pending (5), premature birth with neonatal death, spontaneous abortion with intrauterine death (2 each), spontaneous abortion with neonatal death, and normal outcome (1 each). No outcome was provided for 238 pregnancies (note that 2 different outcomes were reported for each twin, and both were counted). • 146 non-serious mother cases reported exposure to vaccine in utero without the occurrence of any clinical adverse event. The exposure PTs coded to the PTs Maternal exposure during pregnancy (111), Exposure during pregnancy (29) and Maternal exposure timing unspecified (6). Trimester of exposure was reported in 21 of these cases: 1st trimester (15 cases), 2nd trimester (7), and 3rd trimester (2). • 124 mother cases, 49 non-serious and 75 serious, reported clinical events, which occurred in the vaccinated mothers. Pregnancy related events reported in these cases coded to the PTs Abortion spontaneous (25), Uterine contraction during pregnancy, Premature rupture of membranes, Abortion, Abortion missed, and Foetal death (1 each). Other clinical events which occurred in more than 5 cases coded to the PTs Headache (33), Vaccination site pain (24), Pain in extremity and Fatigue (22 each), Myalgia and Pyrexia (16 each), Chills (13) Nausea (12), Pain (11), Arthralgia (9), Lymphadenopathy and Drug ineffective (7 each), Chest pain, Dizziness and Asthenia (6 each), Malaise and COVID-19 (5 each). Trimester of exposure was reported in 22 of these cases: 1st trimester (19 cases), 2nd trimester (1 case), 3rd trimester (2 cases). • 4 serious foetus/baby cases reported the PTs Exposure during pregnancy, Foetal growth restriction, Maternal exposure during pregnancy, Premature baby (2 each), and Death neonatal (1). Trimester of exposure was reported for 2 cases (twins) as occurring during the 1st trimester. <p>Breast feeding baby cases: 133, of which:</p> <ul style="list-style-type: none"> • 116 cases reported exposure to vaccine during breastfeeding (PT Exposure via breast milk) without the occurrence of any clinical adverse events; • 17 cases, 3 serious and 14 non-serious, reported the following clinical events that occurred in the infant/child exposed to vaccine via breastfeeding: Pyrexia (5), Rash (4), Infant irritability (3), Infantile vomiting, Diarrhoea, Insomnia, and Illness (2 each), Poor feeding infant, Lethargy, Abdominal discomfort, Vomiting, Allergy to vaccine, Increased appetite, Anxiety, Crying, Poor quality sleep, Eructation, Agitation, Pain and Urticaria (1 each). <p>Breast feeding mother cases (6):</p> <ul style="list-style-type: none"> • 1 serious case reported 3 clinical events that occurred in a mother during breast feeding (PT Maternal exposure during breast feeding); these events coded to the PTs Chills, Malaise, and Pyrexia • 1 non-serious case reported with very limited information and without associated AEs.

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Table 6. Description of Missing Information

Topic	Description
Missing Information	<p align="center">Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)</p>
	<ul style="list-style-type: none"> In 4 cases (3 non-serious; 1 serious) Suppressed lactation occurred in a breast feeding women with the following co-reported events: Pyrexia (2), Paresis, Headache, Chills, Vomiting, Pain in extremity, Arthralgia, Breast pain, Scar pain, Nausea, Migraine, Myalgia, Fatigue and Breast milk discolouration (1 each). <p>Conclusion: There were no safety signals that emerged from the review of these cases of use in pregnancy and while breast feeding.</p>
Use in Paediatric Individuals <12 Years of Age	<p><u>Paediatric individuals <12 years of age</u></p> <ul style="list-style-type: none"> Number of cases: 34^d (0.1% of the total PM dataset), indicative of administration in paediatric subjects <12 years of age; Country of incidence: UK (29), US (3), Germany and Andorra (1 each); Cases Seriousness: Serious (24), Non-Serious (10); Gender: Females (25), Males (7), Unknown (2); Age (n=34) ranged from 2 months to 9 years, mean = 3.7 years, median = 4.0; Case outcome: resolved/resolving (16), not resolved (13), and unknown (5). Of the 132 reported events, those reported more than once were as follows: Product administered to patient of inappropriate age (27, see Medication Error), Off label use (11), Pyrexia (6), Product use issue (5), Fatigue, Headache and Nausea (4 each), Vaccination site pain (3), Abdominal pain upper, COVID-19, Facial paralysis, Lymphadenopathy, Malaise, Pruritus and Swelling (2 each). <p>Conclusion: No new significant safety information was identified based on a review of these cases compared with the non-paediatric population.</p>
Vaccine Effectiveness	<p>Company conventions for coding cases indicative of lack of efficacy:</p> <p>The coding conventions for lack of efficacy in the context of administration of the COVID-19 vaccine were revised on 15 February 2021, as shown below:</p> <ul style="list-style-type: none"> PT “Vaccination failure” is coded when ALL of the following criteria are met: <ul style="list-style-type: none"> The subject has received the series of two doses per the dosing regimen in local labeling. At least 7 days have elapsed since the second dose of vaccine has been administered. The subject experiences SARS-CoV-2 infection (confirmed laboratory tests). PT “Drug ineffective” is coded when either of the following applies: <ul style="list-style-type: none"> The infection is not confirmed as SARS-CoV-2 through laboratory tests (irrespective of the vaccination schedule). This includes scenarios where LOE is stated or implied, e.g., “the vaccine did not work”, “I got COVID-19”. <ul style="list-style-type: none"> It is unknown: <ul style="list-style-type: none"> Whether the subject has received the series of two doses per the dosing regimen in local labeling; How many days have passed since the first dose (including unspecified number of days like” a few days”, “some days”, etc.); If 7 days have passed since the second dose; The subject experiences a vaccine preventable illness 14 days after receiving the first dose up to and through 6 days after receipt of the second dose. <p>Note: after the immune system as had sufficient time (14 days) to respond to the vaccine, a report of COVID-19 is considered a potential lack of efficacy even if the vaccination course is not complete.</p> <p>Summary of the coding conventions for onset of vaccine preventable disease versus the vaccination date:</p>

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Table 6. Description of Missing Information

Topic	Description		
Missing Information	Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)		
	1st dose (day 1-13)	From day 14 post 1st dose to day 6 post 2nd dose	Day 7 post 2nd dose
	Code only the events describing the SARS-CoV-2 infection	Code “Drug ineffective”	Code “Vaccination failure”
	Scenario Not considered LOE	Scenario considered LOE as “Drug ineffective”	Scenario considered LOE as “Vaccination failure”
	<p>Lack of efficacy cases</p> <ul style="list-style-type: none"> • Number of cases: 1665^b (3.9 % of the total PM dataset) of which 1100 were medically confirmed and 565 non medically confirmed; • Number of lack of efficacy events: 1665 [PT: Drug ineffective (1646) and Vaccination failure (19)^f]. • Country of incidence: US (665), UK (405), Germany (181), France (85), Italy (58), Romania (47), Belgium (33), Israel (30), Poland (28), Spain (21), Austria (18), Portugal (17), Greece (15), Mexico (13), Denmark (8), Canada (7), Hungary, Sweden and United Arab Emirates (5 each), Czech Republic (4), Switzerland (3); the remaining 12 cases originated from 9 different countries. • COVID-19 infection was suspected in 155 cases, confirmed in 228 cases, in 1 case it was reported that the first dose was not effective (no other information). • COVID-19 infection (suspected or confirmed) outcome was reported as resolved/resolving (165), not resolved (205) or unknown (1230) at the time of the reporting; there were 65 cases where a fatal outcome was reported. <p>Drug ineffective cases (1649)</p> <ul style="list-style-type: none"> • Drug ineffective event seriousness: serious (1625), non-serious (21)^e; • Lack of efficacy term was reported: <ul style="list-style-type: none"> ○ after the 1st dose in 788 cases ○ after the 2nd dose in 139 cases ○ in 722 cases it was unknown after which dose the lack of efficacy occurred. • Latency of lack of efficacy term reported after the first dose was known for 176 cases: <ul style="list-style-type: none"> ○ Within 9 days: 2 subjects; ○ Within 14 and 21 days: 154 subjects; ○ Within 22 and 50 days: 20 subjects; • Latency of lack of efficacy term reported after the second dose was known for 69 cases: <ul style="list-style-type: none"> ○ Within 0 and 7 days: 42 subjects; ○ Within 8 and 21 days: 22 subjects; ○ Within 23 and 36 days: 5 subjects. • Latency of lack of efficacy term reported in cases where the number of doses administered was not provided, was known in 409 cases: <ul style="list-style-type: none"> ○ Within 0 and 7 days after vaccination: 281 subjects. ○ Within 8 and 14 days after vaccination: 89 subjects. ○ Within 15 and 44 days after vaccination: 39 subjects. <p>According to the RSI, individuals may not be fully protected until 7 days after their second dose of vaccine, therefore for the above 1649 cases where lack of efficacy was reported after the 1st dose or the</p>		

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Table 6. Description of Missing Information

Topic	Description
Missing Information	Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)
	<p>2nd dose, the reported events may represent signs and symptoms of intercurrent or undiagnosed COVID-19 infection or infection in an individual who was not fully vaccinated, rather than vaccine ineffectiveness.</p> <p style="text-align: center;"><i>Vaccination failure cases (16)</i></p> <ul style="list-style-type: none"> • Vaccination failure seriousness: all serious; • Lack of efficacy term was reported in all cases after the 2nd dose; • Latency of lack of efficacy was known for 14 cases: <ul style="list-style-type: none"> ○ Within 7 and 13 days: 8 subjects; ○ Within 15 and 29 days: 6 subjects. <p>COVID-19 (10) and Asymptomatic COVID-19 (6) were the reported vaccine preventable infections that occurred in these 16 cases.</p> <p>Conclusion: No new safety signals of vaccine lack of efficacy have emerged based on a review of these cases.</p>

- a. From a total of 417 cases, 4 cases were excluded from the analysis. In 3 cases, the MAH was informed that a 33-year-old and two unspecified age pregnant female patients were scheduled to receive bnt162b2 (PT reported Off label use and Product use issue in 2 cases; Circumstance or information capable of leading to medication error in one case). One case reported the PT Morning sickness; however, pregnancy was not confirmed in this case.
- b. 558 additional cases retrieved in this dataset were excluded from the analysis; upon review, 546 cases cannot be considered true lack of efficacy cases because the PT Drug ineffective was coded but the subjects developed SARS-CoV-2 infection during the early days from the first dose (days 1 – 13); the vaccine has not had sufficient time to stimulate the immune system and, consequently, the development of a vaccine preventable disease during this time is not considered a potential lack of effect of the vaccine; in 5 cases the PT Drug ineffective was removed after data lock point (DLP) because the subjects did not develop COVID-19 infection; in 1 case, reporting Treatment failure and Transient ischaemic attack, the Lack of efficacy PT did not refer to BNT162b2 vaccine; 5 cases have been invalidated in the safety database after DLP; 1 case has been deleted from the discussion because the PTs reported Pathogen resistance and Product preparation issue were not indicative of a lack of efficacy. to be eliminated.
- c. Upon review, 31 additional cases were excluded from the analysis as the data reported (e.g. clinical details, height, weight, etc.) were not consistent with paediatric subjects
- d. Upon review, 28 additional cases were excluded from the analysis as the data reported (e.g. clinical details, height, weight, etc.) were not consistent with paediatric subjects.
- e. Different clinical outcomes may be reported for an event that occurred more than once to the same individual
- f. In 2 cases the PT Vaccination failure was replaced with Drug ineffective after DLP. Another case was not included in the discussion of the Vaccination failure cases because correct scheduling (21 days apart between the first and second dose) cannot be confirmed.

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3.1.3. Review of Adverse Events of Special Interest (AESIs)

Please refer to [Appendix 1](#) for the list of the company's AESIs for BNT162b2.

The company's AESI list takes into consideration the lists of AESIs from the following expert groups and regulatory authorities: Brighton Collaboration (SPEAC), ACCESS protocol, US CDC (preliminary list of AESI for VAERS surveillance), MHRA (unpublished guideline).

The AESI terms are incorporated into a TME list and include events of interest due to their association with severe COVID-19 and events of interest for vaccines in general.

The AESI list is comprised of MedDRA PTs, HLTs, HLTs or MedDRA SMQs and can be changed as appropriate based on the evolving safety profile of the vaccine.

Table 7 provides a summary review of cumulative cases within AESI categories in the Pfizer safety database. This is distinct from safety signal evaluations which are conducted and included, as appropriate, in the Summary Monthly Safety Reports submitted regularly to the FDA and other Health Authorities.

Table 7. AESIs Evaluation for BNT162b2

AESIs ^a Category	Post-Marketing Cases Evaluation ^b Total Number of Cases (N=42086)
Anaphylactic Reactions <i>Search criteria: Anaphylactic reaction SMQ (Narrow and Broad, with the algorithm applied), selecting relevant cases according to BC criteria</i>	Please refer to the Risk 'Anaphylaxis' included above in Table 4 .
Cardiovascular AESIs <i>Search criteria: PTs Acute myocardial infarction; Arrhythmia; Cardiac failure; Cardiac failure acute; Cardiogenic shock; Coronary artery disease; Myocardial infarction; Postural orthostatic tachycardia syndrome; Stress cardiomyopathy; Tachycardia</i>	<ul style="list-style-type: none"> • Number of cases: 1403 (3.3% of the total PM dataset), of which 241 are medically confirmed and 1162 are non-medically confirmed; • Country of incidence: UK (268), US (233), Mexico (196), Italy (141), France (128), Germany (102), Spain (46), Greece (45), Portugal (37), Sweden (20), Ireland (17), Poland (16), Israel (13), Austria, Romania and Finland (12 each), Netherlands (11), Belgium and Norway (10 each), Czech Republic (9), Hungary and Canada (8 each), Croatia and Denmark (7 each), Iceland (5); the remaining 30 cases were distributed among 13 other countries; • Subjects' gender: female (1076), male (291) and unknown (36); • Subjects' age group (n = 1346): Adult^c (1078), Elderly^d (266) Child^e and Adolescent^f (1 each); • Number of relevant events: 1441, of which 946 serious, 495 non-serious; in the cases reporting relevant serious events; • Reported relevant PTs: Tachycardia (1098), Arrhythmia (102), Myocardial infarction (89), Cardiac failure (80), Acute myocardial infarction (41), Cardiac failure acute (11), Cardiogenic shock and Postural orthostatic tachycardia syndrome (7 each) and Coronary artery disease (6); • Relevant event onset latency (n = 1209): Range from <24 hours to 21 days, median <24 hours;

Table 7. AESIs Evaluation for BNT162b2

AESIs^a Category	Post-Marketing Cases Evaluation^b Total Number of Cases (N=42086)
	<ul style="list-style-type: none"> • Relevant event outcome^g: fatal (136), resolved/resolving (767), resolved with sequelae (21), not resolved (140) and unknown (380); <p>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue</p>
<p>COVID-19 AESIs <i>Search criteria: Covid-19 SMQ (Narrow and Broad) OR PTs Ageusia; Anosmia</i></p>	<ul style="list-style-type: none"> • Number of cases: 3067 (7.3% of the total PM dataset), of which 1013 are medically confirmed and 2054 are non-medically confirmed; • Country of incidence: US (1272), UK (609), Germany (360), France (161), Italy (94), Spain (69), Romania (62), Portugal (51), Poland (50), Mexico (43), Belgium (42), Israel (41), Sweden (30), Austria (27), Greece (24), Denmark (18), Czech Republic and Hungary (17 each), Canada (12), Ireland (11), Slovakia (9), Latvia and United Arab Emirates (6 each); the remaining 36 cases were distributed among 16 other different countries; • Subjects' gender: female (1650), male (844) and unknown (573); • Subjects' age group (n= 1880): Adult (1315), Elderly (560), Infant^h and Adolescent (2 each), Child (1); • Number of relevant events: 3359, of which 2585 serious, 774 non-serious; • Most frequently reported relevant PTs (>1 occurrence): COVID-19 (1927), SARS-CoV-2 test positive (415), Suspected COVID-19 (270), Ageusia (228), Anosmia (194), SARS-CoV-2 antibody test negative (83), Exposure to SARS-CoV-2 (62), SARS-CoV-2 antibody test positive (53), COVID-19 pneumonia (51), Asymptomatic COVID-19 (31), Coronavirus infection (13), Occupational exposure to SARS-CoV-2 (11), SARS-CoV-2 test false positive (7), Coronavirus test positive (6), SARS-CoV-2 test negative (3) SARS-CoV-2 antibody test (2); • Relevant event onset latency (n = 2070): Range from <24 hours to 374 days, median 5 days; • Relevant event outcome: fatal (136), not resolved (547), resolved/resolving (558), resolved with sequelae (9) and unknown (2110). <p>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue</p>
<p>Dermatological AESIs <i>Search criteria: PT Chillblains; Erythema multiforme</i></p>	<ul style="list-style-type: none"> • Number of cases: 20 cases (0.05% of the total PM dataset), of which 15 are medically confirmed and 5 are non-medically confirmed; • Country of incidence: UK (8), France and Poland (2 each), and the remaining 8 cases were distributed among 8 other different countries; • Subjects' gender: female (17) male and unknown (1 each); • Subjects' age group (n=19): Adult (18), Elderly (1); • Number of relevant events: 20 events, 16 serious, 4 non-serious

Table 7. AESIs Evaluation for BNT162b2

AESIs^a Category	Post-Marketing Cases Evaluation^b Total Number of Cases (N=42086)
	<ul style="list-style-type: none"> • Reported relevant PTs: Erythema multiforme (13) and Chillblains (7) • Relevant event onset latency (n = 18): Range from <24 hours to 17 days, median 3 days; • Relevant event outcome: resolved/resolving (7), not resolved (8) and unknown (6). <p>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.</p>
<p>Haematological AESIs <i>Search criteria: Leukopenias NEC (HLT) (Primary Path) OR Neutropenias (HLT) (Primary Path) OR PTs Immune thrombocytopenia, Thrombocytopenia OR SMQ Haemorrhage terms (excl laboratory terms</i></p>	<ul style="list-style-type: none"> • Number of cases: 932 (2.2 % of the total PM dataset), of which 524 medically confirmed and 408 non-medically confirmed; • Country of incidence: UK (343), US (308), France (50), Germany (43), Italy (37), Spain (27), Mexico and Poland (13 each), Sweden (10), Israel (9), Netherlands (8), Denmark, Finland, Portugal and Ireland (7 each), Austria and Norway (6 each), Croatia (4), Greece, Belgium, Hungary and Switzerland (3 each), Cyprus, Latvia and Serbia (2 each); the remaining 9 cases originated from 9 different countries; • Subjects' gender (n=898): female (676) and male (222); • Subjects' age group (n=837): Adult (543), Elderly (293), Infant (1); • Number of relevant events: 1080, of which 681 serious, 399 non-serious; • Most frequently reported relevant PTs (≥15 occurrences) include: Epistaxis (127), Contusion (112), Vaccination site bruising (96), Vaccination site haemorrhage (51), Petechiae (50), Haemorrhage (42), Haematochezia (34), Thrombocytopenia (33), Vaccination site haematoma (32), Conjunctival haemorrhage and Vaginal haemorrhage (29 each), Haematoma, Haemoptysis and Menorrhagia (27 each), Haematemesis (25), Eye haemorrhage (23), Rectal haemorrhage (22), Immune thrombocytopenia (20), Blood urine present (19), Haematuria, Neutropenia and Purpura (16 each) Diarrhoea haemorrhagic (15); • Relevant event onset latency (n = 787): Range from <24 hours to 33 days, median = 1 day; • Relevant event outcome: fatal (34), resolved/resolving (393), resolved with sequelae (17), not resolved (267) and unknown (371). <p>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue</p>
<p>Hepatic AESIs <i>Search criteria: Liver related investigations, signs and symptoms (SMQ) (Narrow and Broad) OR PT Liver injury</i></p>	<ul style="list-style-type: none"> • Number of cases: 70 cases (0.2% of the total PM dataset), of which 54 medically confirmed and 16 non-medically confirmed; • Country of incidence: UK (19), US (14), France (7), Italy (5), Germany (4), Belgium, Mexico and Spain (3 each), Austria, and Iceland (2 each); the remaining 8 cases originated from 8 different countries; • Subjects' gender: female (43), male (26) and unknown (1); • Subjects' age group (n=64): Adult (37), Elderly (27);

Table 7. AESIs Evaluation for BNT162b2

AESIs^a Category	Post-Marketing Cases Evaluation^b Total Number of Cases (N=42086)
	<ul style="list-style-type: none"> • Number of relevant events: 94, of which 53 serious, 41 non-serious; • Most frequently reported relevant PTs (≥ 3 occurrences) include: Alanine aminotransferase increased (16), Transaminases increased and Hepatic pain (9 each), Liver function test increased (8), Aspartate aminotransferase increased and Liver function test abnormal (7 each), Gamma-glutamyltransferase increased and Hepatic enzyme increased (6 each), Blood alkaline phosphatase increased and Liver injury (5 each), Ascites, Blood bilirubin increased and Hypertransaminasaemia (3 each); • Relevant event onset latency (n = 57): Range from <24 hours to 20 days, median 3 days; • Relevant event outcome: fatal (5), resolved/resolving (27), resolved with sequelae (1), not resolved (14) and unknown (47). <p>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue</p>
<p>Facial Paralysis <i>Search criteria: PTs Facial paralysis, Facial paresis</i></p>	<ul style="list-style-type: none"> • Number of cases: 449ⁱ (1.07% of the total PM dataset), 314 medically confirmed and 135 non-medically confirmed; • Country of incidence: US (124), UK (119), Italy (40), France (27), Israel (20), Spain (18), Germany (13), Sweden (11), Ireland (9), Cyprus (8), Austria (7), Finland and Portugal (6 each), Hungary and Romania (5 each), Croatia and Mexico (4 each), Canada (3), Czech Republic, Malta, Netherlands, Norway, Poland and Puerto Rico (2 each); the remaining 8 cases originated from 8 different countries; • Subjects' gender: female (295), male (133), unknown (21); • Subjects' age group (n=411): Adult (313), Elderly (96), Infant and Child (1 each); • Number of relevant events^k: 453, of which 399 serious, 54 non-serious; • Reported relevant PTs: Facial paralysis (401), Facial paresis (64); • Relevant event onset latency (n = 404): Range from <24 hours to 46 days, median 2 days; • Relevant event outcome: resolved/resolving (184), resolved with sequelae (3), not resolved (183) and unknown (97); <p>Overall Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue. Causality assessment will be further evaluated following availability of additional unblinded data from the clinical study C4591001, which will be unblinded for final analysis approximately mid-April 2021. Additionally, non-interventional post-authorisation safety studies, C4591011 and C4591012 are expected to capture data on a sufficiently large vaccinated population to detect an increased risk of Bell's palsy in vaccinated individuals. The timeline for conducting these analyses will be established based on the size of the vaccinated population captured in the study data sources by the first interim reports (due 30 June</p>

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Table 7. AESIs Evaluation for BNT162b2

AESIs^a Category	Post-Marketing Cases Evaluation^b Total Number of Cases (N=42086)
Immune-Mediated/Autoimmune AESIs <i>Search criteria: Immune-mediated/autoimmune disorders (SMQ) (Broad and Narrow) OR Autoimmune disorders HLGT (Primary Path) OR PTs Cytokine release syndrome; Cytokine storm; Hypersensitivity</i>	<p>2021). Study C4591021, pending protocol endorsement by EMA, is also intended to inform this risk.</p> <ul style="list-style-type: none"> • Number of cases: 1050 (2.5 % of the total PM dataset), of which 760 medically confirmed and 290 non-medically confirmed; • Country of incidence (>10 cases): UK (267), US (257), Italy (70), France and Germany (69 each), Mexico (36), Sweden (35), Spain (32), Greece (31), Israel (21), Denmark (18), Portugal (17), Austria and Czech Republic (16 each), Canada (12), Finland (10). The remaining 74 cases were from 24 different countries. • Subjects' gender (n=682): female (526), male (156). • Subjects' age group (n=944): Adult (746), Elderly (196), Adolescent (2). • Number of relevant events: 1077, of which 780 serious, 297 non-serious. • Most frequently reported relevant PTs (>10 occurrences): Hypersensitivity (596), Neuropathy peripheral (49), Pericarditis (32), Myocarditis (25), Dermatitis (24), Diabetes mellitus and Encephalitis (16 each), Psoriasis (14), Dermatitis Bullous (13), Autoimmune disorder and Raynaud's phenomenon (11 each); • Relevant event onset latency (n = 807): Range from <24 hours to 30 days, median <24 hours. • Relevant event outcome¹: resolved/resolving (517), not resolved (215), fatal (12), resolved with sequelae (22) and unknown (312). <p>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue</p>
Musculoskeletal AESIs <i>Search criteria: PTs Arthralgia; Arthritis; Arthritis bacterial¹; Chronic fatigue syndrome; Polyarthritits; Polyneuropathy; Post viral fatigue syndrome; Rheumatoid arthritis</i>	<ul style="list-style-type: none"> • Number of cases: 3600 (8.5% of the total PM dataset), of which 2045 medically confirmed and 1555 non-medically confirmed; • Country of incidence: UK (1406), US (1004), Italy (285), Mexico (236), Germany (72), Portugal (70), France (48), Greece and Poland (46), Latvia (33), Czech Republic (32), Israel and Spain (26), Sweden (25), Romania (24), Denmark (23), Finland and Ireland (19 each), Austria and Belgium (18 each), Canada (16), Netherlands (14), Bulgaria (12), Croatia and Serbia (9 each), Cyprus and Hungary (8 each), Norway (7), Estonia and Puerto Rico (6 each), Iceland and Lithuania (4 each); the remaining 21 cases originated from 11 different countries; • Subjects' gender (n=3471): female (2760), male (711); • Subjects' age group (n=3372): Adult (2850), Elderly (515), Child (4), Adolescent (2), Infant (1); • Number of relevant events: 3640, of which 1614 serious, 2026 non-serious; • Reported relevant PTs: Arthralgia (3525), Arthritis (70), Rheumatoid arthritis (26), Polyarthritits (5), Polyneuropathy, Post viral fatigue syndrome, Chronic fatigue syndrome (4 each), Arthritis bacterial (1); • Relevant event onset latency (n = 2968): Range from <24 hours to 32 days, median 1 day;

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Table 7. AESIs Evaluation for BNT162b2

AESIs^a Category	Post-Marketing Cases Evaluation^b Total Number of Cases (N=42086)
	<ul style="list-style-type: none"> Relevant event outcome: resolved/resolving (1801), not resolved (959), resolved with sequelae (49), and unknown (853). <p>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.</p>
<p>Neurological AESIs (including demyelination)</p> <p><i>Search criteria: Convulsions (SMQ) (Broad and Narrow) OR Demyelination (SMQ) (Broad and Narrow) OR PTs Ataxia; Cataplexy; Encephalopathy; Fibromyalgia; Intracranial pressure increased; Meningitis; Meningitis aseptic; Narcolepsy</i></p>	<ul style="list-style-type: none"> Number of cases: 501 (1.2% of the total PM dataset), of which 365 medically confirmed and 136 non-medically confirmed. Country of incidence (≥ 9 cases): UK (157), US (68), Germany (49), Mexico (35), Italy (31), France (25), Spain (18), Poland (17), Netherlands and Israel (15 each), Sweden (9). The remaining 71 cases were from 22 different countries. Subjects' gender (n=478): female (328), male (150). Subjects' age group (n=478): Adult (329), Elderly (149); Number of relevant events: 542, of which 515 serious, 27 non-serious. Most frequently reported relevant PTs (>2 occurrences) included: Seizure (204), Epilepsy (83), Generalised tonic-clonic seizure (33), Guillain-Barre syndrome (24), Fibromyalgia and Trigeminal neuralgia (17 each), Febrile convulsion, (15), Status epilepticus (12), Aura and Myelitis transverse (11 each), Multiple sclerosis relapse and Optic neuritis (10 each), Petit mal epilepsy and Tonic convulsion (9 each), Ataxia (8), Encephalopathy and Tonic clonic movements (7 each), Foaming at mouth (5), Multiple sclerosis, Narcolepsy and Partial seizures (4 each), Bad sensation, Demyelination, Meningitis, Postictal state, Seizure like phenomena and Tongue biting (3 each); Relevant event onset latency (n = 423): Range from <24 hours to 48 days, median 1 day; Relevant events outcome: fatal (16), resolved/resolving (265), resolved with sequelae (13), not resolved (89) and unknown (161); <p>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue</p>
<p>Other AESIs</p> <p><i>Search criteria: Herpes viral infections (HLT) (Primary Path) OR PTs Adverse event following immunisation; Inflammation; Manufacturing laboratory analytical testing issue; Manufacturing materials issue; Manufacturing production issue; MERS-CoV test; MERS-CoV test negative; MERS-CoV test positive; Middle East respiratory syndrome; Multiple organ dysfunction syndrome; Occupational exposure to communicable disease; Patient</i></p>	<ul style="list-style-type: none"> Number of cases: 8152 (19.4% of the total PM dataset), of which 4977 were medically confirmed and 3175 non-medically confirmed; Country of incidence (> 20 occurrences): UK (2715), US (2421), Italy (710), Mexico (223), Portugal (210), Germany (207), France (186), Spain (183), Sweden (133), Denmark (127), Poland (120), Greece (95), Israel (79), Czech Republic (76), Romania (57), Hungary (53), Finland (52), Norway (51), Latvia (49), Austria (47), Croatia (42), Belgium (41), Canada (39), Ireland (34), Serbia (28), Iceland (25), Netherlands (22). The remaining 127 cases were from 21 different countries; Subjects' gender (n=7829): female (5969), male (1860); Subjects' age group (n=7479): Adult (6330), Elderly (1125), Adolescent, Child (9 each), Infant (6);

Table 7. AESIs Evaluation for BNT162b2

AESIs^a Category	Post-Marketing Cases Evaluation^b Total Number of Cases (N=42086)
<i>isolation; Product availability issue; Product distribution issue; Product supply issue; Pyrexia; Quarantine; SARS-CoV-1 test; SARS-CoV-1 test negative; SARS-CoV-1 test positive</i>	<ul style="list-style-type: none"> • Number of relevant events: 8241, of which 3674 serious, 4568 non-serious; • Most frequently reported relevant PTs (≥ 6 occurrences) included: Pyrexia (7666), Herpes zoster (259), Inflammation (132), Oral herpes (80), Multiple organ dysfunction syndrome (18), Herpes virus infection (17), Herpes simplex (13), Ophthalmic herpes zoster (10), Herpes ophthalmic and Herpes zoster reactivation (6 each); • Relevant event onset latency (n =6836): Range from <24 hours to 61 days, median 1 day; • Relevant events outcome: fatal (96), resolved/resolving (5008), resolved with sequelae (84), not resolved (1429) and unknown (1685). <p>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue</p>
Pregnancy Related AESIs <i>Search criteria: PTs Amniotic cavity infection; Caesarean section; Congenital anomaly; Death neonatal; Eclampsia; Foetal distress syndrome; Low birth weight baby; Maternal exposure during pregnancy; Placenta praevia; Pre-eclampsia; Premature labour; Stillbirth; Uterine rupture; Vasa praevia</i>	<p>For relevant cases, please refer to Table 6, Description of Missing Information, Use in Pregnancy and While Breast Feeding</p>
Renal AESIs <i>Search criteria: PTs Acute kidney injury; Renal failure.</i>	<ul style="list-style-type: none"> • Number of cases: 69 cases (0.17% of the total PM dataset), of which 57 medically confirmed, 12 non-medically confirmed; • Country of incidence: Germany (17), France and UK (13 each), US (6), Belgium, Italy and Spain (4 each), Sweden (2), Austria, Canada, Denmark, Finland, Luxembourg and Norway (1 each); • Subjects' gender: female (46), male (23); • Subjects' age group (n=68): Adult (7), Elderly (60), Infant (1); • Number of relevant events: 70, all serious; • Reported relevant PTs: Acute kidney injury (40) and Renal failure (30); • Relevant event onset latency (n = 42): Range from <24 hours to 15 days, median 4 days; • Relevant event outcome: fatal (23), resolved/resolving (10), not resolved (15) and unknown (22). <p>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.</p>
Respiratory AESIs <i>Search criteria: Lower respiratory tract infections NEC (HLT)</i>	<ul style="list-style-type: none"> • Number of cases: 130 cases (0.3% of the total PM dataset), of which 107 medically confirmed;

Table 7. AESIs Evaluation for BNT162b2

AESIs^a Category	Post-Marketing Cases Evaluation^b Total Number of Cases (N=42086)
<p><i>(Primary Path) OR Respiratory failures (excl neonatal) (HLT)</i> <i>(Primary Path) OR Viral lower respiratory tract infections (HLT)</i> <i>(Primary Path) OR PTs: Acute respiratory distress syndrome; Endotracheal intubation; Hypoxia; Pulmonary haemorrhage; Respiratory disorder; Severe acute respiratory syndrome</i></p>	<ul style="list-style-type: none"> • Countries of incidence: United Kingdom (20), France (18), United States (16), Germany (14), Spain (13), Belgium and Italy (9), Denmark (8), Norway (5), Czech Republic, Iceland (3 each); the remaining 12 cases originated from 8 different countries. • Subjects' gender (n=130): female (72), male (58). • Subjects's age group (n=126): Elderly (78), Adult (47), Adolescent (1). • Number of relevant events: 137, of which 126 serious, 11 non-serious; • Reported relevant PTs: Respiratory failure (44), Hypoxia (42), Respiratory disorder (36), Acute respiratory distress syndrome (10), Chronic respiratory syndrome (3), Severe acute respiratory syndrome (2). • Relevant event onset latency (n=102): range from < 24 hours to 18 days, median 1 day; • Relevant events outcome: fatal (41), Resolved/resolving (47), not recovered (18) and unknown (31). <p>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.</p>
<p>Thromboembolic Events <i>Search criteria: Embolism and thrombosis (HLGT) (Primary Path), excluding PTs reviewed as Stroke AESIs, OR PTs Deep vein thrombosis; Disseminated intravascular coagulation; Embolism; Embolism venous; Pulmonary embolism</i></p>	<ul style="list-style-type: none"> • Number of cases: 151 (0.3% of the total PM dataset), of which 111 medically confirmed and 40 non-medically confirmed; • Country of incidence: UK (34), US (31), France (20), Germany (15), Italy and Spain (6 each), Denmark and Sweden (5 each), Austria, Belgium and Israel (3 each), Canada, Cyprus, Netherlands and Portugal (2 each); the remaining 12 cases originated from 12 different countries; • Subjects' gender (n= 144): female (89), male (55); • Subjects' age group (n=136): Adult (66), Elderly (70); • Number of relevant events: 168, of which 165 serious, 3 non-serious; • Most frequently reported relevant PTs (>1 occurrence) included: Pulmonary embolism (60), Thrombosis (39), Deep vein thrombosis (35), Thrombophlebitis superficial (6), Venous thrombosis limb (4), Embolism, Microembolism, Thrombophlebitis and Venous thrombosis (3 each) Blue toe syndrome (2); • Relevant event onset latency (n = 124): Range from <24 hours to 28 days, median 4 days; • Relevant event outcome: fatal (18), resolved/resolving (54), resolved with sequelae (6), not resolved (49) and unknown (42). <p>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.</p>
<p>Stroke <i>Search criteria: HLT Central nervous system haemorrhages and cerebrovascular accidents</i></p>	<ul style="list-style-type: none"> • Number of cases: 275 (0.6% of the total PM dataset), of which 180 medically confirmed and 95 non-medically confirmed; • Country of incidence: UK (81), US (66), France (32), Germany (21), Norway (14), Netherlands and Spain (11 each), Sweden (9),

Table 7. AESIs Evaluation for BNT162b2

AESIs^a Category	Post-Marketing Cases Evaluation^b Total Number of Cases (N=42086)
<p><i>(Primary Path) OR HLT Cerebrovascular venous and sinus thrombosis (Primary Path)</i></p>	<p>Israel (6), Italy (5), Belgium (3), Denmark, Finland, Poland and Switzerland (2 each); the remaining 8 cases originated from 8 different countries;</p> <ul style="list-style-type: none"> • Subjects' gender (n= 273): female (182), male (91); • Subjects' age group (n=265): Adult (59), Elderly (205), Child^m (1); • Number of relevant events: 300, all serious; • Most frequently reported relevant PTs (>1 occurrence) included: <ul style="list-style-type: none"> ○ PTs indicative of Ischaemic stroke: Cerebrovascular accident (160), Ischaemic stroke (41), Cerebral infarction (15), Cerebral ischaemia, Cerebral thrombosis, Cerebral venous sinus thrombosis, Ischaemic cerebral infarction and Lacunal infarction (3 each) Basal ganglia stroke, Cerebellar infarction and Thrombotic stroke (2 each); ○ PTs indicative of Haemorrhagic stroke: Cerebral haemorrhage (26), Haemorrhagic stroke (11), Haemorrhage intracranial and Subarachnoid haemorrhage (5 each), Cerebral haematoma (4), Basal ganglia haemorrhage and Cerebellar haemorrhage (2 each); • Relevant event onset latency (n = 241): Range from <24 hours to 41 days, median 2 days; • Relevant event outcome: fatal and resolved/resolving (61 each), resolved with sequelae (10), not resolved (85) and unknown (83). <p>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.</p>
<p>Vasculitic Events <i>Search criteria: Vasculitides HLT</i></p>	<ul style="list-style-type: none"> • Number of cases: 32 cases (0.08% of the total PM dataset), of which 26 medically confirmed and 6 non-medically confirmed; • Country of incidence: UK (13), France (4), Portugal, US and Spain (3 each), Cyprus, Germany, Hungary, Italy and Slovakia and Costa rica (1 each); • Subjects' gender: female (26), male (6); • Subjects' age group (n=31): Adult (15), Elderly (16); • Number of relevant events: 34, of which 25 serious, 9 non-serious; • Reported relevant PTs: Vasculitis (14), Cutaneous vasculitis and Vasculitic rash (4 each), (3), Giant cell arteritis and Peripheral ischaemia (3 each), Behcet's syndrome and Hypersensitivity vasculitis (2 each) Palpable purpura, and Takayasu's arteritis (1 each); • Relevant event onset latency (n = 25): Range from <24 hours to 19 days, median 3 days; • Relevant event outcome: fatal (1), resolved/resolving (13), not resolved (12) and unknown (8). <p>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue</p>

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Table 7. AESIs Evaluation for BNT162b2

AESIs ^a Category	Post-Marketing Cases Evaluation ^b Total Number of Cases (N=42086)
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- a. For the complete list of the AESIs, please refer to Appendix 5;
- b. Please note that this corresponds to evidence from post-EUA/conditional marketing authorisation approval data sources;
- c. Subjects with age ranged between 18 and 64 years;
- d. Subjects with age equal to or above 65 years;
- e. Subjects with age ranged between 2 and 11 years;
- f. Subjects with age ranged between 12 and less than 18 years;
- g. Multiple episodes of the same PT event were reported with a different clinical outcome within some cases hence the sum of the events outcome exceeds the total number of PT events;
- h. Subjects with age ranged between 1 (28 days) and 23 months;
- i. Twenty-four additional cases were excluded from the analysis as they were not cases of peripheral facial nerve palsy because they described other disorders (stroke, cerebral haemorrhage or transient ischaemic attack); 1 case was excluded from the analysis because it was invalid due to an unidentifiable reporter;
- j. This UK case report received from the UK MHRA described a 1-year-old subject who received the vaccine, and had left postauricular ear pain that progressed to left-sided Bell's palsy 1 day following vaccination that had not resolved at the time of the report;
- k. If a case included both PT Facial paresis and PT Facial paralysis, only the PT Facial paralysis was considered in the descriptions of the events as it is most clinically important;
- l. Multiple episodes of the same PT event were reported with a different clinical outcome within some cases hence the sum of the events outcome exceeds the total number of PT events
- m. This UK case report received from the UK MHRA described a 7-year-old female subject who received the vaccine and had stroke (unknown outcome); no follow-up is possible for clarification.
- n. This PT not included in the AESIs/TME list was included in the review as relevant for ACCESS protocol criteria;

3.1.4. Medication error

Cases potentially indicative of medication errors¹ that cumulatively occurred are summarized below.

- Number of relevant medication error cases: 2056² (4.9%) of which 1569 (3.7%) are medically confirmed.
- Number of relevant events: 2792
- Top 10 countries of incidence:
 - US (1201), France (171), UK (138), Germany (88), Czech Republic (87), Sweden (49), Israel (45), Italy (42), Canada (35), Romania (33), Finland (21), Portugal (20), Norway (14), Puerto Rico (13), Poland (12), Austria and Spain (10 each).

Medication error case outcomes:

- Fatal (7)³,
- Recovered/recovering (354, of which 4 are serious),
- Recovered with sequelae (8, of which 3 serious)

¹ MedDRA (version 23.1) Higher Level Terms: Accidental exposures to product; Product administration errors and issues; Product confusion errors and issues; Product dispensing errors and issues; Product label issues; Product monitoring errors and issues; Product preparation errors and issues; Product selection errors and issues; Product storage errors and issues in the product use system; Product transcribing errors and communication issues, OR Preferred Terms: Accidental poisoning; Circumstance or information capable of leading to device use error; Circumstance or information capable of leading to medication error; Contraindicated device used; Deprescribing error; Device use error; Dose calculation error; Drug titration error; Expired device used; Exposure via direct contact; Exposure via eye contact; Exposure via mucosa; Exposure via skin contact; Failure of child resistant product closure; Inadequate aseptic technique in use of product; Incorrect disposal of product; Intercepted medication error; Intercepted product prescribing error; Medication error; Multiple use of single-use product; Product advertising issue; Product distribution issue; Product prescribing error; Product prescribing issue; Product substitution error; Product temperature excursion issue; Product use in unapproved therapeutic environment; Radiation underdose; Underdose; Unintentional medical device removal; Unintentional use for unapproved indication; Vaccination error; Wrong device used; Wrong dosage form; Wrong dosage formulation; Wrong dose; Wrong drug; Wrong patient; Wrong product procured; Wrong product stored; Wrong rate; Wrong route; Wrong schedule; Wrong strength; Wrong technique in device usage process; Wrong technique in product usage process.

² Thirty-five (35) cases were excluded from the analysis because describing medication errors occurring in an unspecified number of individuals or describing medication errors occurring with co suspects were determined to be non-contributory.

³ All the medication errors reported in these cases were assessed as non-serious occurrences with an unknown outcome; based on the available information including the causes of death, the relationship between the medication error and the death is weak. .

- Not recovered (189, of which 84 are serious),
- Unknown (1498, of which 33 are serious).

1371 cases reported only MEs without any associated clinical adverse event. The PTs most frequently reported (≥ 12 occurrences) were: Poor quality product administered (539), Product temperature excursion issue (253), Inappropriate schedule of product administration (225), Product preparation error (206), Underdose (202), Circumstance or information capable of leading to medication error (120), Product preparation issue (119), Wrong technique in product usage process (76), Incorrect route of product administration (66), Accidental overdose (33), Product administered at inappropriate site (27), Incorrect dose administered and Accidental exposure to the product (25 each), Exposure via skin contact (22), Wrong product administered (17), Incomplete course of vaccination, and Product administration error (14 each) Product administered to patient of inappropriate age (12).

In 685 cases, there were co-reported AEs. The most frequently co-associated AEs (> 40 occurrences) were: Headache (187), Pyrexia (161), Fatigue (135), Chills (127), Pain (107), Vaccination site pain (100), Nausea (89), Myalgia (88), Pain in extremity (85) Arthralgia (68), Off label use (57), Dizziness (52), Lymphadenopathy (47), Asthenia (46) and Malaise (41). These cases are summarized in Table 8.

Table 8. ME PTs by seriousness with or without harm co-association (Through 28 February 2021)

ME PTs	Serious		Non-Serious	
	With Harm	Without Harm	With Harm	Without Harm
Accidental exposure to product	0	0	0	5
Accidental overdose	4	1	9	6
Booster dose missed	0	0	0	1
Circumstance or information capable of leading to medication error	0	0	5	11
Contraindicated product administered	1	0	0	2
Expired product administered	0	0	0	2
Exposure via skin contact	0	0	0	5
Inappropriate schedule of product administration	0	2	8	264
Incorrect dose administered	1	1	0	0

Table 8. ME PTs by seriousness with or without harm co-association (Through 28 February 2021)

ME PTs	Serious		Non-Serious	
	With Harm	Without Harm	With Harm	Without Harm
Incorrect route of product administration	2	6	16	127
Lack of vaccination site rotation	1	0	0	0
Medication error	0	0	0	1
Poor quality product administered	1	0	0	34
Product administered at inappropriate site	2	1	13	29
Product administered to patient of inappropriate age	0	4	0	40
Product administration error	1	0	0	3
Product dose omission issue	0	1	0	3
Product preparation error	1	0	4	11
Product preparation issue	1	1	0	14

Overall, there were 68 cases with co-reported AEs reporting Harm and 599 cases with co-reported AEs without harm. Additionally, Intercepted medication errors was reported in 1 case (PTs Malaise, clinical outcome unknow) and Potential medication errors were reported in 17 cases.

4. DISCUSSION

Pfizer performs frequent and rigorous signal detection on BNT162b2 cases. The findings of these signal detection analyses are consistent with the known safety profile of the vaccine. This cumulative analysis to support the Biologics License Application for BNT162b2, is an integrated analysis of post-authorization safety data, from U.S. and foreign experience, focused on Important Identified Risks, Important Potential Risks, and areas of Important Missing Information identified in the Pharmacovigilance Plan, as well as adverse events of special interest and vaccine administration errors (whether or not associated with an adverse event). The data do not reveal any novel safety concerns or risks requiring label changes and support a favorable benefit risk profile of to the BNT162b2 vaccine.

5. SUMMARY AND CONCLUSION

Review of the available data for this cumulative PM experience, confirms a favorable benefit: risk balance for BNT162b2.

Pfizer will continue routine pharmacovigilance activities on behalf of BioNTech according to the Pharmacovigilance Agreement in place, in order to assure patient safety and will inform the Agency if an evaluation of the safety data yields significant new information for BNT162b2.

APPENDIX 1. LIST OF ADVERSE EVENTS OF SPECIAL INTEREST

1p36 deletion syndrome;2-Hydroxyglutaric aciduria;5'nucleotidase increased;Acoustic neuritis;Acquired C1 inhibitor deficiency;Acquired epidermolysis bullosa;Acquired epileptic aphasia;Acute cutaneous lupus erythematosus;Acute disseminated encephalomyelitis;Acute encephalitis with refractory, repetitive partial seizures;Acute febrile neutrophilic dermatosis;Acute flaccid myelitis;Acute haemorrhagic leukoencephalitis;Acute haemorrhagic oedema of infancy;Acute kidney injury;Acute macular outer retinopathy;Acute motor axonal neuropathy;Acute motor-sensory axonal neuropathy;Acute myocardial infarction;Acute respiratory distress syndrome;Acute respiratory failure;Addison's disease;Administration site thrombosis;Administration site vasculitis;Adrenal thrombosis;Adverse event following immunisation;Ageusia;Agranulocytosis;Air embolism;Alanine aminotransferase abnormal;Alanine aminotransferase increased;Alcoholic seizure;Allergic bronchopulmonary mycosis;Allergic oedema;Alloimmune hepatitis;Alopecia areata;Alpers disease;Alveolar proteinosis;Ammonia abnormal;Ammonia increased;Amniotic cavity infection;Amygdalohippocampectomy;Amyloid arthropathy;Amyloidosis;Amyloidosis senile;Anaphylactic reaction;Anaphylactic shock;Anaphylactic transfusion reaction;Anaphylactoid reaction;Anaphylactoid shock;Anaphylactoid syndrome of pregnancy;Angioedema;Angiopathic neuropathy;Ankylosing spondylitis;Anosmia;Anti-acetylcholine receptor antibody positive;Anti-actin antibody positive;Anti-aquaporin-4 antibody positive;Anti-basal ganglia antibody positive;Anti-cyclic citrullinated peptide antibody positive;Anti-epithelial antibody positive;Anti-erythrocyte antibody positive;Anti-exosome complex antibody positive;Anti-GAD antibody negative;Anti-GAD antibody positive;Anti-ganglioside antibody positive;Antigliadin antibody positive;Anti-glomerular basement membrane antibody positive;Anti-glomerular basement membrane disease;Anti-glycyl-tRNA synthetase antibody positive;Anti-HLA antibody test positive;Anti-IA2 antibody positive;Anti-insulin antibody increased;Anti-insulin antibody positive;Anti-insulin receptor antibody increased;Anti-insulin receptor antibody positive;Anti-interferon antibody negative;Anti-interferon antibody positive;Anti-islet cell antibody positive;Antimitochondrial antibody positive;Anti-muscle specific kinase antibody positive;Anti-myelin-associated glycoprotein antibodies positive;Anti-myelin-associated glycoprotein associated polyneuropathy;Antimyocardial antibody positive;Anti-neuronal antibody positive;Antineutrophil cytoplasmic antibody increased;Antineutrophil cytoplasmic antibody positive;Anti-neutrophil cytoplasmic antibody positive vasculitis;Anti-NMDA antibody positive;Antinuclear antibody increased;Antinuclear antibody positive;Antiphospholipid antibodies positive;Antiphospholipid syndrome;Anti-platelet antibody positive;Anti-prothrombin antibody positive;Antiribosomal P antibody positive;Anti-RNA polymerase III antibody positive;Anti-saccharomyces cerevisiae antibody test positive;Anti-sperm antibody positive;Anti-SRP antibody positive;Antisynthetase syndrome;Anti-thyroid antibody positive;Anti-transglutaminase antibody increased;Anti-VGCC antibody positive;Anti-VGKC antibody positive;Anti-vimentin antibody positive;Antiviral prophylaxis;Antiviral treatment;Anti-zinc transporter 8 antibody positive;Aortic embolus;Aortic thrombosis;Aortitis;Aplasia pure red cell;Aplastic anaemia;Application site thrombosis;Application site vasculitis;Arrhythmia;Arterial bypass occlusion;Arterial bypass thrombosis;Arterial thrombosis;Arteriovenous fistula thrombosis;Arteriovenous graft site stenosis;Arteriovenous graft thrombosis;Arteritis;Arteritis

coronary;Arthralgia;Arthritis;Arthritis enteropathic;Ascites;Aseptic cavernous sinus thrombosis;Aspartate aminotransferase abnormal;Aspartate aminotransferase increased;Aspartate-glutamate-transporter deficiency;AST to platelet ratio index increased;AST/ALT ratio abnormal;Asthma;Asymptomatic COVID-19;Ataxia;Atheroembolism;Atonic seizures;Atrial thrombosis;Atrophic thyroiditis;Atypical benign partial epilepsy;Atypical pneumonia;Aura;Autoantibody positive;Autoimmune anaemia;Autoimmune aplastic anaemia;Autoimmune arthritis;Autoimmune blistering disease;Autoimmune cholangitis;Autoimmune colitis;Autoimmune demyelinating disease;Autoimmune dermatitis;Autoimmune disorder;Autoimmune encephalopathy;Autoimmune endocrine disorder;Autoimmune enteropathy;Autoimmune eye disorder;Autoimmune haemolytic anaemia;Autoimmune heparin-induced thrombocytopenia;Autoimmune hepatitis;Autoimmune hyperlipidaemia;Autoimmune hypothyroidism;Autoimmune inner ear disease;Autoimmune lung disease;Autoimmune lymphoproliferative syndrome;Autoimmune myocarditis;Autoimmune myositis;Autoimmune nephritis;Autoimmune neuropathy;Autoimmune neutropenia;Autoimmune pancreatitis;Autoimmune pancytopenia;Autoimmune pericarditis;Autoimmune retinopathy;Autoimmune thyroid disorder;Autoimmune thyroiditis;Autoimmune uveitis;Autoinflammation with infantile enterocolitis;Autoinflammatory disease;Automatism epileptic;Autonomic nervous system imbalance;Autonomic seizure;Axial spondyloarthritis;Axillary vein thrombosis;Axonal and demyelinating polyneuropathy;Axonal neuropathy;Bacterascites;Baltic myoclonic epilepsy;Band sensation;Basedow's disease;Basilar artery thrombosis;Basophilopenia;B-cell aplasia;Behcet's syndrome;Benign ethnic neutropenia;Benign familial neonatal convulsions;Benign familial pemphigus;Benign rolandic epilepsy;Beta-2 glycoprotein antibody positive;Bickerstaff's encephalitis;Bile output abnormal;Bile output decreased;Biliary ascites;Bilirubin conjugated abnormal;Bilirubin conjugated increased;Bilirubin urine present;Biopsy liver abnormal;Biotinidase deficiency;Birdshot chorioretinopathy;Blood alkaline phosphatase abnormal;Blood alkaline phosphatase increased;Blood bilirubin abnormal;Blood bilirubin increased;Blood bilirubin unconjugated increased;Blood cholinesterase abnormal;Blood cholinesterase decreased;Blood pressure decreased;Blood pressure diastolic decreased;Blood pressure systolic decreased;Blue toe syndrome;Brachiocephalic vein thrombosis;Brain stem embolism;Brain stem thrombosis;Bromosulphthalein test abnormal;Bronchial oedema;Bronchitis;Bronchitis mycoplasmal;Bronchitis viral;Bronchopulmonary aspergillosis allergic;Bronchospasm;Budd-Chiari syndrome;Bulbar palsy;Butterfly rash;C1q nephropathy;Caesarean section;Calcium embolism;Capillaritis;Caplan's syndrome;Cardiac amyloidosis;Cardiac arrest;Cardiac failure;Cardiac failure acute;Cardiac sarcoidosis;Cardiac ventricular thrombosis;Cardiogenic shock;Cardiolipin antibody positive;Cardiopulmonary failure;Cardio-respiratory arrest;Cardio-respiratory distress;Cardiovascular insufficiency;Carotid arterial embolus;Carotid artery thrombosis;Cataplexy;Catheter site thrombosis;Catheter site vasculitis;Cavernous sinus thrombosis;CDKL5 deficiency disorder;CEC syndrome;Cement embolism;Central nervous system lupus;Central nervous system vasculitis;Cerebellar artery thrombosis;Cerebellar embolism;Cerebral amyloid angiopathy;Cerebral arteritis;Cerebral artery embolism;Cerebral artery thrombosis;Cerebral gas embolism;Cerebral microembolism;Cerebral septic infarct;Cerebral thrombosis;Cerebral venous sinus thrombosis;Cerebral venous thrombosis;Cerebrospinal thrombotic

tamponade;Cerebrovascular accident;Change in seizure presentation;Chest discomfort;Child-Pugh-Turcotte score abnormal;Child-Pugh-Turcotte score increased;Chillblains;Choking;Choking sensation;Cholangitis sclerosing;Chronic autoimmune glomerulonephritis;Chronic cutaneous lupus erythematosus;Chronic fatigue syndrome;Chronic gastritis;Chronic inflammatory demyelinating polyradiculoneuropathy;Chronic lymphocytic inflammation with pontine perivascular enhancement responsive to steroids;Chronic recurrent multifocal osteomyelitis;Chronic respiratory failure;Chronic spontaneous urticaria;Circulatory collapse;Circumoral oedema;Circumoral swelling;Clinically isolated syndrome;Clonic convulsion;Coeliac disease;Cogan's syndrome;Cold agglutinins positive;Cold type haemolytic anaemia;Colitis;Colitis erosive;Colitis herpes;Colitis microscopic;Colitis ulcerative;Collagen disorder;Collagen-vascular disease;Complement factor abnormal;Complement factor C1 decreased;Complement factor C2 decreased;Complement factor C3 decreased;Complement factor C4 decreased;Complement factor decreased;Computerised tomogram liver abnormal;Concentric sclerosis;Congenital anomaly;Congenital bilateral perisylvian syndrome;Congenital herpes simplex infection;Congenital myasthenic syndrome;Congenital varicella infection;Congestive hepatopathy;Convulsion in childhood;Convulsions local;Convulsive threshold lowered;Coombs positive haemolytic anaemia;Coronary artery disease;Coronary artery embolism;Coronary artery thrombosis;Coronary bypass thrombosis;Coronavirus infection;Coronavirus test;Coronavirus test negative;Coronavirus test positive;Corpus callosotomy;Cough;Cough variant asthma;COVID-19;COVID-19 immunisation;COVID-19 pneumonia;COVID-19 prophylaxis;COVID-19 treatment;Cranial nerve disorder;Cranial nerve palsies multiple;Cranial nerve paralysis;CREST syndrome;Crohn's disease;Cryofibrinogenaemia;Cryoglobulinaemia;CSF oligoclonal band present;CSWS syndrome;Cutaneous amyloidosis;Cutaneous lupus erythematosus;Cutaneous sarcoidosis;Cutaneous vasculitis;Cyanosis;Cyclic neutropenia;Cystitis interstitial;Cytokine release syndrome;Cytokine storm;De novo purine synthesis inhibitors associated acute inflammatory syndrome;Death neonatal;Deep vein thrombosis;Deep vein thrombosis postoperative;Deficiency of bile secretion;Deja vu;Demyelinating polyneuropathy;Demyelination;Dermatitis;Dermatitis bullous;Dermatitis herpetiformis;Dermatomyositis;Device embolisation;Device related thrombosis;Diabetes mellitus;Diabetic ketoacidosis;Diabetic mastopathy;Dialysis amyloidosis;Dialysis membrane reaction;Diastolic hypotension;Diffuse vasculitis;Digital pitting scar;Disseminated intravascular coagulation;Disseminated intravascular coagulation in newborn;Disseminated neonatal herpes simplex;Disseminated varicella;Disseminated varicella zoster vaccine virus infection;Disseminated varicella zoster virus infection;DNA antibody positive;Double cortex syndrome;Double stranded DNA antibody positive;Dreamy state;Dressler's syndrome;Drop attacks;Drug withdrawal convulsions;Dyspnoea;Early infantile epileptic encephalopathy with burst-suppression;Eclampsia;Eczema herpeticum;Embolia cutis medicamentosa;Embolic cerebellar infarction;Embolic cerebral infarction;Embolic pneumonia;Embolic stroke;Embolism;Embolism arterial;Embolism venous;Encephalitis;Encephalitis allergic;Encephalitis autoimmune;Encephalitis brain stem;Encephalitis haemorrhagic;Encephalitis periaxialis diffusa;Encephalitis post immunisation;Encephalomyelitis;Encephalopathy;Endocrine disorder;Endocrine ophthalmopathy;Endotracheal intubation;Enteritis;Enteritis leukopenic;Enterobacter pneumonia;Enterocolitis;Enteropathic spondylitis;Eosinopenia;Eosinophilic

fasciitis;Eosinophilic granulomatosis with polyangiitis;Eosinophilic oesophagitis;Epidermolysis;Epilepsy;Epilepsy surgery;Epilepsy with myoclonic-atonic seizures;Epileptic aura;Epileptic psychosis;Erythema;Erythema induratum;Erythema multiforme;Erythema nodosum;Evans syndrome;Exanthema subitum;Expanded disability status scale score decreased;Expanded disability status scale score increased;Exposure to communicable disease;Exposure to SARS-CoV-2;Eye oedema;Eye pruritus;Eye swelling;Eyelid oedema;Face oedema;Facial paralysis;Facial paresis;Faciobrachial dystonic seizure;Fat embolism;Febrile convulsion;Febrile infection-related epilepsy syndrome;Febrile neutropenia;Felty's syndrome;Femoral artery embolism;Fibrillary glomerulonephritis;Fibromyalgia;Flushing;Foaming at mouth;Focal cortical resection;Focal dyscognitive seizures;Foetal distress syndrome;Foetal placental thrombosis;Foetor hepaticus;Foreign body embolism;Frontal lobe epilepsy;Fulminant type 1 diabetes mellitus;Galactose elimination capacity test abnormal;Galactose elimination capacity test decreased;Gamma-glutamyltransferase abnormal;Gamma-glutamyltransferase increased;Gastritis herpes;Gastrointestinal amyloidosis;Gelastic seizure;Generalised onset non-motor seizure;Generalised tonic-clonic seizure;Genital herpes;Genital herpes simplex;Genital herpes zoster;Giant cell arteritis;Glomerulonephritis;Glomerulonephritis membranoproliferative;Glomerulonephritis membranous;Glomerulonephritis rapidly progressive;Glossopharyngeal nerve paralysis;Glucose transporter type 1 deficiency syndrome;Glutamate dehydrogenase increased;Glycocholic acid increased;GM2 gangliosidosis;Goodpasture's syndrome;Graft thrombosis;Granulocytopenia;Granulocytopenia neonatal;Granulomatosis with polyangiitis;Granulomatous dermatitis;Grey matter heterotopia;Guanase increased;Guillain-Barre syndrome;Haemolytic anaemia;Haemophagocytic lymphohistiocytosis;Haemorrhage;Haemorrhagic ascites;Haemorrhagic disorder;Haemorrhagic pneumonia;Haemorrhagic varicella syndrome;Haemorrhagic vasculitis;Hantavirus pulmonary infection;Hashimoto's encephalopathy;Hashitoxicosis;Hemimegalencephaly;Henoch-Schonlein purpura;Henoch-Schonlein purpura nephritis;Hepaplastin abnormal;Hepaplastin decreased;Heparin-induced thrombocytopenia;Hepatic amyloidosis;Hepatic artery embolism;Hepatic artery flow decreased;Hepatic artery thrombosis;Hepatic enzyme abnormal;Hepatic enzyme decreased;Hepatic enzyme increased;Hepatic fibrosis marker abnormal;Hepatic fibrosis marker increased;Hepatic function abnormal;Hepatic hydrothorax;Hepatic hypertrophy;Hepatic hypoperfusion;Hepatic lymphocytic infiltration;Hepatic mass;Hepatic pain;Hepatic sequestration;Hepatic vascular resistance increased;Hepatic vascular thrombosis;Hepatic vein embolism;Hepatic vein thrombosis;Hepatic venous pressure gradient abnormal;Hepatic venous pressure gradient increased;Hepatitis;Hepatobiliary scan abnormal;Hepatomegaly;Hepatosplenomegaly;Hereditary angioedema with C1 esterase inhibitor deficiency;Herpes dermatitis;Herpes gestationis;Herpes oesophagitis;Herpes ophthalmic;Herpes pharyngitis;Herpes sepsis;Herpes simplex;Herpes simplex cervicitis;Herpes simplex colitis;Herpes simplex encephalitis;Herpes simplex gastritis;Herpes simplex hepatitis;Herpes simplex meningitis;Herpes simplex meningoencephalitis;Herpes simplex meningomyelitis;Herpes simplex necrotising retinopathy;Herpes simplex oesophagitis;Herpes simplex otitis externa;Herpes simplex pharyngitis;Herpes simplex pneumonia;Herpes simplex reactivation;Herpes simplex sepsis;Herpes simplex viraemia;Herpes simplex virus conjunctivitis neonatal;Herpes simplex visceral;Herpes virus

infection;Herpes zoster;Herpes zoster cutaneous disseminated;Herpes zoster infection neurological;Herpes zoster meningitis;Herpes zoster meningoencephalitis;Herpes zoster meningomyelitis;Herpes zoster meningoradiculitis;Herpes zoster necrotising retinopathy;Herpes zoster oticus;Herpes zoster pharyngitis;Herpes zoster reactivation;Herpetic radiculopathy;Histone antibody positive;Hoigne's syndrome;Human herpesvirus 6 encephalitis;Human herpesvirus 6 infection;Human herpesvirus 6 infection reactivation;Human herpesvirus 7 infection;Human herpesvirus 8 infection;Hyperammonaemia;Hyperbilirubinaemia;Hypercholia;Hypergammaglobulinaemia benign monoclonal;Hyperglycaemic seizure;Hypersensitivity;Hypersensitivity vasculitis;Hyperthyroidism;Hypertransaminaemia;Hyperventilation;Hypoalbuminaemia;Hypocalcaemic seizure;Hypogammaglobulinaemia;Hypoglossal nerve paralysis;Hypoglossal nerve paresis;Hypoglycaemic seizure;Hyponatraemic seizure;Hypotension;Hypotensive crisis;Hypothenar hammer syndrome;Hypothyroidism;Hypoxia;Idiopathic CD4 lymphocytopenia;Idiopathic generalised epilepsy;Idiopathic interstitial pneumonia;Idiopathic neutropenia;Idiopathic pulmonary fibrosis;IgA nephropathy;IgM nephropathy;IIIrd nerve paralysis;IIIrd nerve paresis;Iliac artery embolism;Immune thrombocytopenia;Immune-mediated adverse reaction;Immune-mediated cholangitis;Immune-mediated cholestasis;Immune-mediated cytopenia;Immune-mediated encephalitis;Immune-mediated encephalopathy;Immune-mediated endocrinopathy;Immune-mediated enterocolitis;Immune-mediated gastritis;Immune-mediated hepatic disorder;Immune-mediated hepatitis;Immune-mediated hyperthyroidism;Immune-mediated hypothyroidism;Immune-mediated myocarditis;Immune-mediated myositis;Immune-mediated nephritis;Immune-mediated neuropathy;Immune-mediated pancreatitis;Immune-mediated pneumonitis;Immune-mediated renal disorder;Immune-mediated thyroiditis;Immune-mediated uveitis;Immunoglobulin G4 related disease;Immunoglobulins abnormal;Implant site thrombosis;Inclusion body myositis;Infantile genetic agranulocytosis;Infantile spasms;Infected vasculitis;Infective thrombosis;Inflammation;Inflammatory bowel disease;Infusion site thrombosis;Infusion site vasculitis;Injection site thrombosis;Injection site urticaria;Injection site vasculitis;Instillation site thrombosis;Insulin autoimmune syndrome;Interstitial granulomatous dermatitis;Interstitial lung disease;Intracardiac mass;Intracardiac thrombus;Intracranial pressure increased;Intrapericardial thrombosis;Intrinsic factor antibody abnormal;Intrinsic factor antibody positive;IPEX syndrome;Irregular breathing;IRVAN syndrome;IVth nerve paralysis;IVth nerve paresis;JC polyomavirus test positive;JC virus CSF test positive;Jeavons syndrome;Jugular vein embolism;Jugular vein thrombosis;Juvenile idiopathic arthritis;Juvenile myoclonic epilepsy;Juvenile polymyositis;Juvenile psoriatic arthritis;Juvenile spondyloarthritis;Kaposi sarcoma inflammatory cytokine syndrome;Kawasaki's disease;Kayser-Fleischer ring;Keratoderma blenorrhagica;Ketosis-prone diabetes mellitus;Kounis syndrome;Lafora's myoclonic epilepsy;Lamb's excrescences;Laryngeal dyspnoea;Laryngeal oedema;Laryngeal rheumatoid arthritis;Laryngospasm;Laryngotracheal oedema;Latent autoimmune diabetes in adults;LE cells present;Lemierre syndrome;Lennox-Gastaut syndrome;Leucine aminopeptidase increased;Leukoencephalomyelitis;Leukoencephalopathy;Leukopenia;Leukopenia neonatal;Lewis-Sumner syndrome;Lhermitte's sign;Lichen planopilaris;Lichen planus;Lichen sclerosus;Limbic encephalitis;Linear IgA disease;Lip oedema;Lip swelling;Liver function test abnormal;Liver function test decreased;Liver function test increased;Liver induration;Liver injury;Liver iron concentration abnormal;Liver iron concentration

increased;Liver opacity;Liver palpable;Liver sarcoidosis;Liver scan abnormal;Liver tenderness;Low birth weight baby;Lower respiratory tract herpes infection;Lower respiratory tract infection;Lower respiratory tract infection viral;Lung abscess;Lupoid hepatic cirrhosis;Lupus cystitis;Lupus encephalitis;Lupus endocarditis;Lupus enteritis;Lupus hepatitis;Lupus myocarditis;Lupus myositis;Lupus nephritis;Lupus pancreatitis;Lupus pleurisy;Lupus pneumonitis;Lupus vasculitis;Lupus-like syndrome;Lymphocytic hypophysitis;Lymphocytopenia neonatal;Lymphopenia;MAGIC syndrome;Magnetic resonance imaging liver abnormal;Magnetic resonance proton density fat fraction measurement;Mahler sign;Manufacturing laboratory analytical testing issue;Manufacturing materials issue;Manufacturing production issue;Marburg's variant multiple sclerosis;Marchiafava-Bignami disease;Marine Lenhart syndrome;Mastocytic enterocolitis;Maternal exposure during pregnancy;Medical device site thrombosis;Medical device site vasculitis;MELAS syndrome;Meningitis;Meningitis aseptic;Meningitis herpes;Meningoencephalitis herpes simplex neonatal;Meningoencephalitis herpetic;Meningomyelitis herpes;MERS-CoV test;MERS-CoV test negative;MERS-CoV test positive;Mesangioproliferative glomerulonephritis;Mesenteric artery embolism;Mesenteric artery thrombosis;Mesenteric vein thrombosis;Metapneumovirus infection;Metastatic cutaneous Crohn's disease;Metastatic pulmonary embolism;Microangiopathy;Microembolism;Microscopic polyangiitis;Middle East respiratory syndrome;Migraine-triggered seizure;Miliary pneumonia;Miller Fisher syndrome;Mitochondrial aspartate aminotransferase increased;Mixed connective tissue disease;Model for end stage liver disease score abnormal;Model for end stage liver disease score increased;Molar ratio of total branched-chain amino acid to tyrosine;Molybdenum cofactor deficiency;Monocytopenia;Mononeuritis;Mononeuropathy multiplex;Morphoea;Morvan syndrome;Mouth swelling;Moyamoya disease;Multifocal motor neuropathy;Multiple organ dysfunction syndrome;Multiple sclerosis;Multiple sclerosis relapse;Multiple sclerosis relapse prophylaxis;Multiple subpial transection;Multisystem inflammatory syndrome in children;Muscular sarcoidosis;Myasthenia gravis;Myasthenia gravis crisis;Myasthenia gravis neonatal;Myasthenic syndrome;Myelitis;Myelitis transverse;Myocardial infarction;Myocarditis;Myocarditis post infection;Myoclonic epilepsy;Myoclonic epilepsy and ragged-red fibres;Myokymia;Myositis;Narcolepsy;Nasal herpes;Nasal obstruction;Necrotising herpetic retinopathy;Neonatal Crohn's disease;Neonatal epileptic seizure;Neonatal lupus erythematosus;Neonatal mucocutaneous herpes simplex;Neonatal pneumonia;Neonatal seizure;Nephritis;Nephrogenic systemic fibrosis;Neuralgic amyotrophy;Neuritis;Neuritis cranial;Neuromyelitis optica pseudo relapse;Neuromyelitis optica spectrum disorder;Neuromyotonia;Neuronal neuropathy;Neuropathy peripheral;Neuropathy, ataxia, retinitis pigmentosa syndrome;Neuropsychiatric lupus;Neurosarcoidosis;Neutropenia;Neutropenia neonatal;Neutropenic colitis;Neutropenic infection;Neutropenic sepsis;Nodular rash;Nodular vasculitis;Noninfectious myelitis;Noninfective encephalitis;Noninfective encephalomyelitis;Noninfective oophoritis;Obstetrical pulmonary embolism;Occupational exposure to communicable disease;Occupational exposure to SARS-CoV-2;Ocular hyperaemia;Ocular myasthenia;Ocular pemphigoid;Ocular sarcoidosis;Ocular vasculitis;Oculofacial paralysis;Oedema;Oedema blister;Oedema due to hepatic disease;Oedema mouth;Oesophageal achalasia;Ophthalmic artery thrombosis;Ophthalmic herpes simplex;Ophthalmic herpes zoster;Ophthalmic vein thrombosis;Optic neuritis;Optic

neuropathy;Optic perineuritis;Oral herpes;Oral lichen planus;Oropharyngeal oedema;Oropharyngeal spasm;Oropharyngeal swelling;Osmotic demyelination syndrome;Ovarian vein thrombosis;Overlap syndrome;Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection;Paget-Schroetter syndrome;Palindromic rheumatism;Palisaded neutrophilic granulomatous dermatitis;Palmoplantar keratoderma;Palpable purpura;Pancreatitis;Panencephalitis;Papillophlebitis;Paracancerous pneumonia;Paradoxical embolism;Parainfluenzae viral laryngotracheobronchitis;Paraneoplastic dermatomyositis;Paraneoplastic pemphigus;Paraneoplastic thrombosis;Paresis cranial nerve;Parietal cell antibody positive;Paroxysmal nocturnal haemoglobinuria;Partial seizures;Partial seizures with secondary generalisation;Patient isolation;Pelvic venous thrombosis;Pemphigoid;Pemphigus;Penile vein thrombosis;Pericarditis;Pericarditis lupus;Perihepatic discomfort;Periorbital oedema;Periorbital swelling;Peripheral artery thrombosis;Peripheral embolism;Peripheral ischaemia;Peripheral vein thrombus extension;Periportal oedema;Peritoneal fluid protein abnormal;Peritoneal fluid protein decreased;Peritoneal fluid protein increased;Peritonitis lupus;Pernicious anaemia;Petit mal epilepsy;Pharyngeal oedema;Pharyngeal swelling;Pityriasis lichenoides et varioliformis acuta;Placenta praevia;Pleuroparenchymal fibroelastosis;Pneumobilia;Pneumonia;Pneumonia adenoviral;Pneumonia cytomegaloviral;Pneumonia herpes viral;Pneumonia influenzal;Pneumonia measles;Pneumonia mycoplasmal;Pneumonia necrotising;Pneumonia parainfluenzae viral;Pneumonia respiratory syncytial viral;Pneumonia viral;POEMS syndrome;Polyarteritis nodosa;Polyarthritis;Polychondritis;Polyglandular autoimmune syndrome type I;Polyglandular autoimmune syndrome type II;Polyglandular autoimmune syndrome type III;Polyglandular disorder;Polymicrogyria;Polymyalgia rheumatica;Polymyositis;Polyneuropathy;Polyneuropathy idiopathic progressive;Portal pyaemia;Portal vein embolism;Portal vein flow decreased;Portal vein pressure increased;Portal vein thrombosis;Portosplenomesenteric venous thrombosis;Post procedural hypotension;Post procedural pneumonia;Post procedural pulmonary embolism;Post stroke epilepsy;Post stroke seizure;Post thrombotic retinopathy;Post thrombotic syndrome;Post viral fatigue syndrome;Postictal headache;Postictal paralysis;Postictal psychosis;Postictal state;Postoperative respiratory distress;Postoperative respiratory failure;Postoperative thrombosis;Postpartum thrombosis;Postpartum venous thrombosis;Postpericardiotomy syndrome;Post-traumatic epilepsy;Postural orthostatic tachycardia syndrome;Precerebral artery thrombosis;Pre-eclampsia;Preictal state;Premature labour;Premature menopause;Primary amyloidosis;Primary biliary cholangitis;Primary progressive multiple sclerosis;Procedural shock;Proctitis herpes;Proctitis ulcerative;Product availability issue;Product distribution issue;Product supply issue;Progressive facial hemiatrophy;Progressive multifocal leukoencephalopathy;Progressive multiple sclerosis;Progressive relapsing multiple sclerosis;Prosthetic cardiac valve thrombosis;Pruritus;Pruritus allergic;Pseudovasculitis;Psoriasis;Psoriatic arthropathy;Pulmonary amyloidosis;Pulmonary artery thrombosis;Pulmonary embolism;Pulmonary fibrosis;Pulmonary haemorrhage;Pulmonary microemboli;Pulmonary oil microembolism;Pulmonary renal syndrome;Pulmonary sarcoidosis;Pulmonary sepsis;Pulmonary thrombosis;Pulmonary tumour thrombotic microangiopathy;Pulmonary vasculitis;Pulmonary veno-occlusive disease;Pulmonary venous thrombosis;Pyoderma gangrenosum;Pyostomatitis vegetans;Pyrexia;Quarantine;Radiation leukopenia;Radiculitis

brachial;Radiologically isolated syndrome;Rash;Rash erythematous;Rash pruritic;Rasmussen encephalitis;Raynaud's phenomenon;Reactive capillary endothelial proliferation;Relapsing multiple sclerosis;Relapsing-remitting multiple sclerosis;Renal amyloidosis;Renal arteritis;Renal artery thrombosis;Renal embolism;Renal failure;Renal vascular thrombosis;Renal vasculitis;Renal vein embolism;Renal vein thrombosis;Respiratory arrest;Respiratory disorder;Respiratory distress;Respiratory failure;Respiratory paralysis;Respiratory syncytial virus bronchiolitis;Respiratory syncytial virus bronchitis;Retinal artery embolism;Retinal artery occlusion;Retinal artery thrombosis;Retinal vascular thrombosis;Retinal vasculitis;Retinal vein occlusion;Retinal vein thrombosis;Retinol binding protein decreased;Retinopathy;Retrograde portal vein flow;Retroperitoneal fibrosis;Reversible airways obstruction;Reynold's syndrome;Rheumatic brain disease;Rheumatic disorder;Rheumatoid arthritis;Rheumatoid factor increased;Rheumatoid factor positive;Rheumatoid factor quantitative increased;Rheumatoid lung;Rheumatoid neutrophilic dermatosis;Rheumatoid nodule;Rheumatoid nodule removal;Rheumatoid scleritis;Rheumatoid vasculitis;Saccadic eye movement;SAPHO syndrome;Sarcoidosis;SARS-CoV-1 test;SARS-CoV-1 test negative;SARS-CoV-1 test positive;SARS-CoV-2 antibody test;SARS-CoV-2 antibody test negative;SARS-CoV-2 antibody test positive;SARS-CoV-2 carrier;SARS-CoV-2 sepsis;SARS-CoV-2 test;SARS-CoV-2 test false negative;SARS-CoV-2 test false positive;SARS-CoV-2 test negative;SARS-CoV-2 test positive;SARS-CoV-2 viraemia;Satoyoshi syndrome;Schizencephaly;Scleritis;Sclerodactylia;Scleroderma;Scleroderma associated digital ulcer;Scleroderma renal crisis;Scleroderma-like reaction;Secondary amyloidosis;Secondary cerebellar degeneration;Secondary progressive multiple sclerosis;Segmented hyalinising vasculitis;Seizure;Seizure anoxic;Seizure cluster;Seizure like phenomena;Seizure prophylaxis;Sensation of foreign body;Septic embolus;Septic pulmonary embolism;Severe acute respiratory syndrome;Severe myoclonic epilepsy of infancy;Shock;Shock symptom;Shrinking lung syndrome;Shunt thrombosis;Silent thyroiditis;Simple partial seizures;Sjogren's syndrome;Skin swelling;SLE arthritis;Smooth muscle antibody positive;Sneezing;Spinal artery embolism;Spinal artery thrombosis;Splenic artery thrombosis;Splenic embolism;Splenic thrombosis;Splenic vein thrombosis;Spondylitis;Spondyloarthropathy;Spontaneous heparin-induced thrombocytopenia syndrome;Status epilepticus;Stevens-Johnson syndrome;Stiff leg syndrome;Stiff person syndrome;Stillbirth;Still's disease;Stoma site thrombosis;Stoma site vasculitis;Stress cardiomyopathy;Stridor;Subacute cutaneous lupus erythematosus;Subacute endocarditis;Subacute inflammatory demyelinating polyneuropathy;Subclavian artery embolism;Subclavian artery thrombosis;Subclavian vein thrombosis;Sudden unexplained death in epilepsy;Superior sagittal sinus thrombosis;Susac's syndrome;Suspected COVID-19;Swelling;Swelling face;Swelling of eyelid;Swollen tongue;Sympathetic ophthalmia;Systemic lupus erythematosus;Systemic lupus erythematosus disease activity index abnormal;Systemic lupus erythematosus disease activity index decreased;Systemic lupus erythematosus disease activity index increased;Systemic lupus erythematosus rash;Systemic scleroderma;Systemic sclerosis pulmonary;Tachycardia;Tachypnoea;Takayasu's arteritis;Temporal lobe epilepsy;Terminal ileitis;Testicular autoimmunity;Throat tightness;Thromboangiitis obliterans;Thrombocytopenia;Thrombocytopenic purpura;Thrombophlebitis;Thrombophlebitis migrans;Thrombophlebitis

neonatal;Thrombophlebitis septic;Thrombophlebitis superficial;Thromboplastin antibody positive;Thrombosis;Thrombosis corpora cavernosa;Thrombosis in device;Thrombosis mesenteric vessel;Thrombotic cerebral infarction;Thrombotic microangiopathy;Thrombotic stroke;Thrombotic thrombocytopenic purpura;Thyroid disorder;Thyroid stimulating immunoglobulin increased;Thyroiditis;Tongue amyloidosis;Tongue biting;Tongue oedema;Tonic clonic movements;Tonic convulsion;Tonic posturing;Topectomy;Total bile acids increased;Toxic epidermal necrolysis;Toxic leukoencephalopathy;Toxic oil syndrome;Tracheal obstruction;Tracheal oedema;Tracheobronchitis;Tracheobronchitis mycoplasmal;Tracheobronchitis viral;Transaminases abnormal;Transaminases increased;Transfusion-related alloimmune neutropenia;Transient epileptic amnesia;Transverse sinus thrombosis;Trigeminal nerve paresis;Trigeminal neuralgia;Trigeminal palsy;Truncus coeliacus thrombosis;Tuberous sclerosis complex;Tubulointerstitial nephritis and uveitis syndrome;Tumefactive multiple sclerosis;Tumour embolism;Tumour thrombosis;Type 1 diabetes mellitus;Type I hypersensitivity;Type III immune complex mediated reaction;Uhthoff's phenomenon;Ulcerative keratitis;Ultrasound liver abnormal;Umbilical cord thrombosis;Uncinate fits;Undifferentiated connective tissue disease;Upper airway obstruction;Urine bilirubin increased;Urobilinogen urine decreased;Urobilinogen urine increased;Urticaria;Urticaria papular;Urticarial vasculitis;Uterine rupture;Uveitis;Vaccination site thrombosis;Vaccination site vasculitis;Vagus nerve paralysis;Varicella;Varicella keratitis;Varicella post vaccine;Varicella zoster gastritis;Varicella zoster oesophagitis;Varicella zoster pneumonia;Varicella zoster sepsis;Varicella zoster virus infection;Vasa praevia;Vascular graft thrombosis;Vascular pseudoaneurysm thrombosis;Vascular purpura;Vascular stent thrombosis;Vasculitic rash;Vasculitic ulcer;Vasculitis;Vasculitis gastrointestinal;Vasculitis necrotising;Vena cava embolism;Vena cava thrombosis;Venous intravasation;Venous recanalisation;Venous thrombosis;Venous thrombosis in pregnancy;Venous thrombosis limb;Venous thrombosis neonatal;Vertebral artery thrombosis;Vessel puncture site thrombosis;Visceral venous thrombosis;VIth nerve paralysis;VIth nerve paresis;Vitiligo;Vocal cord paralysis;Vocal cord paresis;Vogt-Koyanagi-Harada disease;Warm type haemolytic anaemia;Wheezing;White nipple sign;XIth nerve paralysis;X-ray hepatobiliary abnormal;Young's syndrome;Zika virus associated Guillain Barre syndrome.

2.4 NONCLINICAL OVERVIEW

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LIST OF ABBREVIATIONS AND DEFINITION OF TERMS

A:G	Albumin:globulin ratio
ACE	Angiotension-converting enzyme
ADME	Absorption, distribution, metabolism, excretion
ALC-0159	Proprietary PEG-lipid included as an excipient in the LNP formulation used in BNT162b2
ALC-0315	Proprietary amino-lipid included as an excipient in the LNP formulation used in BNT162b2
ALT	Alanine aminotransferase
AST	Aspartate aminotransferase
BAL	Bronchoalveolar lavage
CAS	Chemical abstracts service
CBER	Center for Biologics Evaluation and Research
CD	Cluster of differentiation
COVID-19	Coronavirus Disease 2019
DART	Developmental and reproductive toxicity
DNA	Deoxyribonucleic acid
DSPC	1,2-distearoyl-sn-glycero-3-phosphocholine
ELISA	Enzyme-linked immunosorbent assay
EUA	Emergency Use Authorization
F0	Parental generation administered vaccine
F1	First generation offspring of F0 generation
GD	Gestation day
GGT	Gamma-glutamyl transferase
GLP	Good Laboratory Practice
H	Human (in metabolite scheme)
[³ H]-CHE	Radiolabeled [Cholesteryl-1,2- ³ H(N)]-Cholesteryl Hexadecyl Ether
HGB	Hemoglobin
IFN	Interferon
IgG	Immunoglobulin G
IL	Interleukin
IM	Intramuscular(ly)
IND	Investigational New Drug Application
IV	Intravenous(ly)
LC/MS	Liquid chromatography-tandem mass spectrometry
LD	Lactation day
LNP	Lipid-nanoparticle
Luc	Luciferase (from firefly <i>Pyroactomena lucifera</i>)
LUC	Large unstained cell
Mk	Monkey (in metabolite scheme)
Mo	Mouse (in metabolite scheme)
modRNA	Nucleoside-modified mRNA
mRNA	Messenger RNA
NA	Not applicable

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LIST OF ABBREVIATIONS AND DEFINITION OF TERMS - CONTINUED

NHP	Nonhuman primate
OECD	Organisation for Economic Co-operation and Development
P2 S	Spike protein P2 mutant
PEG	Polyethylene glycol
PK	Pharmacokinetics
PLT	Platelet
PND	Postnatal day
PT	Prothrombin time
QC	Quality control review
QW	Once weekly
R	Rat (in metabolite scheme)
RBC	Red blood cell
RBD	Receptor binding domain
RdRp	RNA-dependent RNA-polymerase
RDW	Red cell distribution width
RETIC	Reticulocyte
RNA	Ribonucleic acid
RT-PCR	Reverse transcription-polymerase chain reaction
S	SARS-CoV-2 spike glycoprotein
S1	S1 domain of the SARS-CoV-2 spike glycoprotein
S9	Supernatant fraction obtained from liver homogenate by centrifuging at 9000 g
SARS	Severe Acute Respiratory Syndrome
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2; coronavirus causing COVID-19
Tfh	T follicular helper cell
Th1	Type 1 T helper cells
TK	Toxicokinetic
TNF	Tumor necrosis factor
V8	Variant 8; P2 S
V9	Variant 9; P2 S
WBC	White blood cell
WHO	World Health Organization

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2.4.1. OVERVIEW OF NONCLINICAL TESTING STRATEGY

BNT162b2 (BioNTech code number BNT162, Pfizer code number PF-07302048) is an investigational vaccine intended to prevent COVID-19, which is caused by SARS-CoV-2. BNT162b2 is a nucleoside modified mRNA (modRNA) expressing full-length S with two proline mutations (P2) to lock the transmembrane protein in an antigenically optimal prefusion conformation (Pallesen et al, 2017; Wrapp et al, 2020). The vaccine is formulated in lipid nanoparticles (LNPs). The LNP is composed of 4 lipids: ALC-0315, ALC-0159, DSPC, and cholesterol. Other excipients in the formulation include sucrose, NaCl, KCl, Na₂HPO₄, and KH₂PO₄. The dose selected for BNT162b2, with efficacy demonstrated in Phase 2/3 clinical evaluation and intended for commercial use, is 30 µg administered IM as two doses given 21 days apart.

In nonclinical studies, two variants of BNT162b2 were tested; designated “variant 8” and “variant 9” (V8 and V9, respectively). The variants differ only in their codon optimization sequences which are designed to improve antigen expression, otherwise the amino acid sequences of the encoded antigens are identical. Only BNT162b2 (V9) has been evaluated in the clinic, is currently authorized under EUA, and is the subject of this BLA application. The characteristics of each variant are described in the table below (Table 2.4.1-1).

Table 2.4.1-1. Nomenclature of the Vaccine Candidates

Product Code	RNA Platform	Antigen Variant	Description/Translated Protein	Variant Code	GLP Tox Data	Clinical Candidate
BNT162b2	modRNA	V8 ^a	P2 S	RBP020.1	Yes	No
BNT162b2	modRNA	V9^a	P2 S	RBP020.2	Yes	Yes

a. The V8 and V9 variants of the P2 S antigen have the same amino acid sequence. Different codon optimizations were used for their ribonucleotide sequences.

Bold: BNT162b2 (V9) vaccine candidate submitted for licensure.

The primary pharmacology, distribution, metabolism, and safety of BNT162b2 were evaluated in nonclinical pharmacology, pharmacokinetic, and toxicity studies in vitro and in vivo (Table 2.4.1-2).

Immunogenicity of BNT162b2 was evaluated in mice (2.4.2.1.3), rats (2.4.2.1.5) and nonhuman primates (2.4.2.1.4). For assessment of serum antibody responses in mice and rats, S1 and RBD-binding IgG responses were tested by an ELISA. Functional antibody responses were tested by a SARS-CoV-2 pseudotype neutralization assay (pVNT). In nonhuman primate studies, S1-binding IgG responses were tested in a direct Luminex-based immunoassay (dLIA) and functional antibody responses were assessed in a SARS-CoV-2 neutralization assay. S-specific T cell responses were assessed in mouse and nonhuman primate studies in an IFNγ ELISpot and by intracellular cytokine staining flow cytometry-based analysis of the Th1/Th2 profile using splenocytes.

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A SARS-CoV-2 challenge study in BNT162b2 (V9)-immunized nonhuman primates was also conducted to assess protection against infection and to demonstrate lack of disease enhancement ([Section 2.4.2.1.4.2](#)).

Platform properties that support BNT162b2 were initially demonstrated with non-SARS-CoV-2 antigens. Non-GLP in vivo testing of an LNP-formulated modRNA encoding luciferase examined biodistribution in BALB/c mice and Wistar Han rats after IM injection ([Section 2.4.3.4](#)) and the PK of the two novel excipients in the LNP formulation, ALC-0315 and ALC-0159, in Wistar Han rats ([Section 2.4.3.3](#)). In addition, the metabolism of ALC-0315 and ALC-0159 was evaluated in mouse, rat, monkey, and human blood, liver microsomes, S9 fractions, and hepatocytes and in vivo in rat plasma, urine, feces, and liver samples from the PK study ([Table 2.4.1-2](#); [Section 2.4.3.5](#)).

BNT162b2 (V8) and (V9) have been studied in GLP-compliant repeat-dose toxicity studies in rats ([Table 2.4.1-2](#)). Two GLP repeat-dose toxicity studies for BNT162b2 (V8) and BNT162b2 (V9), one study for each variant, have been completed. The study designs are described in [Section 2.4.4](#) and are based on WHO guidelines for vaccine development ([WHO, 2005](#)). A DART study with BNT162b2 (V9) in rats has also been completed. No additional toxicity studies are planned for BNT162b2.

IM administration was chosen for the toxicity studies as this is the intended route of administration. Rats were chosen for toxicity assessments as they are a commonly used animal species for the evaluation of toxicity, and they mount an antigen-specific immune response to vaccination with BNT162b2.

The design of the nonclinical repeat-dose toxicity studies was consistent with the WHO Guidelines on Nonclinical Evaluation of Vaccines, the EMA Note for Guidance on Preclinical Pharmacological and Toxicological Testing of Vaccines, and Japan guidance on the nonclinical safety assessment of vaccines. In addition, the 2020 CBER guidance on “Development and Licensure of Vaccines to Prevent COVID-19” ([US FDA, 2020](#)) was considered when assembling the nonclinical safety licensure package as well as feedback from regulatory agencies. All GLP-compliant studies were conducted in accordance with Good Laboratory Practice for Nonclinical Laboratory Studies, Code of US Federal Regulations (21 CFR Part 58), in an OECD Mutual Acceptance of Data member state. All nonclinical studies described herein were conducted by or for Pfizer Inc or BioNTech RNA Pharmaceuticals GmbH. The location of records for inspection is included in each final study report.

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Table 2.4.1-2. Nonclinical Studies

Study Number	Study Type	Species / Test System	Test Item	Dose [RNA]	Cross reference
Pharmacology - BNT162b2 studies					
R-20-0085	In vivo immunogenicity	BALB/c mice	BNT162b2 (V9)	0.2, 1, 5 µg	Section 2.4.2.1.3
R-20-0112	In vivo immunogenicity	BALB/c mice	BNT162a1, BNT162b1, BNT162b2 (V9), BNT162c2	5 µg	Section 2.4.2.1.3
R-20-0211	In vitro protein expression	Cell culture	BNT162b2 (V9)	varied	Section 2.4.2.1.2
VR-VTR-10741	In vitro protein expression	Cell culture	BNT162b2 (V9)	varied	Section 2.4.2.1.2
VR-VTR-10671	In vivo immunogenicity and SARS-CoV-2 challenge	Rhesus macaques	BNT162b2 (V9)	30 and 100 µg	Section 2.4.2.1.4
ADME					
PF-07302048_06Jul20_072424	PK of ALC-0315 and ALC-0159	Wistar Han Rats	modRNA encoding luciferase formulated in LNP comparable to BNT162b2	1 mg/kg	Section 2.4.3.3
R-20-0072	In vivo distribution	BALB/c mice	modRNA encoding luciferase formulated in LNP comparable to BNT162b2	2 µg	Section 2.4.3.4
185350	In vivo distribution	Wistar Han Rats	modRNA encoding luciferase formulated in LNP comparable to BNT162b2 with trace amounts of [³ H]-CHE as non-diffusible label	50 µg	Section 2.4.3.4
01049-20008	In vitro metabolism	CD-1/ICR mouse, Wistar Han and/or Sprague Dawley rat, cynomolgus monkey and human liver microsomes, S9 fraction, hepatocytes	ALC-0315	NA	Section 2.4.3.5
01049-20009					
01049-20010					
01049-20020			ALC-0159	NA	
01049-20021					
01049-20022					

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Table 2.4.1-2. Nonclinical Studies - Continued

Study Number	Study Type	Species / Test System	Test Item	Dose [RNA]	Cross reference
PF-07302048 _05Aug20_043725	In vitro and in vivo metabolism	Blood, liver S9 fractions and hepatocytes from CD-1 mouse, Wistar Han rat, cynomolgus monkey and human. In vivo samples from Wistar Han rat plasma, urine, feces, and liver	In vitro: ALC-0315 and ALC-0159 In vivo: modRNA encoding luciferase formulated in LNP comparable to BNT162b2	1 mg/kg modRNA (in vivo samples)	Section 2.4.3.5
Toxicology – Studies with BNT162b2 variants					
38166	Repeat-dose toxicity	Wistar Han Rats	BNT162b2 (V8)	100 µg	Section 2.4.4.3
20GR142	Repeat-dose toxicity	Wistar Han Rats	BNT162b2 (V9)	30 µg	Section 2.4.4.3
20256434	Development and Reproductive Toxicity	Wistar Han Rats	BNT162b2 (V9)	30 µg	Section 2.4.4.6

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2.4.2. PHARMACOLOGY

2.4.2.1. Primary Pharmacodynamics

2.4.2.1.1. Summary

BNT162b2 (BioNTech code number BNT162, Pfizer code number PF-07302048) is a nucleoside-modified mRNA (modRNA) vaccine that encodes the SARS-CoV-2 full-length spike glycoprotein (S). The glycoprotein encoded by both BNT162b2 variants includes two amino acid substitutions to proline (P2 S) locking the transmembrane protein in an antigenically optimal prefusion conformation (Wrapp et al, 2020; Pallesen et al, 2017). The RNA is formulated with functional and structural lipids, which protect the RNA from degradation and enable transfection of the RNA into host cells after IM injection. S is a major target of virus neutralizing antibodies and is a key antigen for vaccine development. The well-resolved trimeric prefusion structure and the high affinity binding to ACE2 and human neutralizing antibodies demonstrate that the recombinant P2 S authentically presents the ACE2 binding site and other epitopes targeted by many SARS-CoV-2 neutralizing antibodies.

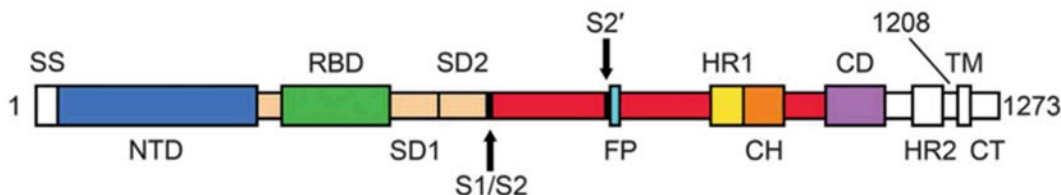
In vitro studies and in vivo studies in mice and nonhuman primates demonstrate the mechanism of action for this RNA-based vaccine, which is to encode SARS-CoV-2 S that induces an immune response characterized by both a strong neutralizing antibody response and Th1-type CD4⁺ and an IFN γ ⁺ CD8⁺ T-cell response. BNT162b2 immunization protected rhesus macaques from infectious SARS-CoV-2 challenge, with reduced detection of viral RNA in vaccine-immunized animals compared to saline-immunized animals and with no evidence of clinical exacerbation.

2.4.2.1.2. BNT162b2, A Lipid Nanoparticle Encapsulated RNA Vaccine Encoding the SARS-CoV-2 P2 S as a Vaccine Antigen

BNT162b2 is based on a nucleoside-modified mRNA (modRNA) platform technology. Vaccination with modRNA formulated in LNPs is characterized by strong expansion of Th1-skewed antigen-specific T follicular helper (Tfh) cells, which stimulate and expand germinal center B cells, thereby resulting in particularly strong, long lived, high-affinity antibody responses (Sahin et al, 2014; Pardi et al, 2018). ModRNA vaccine candidates against other infectious diseases induce strong antibody responses and prime and expand multifunctional CD4⁺ and CD8⁺ T cells (Pardi et al, 2017; Pardi et al, 2018).

SARS-CoV-2 S is a large, trimeric glycoprotein that exists predominantly in a prefusion conformation on the virion (Ke et al, 2020). It is cleaved by furin into an N-terminal S1 and a C-terminal S2 fragment. S attaches to the host cell receptor, ACE2, by its receptor binding domain which is contained in the S1 furin cleavage fragment. Spontaneously and during cell entry, the S1 fragment dissociates, and the S2 fragment undergoes a fold-back rearrangement to the post-fusion conformation in a process that facilitates fusion of viral and host cell membranes. S is the main target of virus neutralizing antibodies (Zakhartchouk et al, 2007; Yong et al, 2019). Most of the antibodies with SARS-CoV-2 neutralizing activity are directed against the RBD (Jiang et al, 2020; Zost et al, 2020).

Figure 2.4.2-1. Schematic of the Organization of the SARS-CoV-2 S Glycoprotein



The S1 furin cleavage fragment includes the signal sequence (SS), the N terminal domain (NTD), the receptor binding domain (RBD, which binds the human cellular receptor, ACE-2), subdomain 1 (SD1), and subdomain 2 (SD2). The furin cleavage site (S1/S2) separates S1 from the S2 fragment, which contains the S2 protease cleavage site (S2') followed by a fusion peptide (FP), heptad repeats (HR1 and HR2), a central helix (CH) domain, the connector domain (CD), the transmembrane domain (TM) and a cytoplasmic tail (CT).
Source: modified from [Wrapp et al, 2020](#).

BNT162b2 (V9) encodes a full-length P2 S transmembrane protein that contains two consecutive prolines introduced at amino acid positions 986 and 987, between the central helix (CH) and heptad repeat 1 (HR1) (Figure 2.4.2-1) ([Wrapp et al, 2020](#); [Pallesen et al, 2017](#)). Two codon optimized forms of the coding sequence for this antigen were tested preclinically and were designated “variant 8” and “variant 9” (V8 and V9), with the vaccine candidate tested clinically and being proposed for licensure or authorization, V9, expressed from a codon optimized RNA gene with a higher content of cytosine ribonucleotides for increased protein expression. The RNA-expressed P2 S is membrane bound and elicits a potent humoral neutralizing antibody response and Th1-type CD4⁺ and CD8⁺ cellular response to block virus infection and kill virus infected cells, respectively.

Efficient in vitro expression of the P2 S protein was demonstrated following in vitro transfection of cells with BNT162b2 RNA drug substance and BNT162b2 drug product. Electron cryomicroscopy analysis of purified recombinant P2 S, expressed from DNA encoding the same S amino acid sequence as BNT162b2 RNA (except for the addition of a C-terminal tag for protein purification) revealed high similarity to previously reported structures ([Cai et al, 2020](#)). The well-resolved trimeric prefusion structure and the high affinity binding to ACE2 and human neutralizing antibodies demonstrate that the recombinant full-length P2 S protein authentically presents the ACE-2 binding site.

2.4.2.1.3. Immunogenicity of BNT162b2 (V9) in Mice

BNT162b2 was highly immunogenic in mice with strong antigen-binding IgG and high titer neutralizing antibody responses together with a Th1-phenotype CD4⁺ response as well as an IFN γ ⁺, IL-2⁺ CD8⁺ T-cell response after a single immunization. Total IgG ELISA showed that the vaccine induced a strong, dose-dependent IgG response that recognizes S1 and the RBD and elicited high neutralizing titers in a pseudotype neutralization assay.

Stimulation of fresh splenocytes, collected 28 days after immunization, with an S protein specific overlapping peptide pool demonstrated robust CD4⁺ and CD8⁺ T-cell IFN γ responses and a Th1-dominant profile was demonstrated in quantification of cytokines (IL-2 and IFN γ) in the corresponding culture supernatants.

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In summary, BNT162b2 induced a strong, neutralizing antibody response. CD4⁺ and CD8⁺ T-cell responses were detectable 12 and 28 days after one immunization and exhibited a Th1-dominant T cell response characteristic of RNA-based vaccines.

2.4.2.1.4. Evaluation of BNT162b2 (V9) Immunogenicity and Protection Against SARS-CoV-2 Challenge in Rhesus Macaques

BNT162b2 was assessed for immunogenicity and for protection against an infectious SARS-CoV-2 challenge in rhesus macaques. SARS-CoV-2 infection in humans manifests as both asymptomatic infection and as the disease COVID-19, with diverse signs, symptoms, and levels of severity. Based on published reports, SARS-CoV-2 challenged rhesus macaques develop an acute, transient infection in the upper and lower respiratory tract and have evidence of viral replication in the gastrointestinal tract, similar to humans (Zou et al, 2020; Kim et al, 2020). Varying degrees of pulmonary inflammation, primarily at the peak of infection at approximately Day 2 to 4 post-challenge, have been reported in the literature (Munster et al, 2020). The human and rhesus ACE-2 receptor have 100% amino acid identity at the critical binding residues, which may account for the fidelity of this SARS-CoV-2 animal model (Zhou et al, 2020).

2.4.2.1.4.1. Immunogenicity in Rhesus Macaques

Rhesus macaques immunized IM with 30 µg or 100 µg of BNT162b2 on Days 0 and 21 had readily detectable S1-binding IgG and SARS-CoV-2 neutralizing titers (NT50) as early as 14 days after a single immunization, with substantial increases following the second immunization. On Day 28, seven days after Dose 2 at the 30 µg dose level, the neutralizing geometric mean titer (GMT) reached 8-fold the GMT of a 38 member panel of human convalescent sera (HCS); at the 100 µg dose level, the neutralizing GMT was 18-fold the HCS GMT. The HCS sera were drawn from SARS-CoV-2 infected individuals 18 to 83 years of age, at least 14 days after PCR-confirmed diagnosis and at a time when individuals were asymptomatic. The HCS panel provides a currently accessible benchmark to judge the quality of the humoral immune response to the vaccine. A decline of both, S1-binding IgG levels and neutralizing titers, was observed out to the latest measured time point (Day 56) but remained above the neutralizing GMT and the S1-binding geometric mean concentration (GMC) of the HCS.

As seen following mouse immunization, strong S-specific Th1-dominant IFN γ ⁺ T-cell responses were detected in all immunized rhesus macaques. By intracellular cytokine staining analysis, there was a dose-dependent increase in S-specific CD4⁺ T cell responses with a strong Th1-bias evidenced by high frequency of IFN γ ⁺, IL-2⁺, or TNF- α ⁺ cells. Notably, CD8⁺ T-cell responses were also detectable in BNT162b2-immunized animals.

2.4.2.1.4.2. SARS-CoV-2 Challenge of BNT162b2 (V9)-Immunized Nonhuman Primates

Groups of 2-4 year old male rhesus macaques that had received two IM immunizations with 100 µg BNT162b2 V9 (n=6) or saline (Control; n=3) 21 days apart were challenged 55 days after the second immunization with 1.05×10^6 plaque forming units of SARS-CoV-2 (strain USA-WA1/2020), split equally between the intranasal (IN) and intratracheal (IT) routes, as

previously described (Singh et al, 2020) (VR-VTR-10671). SARS-CoV-2 RNA was measured by reverse transcription- quantitative polymerase chain reaction (RT-qPCR) in bronchoalveolar lavage fluid, nasal swabs, and oropharyngeal swabs. The difference in viral RNA detection in BAL fluid between BNT162b2-immunised and control-immunised rhesus macaques after challenge is highly statistically significant (by a nonparametric test, $p=0.0014$). None of the challenged animals showed clinical signs of significant illness, indicating that the 2-4 years old male rhesus challenge model is primarily an infection model for SARS-CoV-2, not a COVID-19 disease model. No radiographic or histological evidence of vaccine-elicited enhanced disease was observed. In summary, BNT162b2 provided complete protection from the presence of detectable viral RNA in the lungs compared to the saline control with no evidence of vaccine-elicited disease enhancement.

2.4.2.1.5. Immunogenicity Testing After Weekly Immunization of Rats in GLP Compliant Repeat Dose Toxicology Studies and a Developmental and Reproductive Toxicity Study

The nonclinical safety data package consists of two GLP-compliant repeat-dose rat toxicity studies, in which both BNT162b2 variants (V8 and V9) were evaluated, and a DART study, in which BNT162b2 (V9) was evaluated (Section 2.4.4). In all studies, Study 38166 (evaluating V8) as well as Study 20GR142 and Study 20256434 (evaluating V9), the vaccine candidates were immunogenic.

In Study 38166, male and female rats received three weekly IM doses of BNT162b2 (V8). Serum samples were collected from main study animals on Day 17 (two days after the third dose) at the end of the dosing phase and on Day 38 at the end of a 3-week recovery phase. The sera were analyzed by ELISA for IgG that bound S1 and RBD as well as for SARS-CoV-2-S pseudovirus neutralizing antibodies. The vaccine candidates elicited IgG that recognized S1 and RBD. After immunization, animals developed high titers of antigen-specific antibodies as well as pseudovirus neutralization titers.

In Study 20GR142, male and female rats received three weekly IM doses of BNT162b2 (V9). Serum samples were collected from study animals prior to vaccine administration, at the end of the dosing phase on Day 17 (two days after the third dose), and at the end of the 3-week recovery phase on Recovery Phase Day 21. Sera were analyzed for SARS-CoV-2 neutralizing antibodies. After immunization, BNT162b2 (V9) elicited SARS-CoV-2 neutralizing antibody responses in males and females at the end of the dosing and recovery phases of the study. SARS-CoV-2 neutralizing antibody responses were not observed in animals prior to vaccine administration or in saline-administered control animals.

In Study 20256434, female rats were administered 4 total IM doses of BNT162b2 (V9) 21 and 14 days prior to mating and on GD9 and GD20. Serum samples were collected from females prior to vaccine administration, just prior to mating (M0), at the end of gestation (GD21), and at the end of lactation (LD21) and offspring (fetuses on GD21 and pups on PND21). Sera were analyzed for SARS-CoV-2 neutralizing antibodies. After immunization, SARS-CoV-2 neutralizing titers were detected in all maternal females as well as in their offspring (fetuses and pups). SARS-CoV-2 neutralizing antibody titers were not observed in animals prior to vaccine administration or in saline-administered control animals.

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2.4.2.2. Secondary Pharmacodynamics

No secondary pharmacodynamics studies were conducted with BNT162b2.

2.4.2.3. Safety Pharmacology

No safety pharmacology studies were conducted with BNT162b2 as they are not considered necessary for the development of vaccines according to the WHO guideline ([WHO, 2005](#)).

2.4.2.4. Pharmacodynamic Drug Interactions

Nonclinical studies evaluating pharmacodynamic drug interactions with BNT162b2 were not conducted as they are generally not considered necessary to support development and licensure of vaccine products for infectious diseases (WHO, 2005).

2.4.3. PHARMACOKINETICS

2.4.3.1. Brief Summary

Assessment of the ADME profile of BNT162b2 (BioNTech code number BNT162, Pfizer code number PF-07302048) included evaluating the PK and metabolism of two novel lipid excipients (ALC-0315 and ALC-0159) in the LNP and potential biodistribution of BNT162b2 using luciferase expression as a surrogate reporter. The luciferase reporter was used as it was a readily available reporter that has been widely used to develop an understanding of protein/organ expression (Chen et al, 2020; Elia et al, 2020; Fukuchi et al, 2020; Hassett et al, 2019; Truong et al, 2019; Barry et al, 2012; Jeon et al, 2006). An intravenous rat PK study, using LNPs with the identical lipid composition as BNT162b2, demonstrated that ALC-0315 and ALC-0159 distribute from the plasma to the liver. While there was no detectable excretion of either lipid in the urine, the percent of dose excreted unchanged in feces was ~1% for ALC-0315 and ~50% for ALC-0159.

The biodistribution of BNT162b2 was evaluated using luciferase expression as a surrogate reporter in BALB/c mice. Mice were administered a luciferase expressing modRNA formulated like BNT162b2, with the identical lipid composition. Luciferase expression was measured in vivo following luciferin application. Luciferase expression was identified at the injection site at 6 hours after injection and was not detected after 9 days. Expression in the liver was also present to a lesser extent at 6 hours after injection and was not detected by 48 hours after injection. The distribution was also examined in male and female Wistar Han rats using LNPs with a comparable lipid composition to BNT162b2 but with a surrogate luciferase RNA and containing trace amounts of radiolabeled [³H]-CHE, a non-exchangeable, non-metabolizable lipid marker. The greatest mean concentration of LNP was found remaining in the injection site in both sexes. Total recovery (% of injected dose) of LNP outside the injection site was greatest in the liver and was much less in the spleen, adrenal glands, and ovaries.

The in vitro metabolism of ALC-0315 and ALC-0159 was evaluated in blood, liver microsomes, S9 fractions, and hepatocytes from mice, rats, monkeys, and humans. The in vivo metabolism was examined in rat plasma, urine, feces, and liver samples from the PK study. Metabolism of ALC-0315 and ALC-0159 appears to occur slowly in vitro and in vivo. ALC-0315 and ALC-0159 are metabolized by hydrolytic metabolism of the ester and amide functionalities, respectively, and this hydrolytic metabolism is observed across the species evaluated.

In summary, the nonclinical ADME studies indicate that the LNP distributes to the liver. Approximately 50% of ALC-0159 is excreted unchanged in feces, while metabolism played a role in the elimination of ALC-0315.

2.4.3.2. Methods of Analysis

No methods of analysis have been validated to support GLP TK studies of components of BNT162b2; however, a qualified LC/MS method was developed to support quantitation of the two novel LNP excipients for the non-GLP IV PK study in rats

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(Study PF-07302048_06Jul20_072424). Methods for immunogenicity and efficacy studies are described in Section 2.6.2.12.

2.4.3.3. Absorption

2.4.3.3.1. In Vitro Absorption

No absorption studies were conducted for BNT162b2, as the administration route is IM.

2.4.3.3.2. Single-Dose Pharmacokinetics

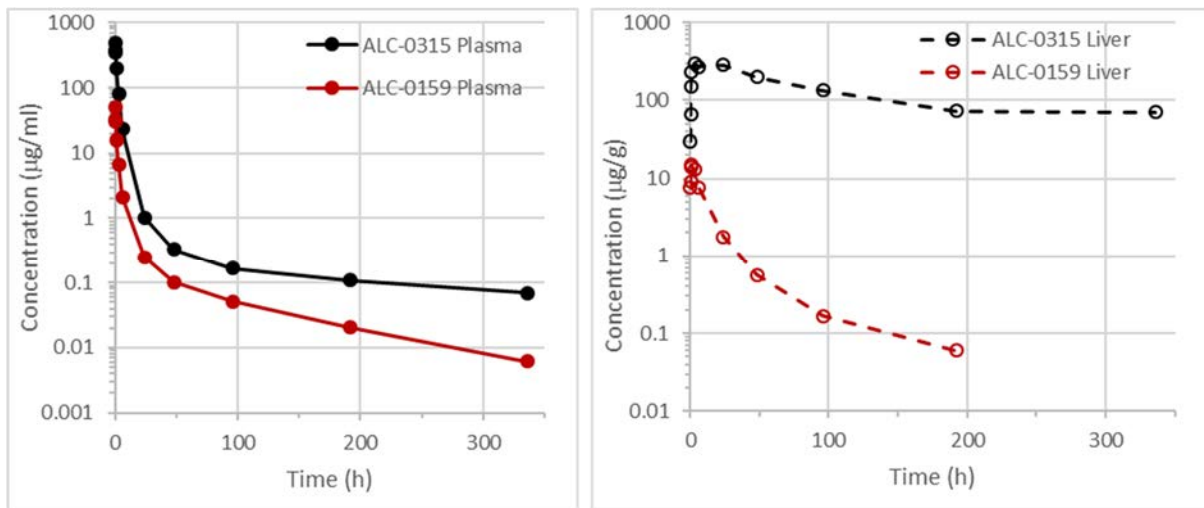
An intravenous rat PK study (PF-07302048_06Jul20_072424; Tabulated Summary 2.6.5.3) was performed using LNPs containing surrogate luciferase RNA, with the identical lipid composition as BNT162b2. This study was conducted to explore the disposition of ALC-0315 and ALC-0159 that had reached the systemic circulation following IM administration; thus, the IV route was felt to be appropriate. The findings are depicted in Table 2.4.3-1 and Figure 2.4.3-1.

Table 2.4.3-1. PK of ALC-0315 and ALC-0159 in Wistar Han Rats After IV Administration of LNPs Containing Surrogate Luciferase RNA at 1 mg/kg

Analyte	Dose of Analyte (mg/kg)	Gender /N	t _{1/2} (h)	AUC _{inf} (µg•h/mL)	AUC _{last} (µg•h/mL)	Estimated fraction of dose distributed to liver (%) ^a
ALC-0315	15.3	Male/3 ^b	139	1030	1020	60
ALC-0159	1.96	Male/3 ^b	72.7	99.2	98.6	20

a. Calculated as highest mean amount in the liver (µg)/total mean dose (µg) of ALC-0315 or ALC-0159.
 b. 3 animals per timepoint; non-serial sampling.

Figure 2.4.3-1. Plasma and Liver Concentrations of ALC-0315 and ALC-0159 in Wistar Han Rats After IV Administration of LNPs Containing Surrogate Luciferase RNA at 1 mg/kg



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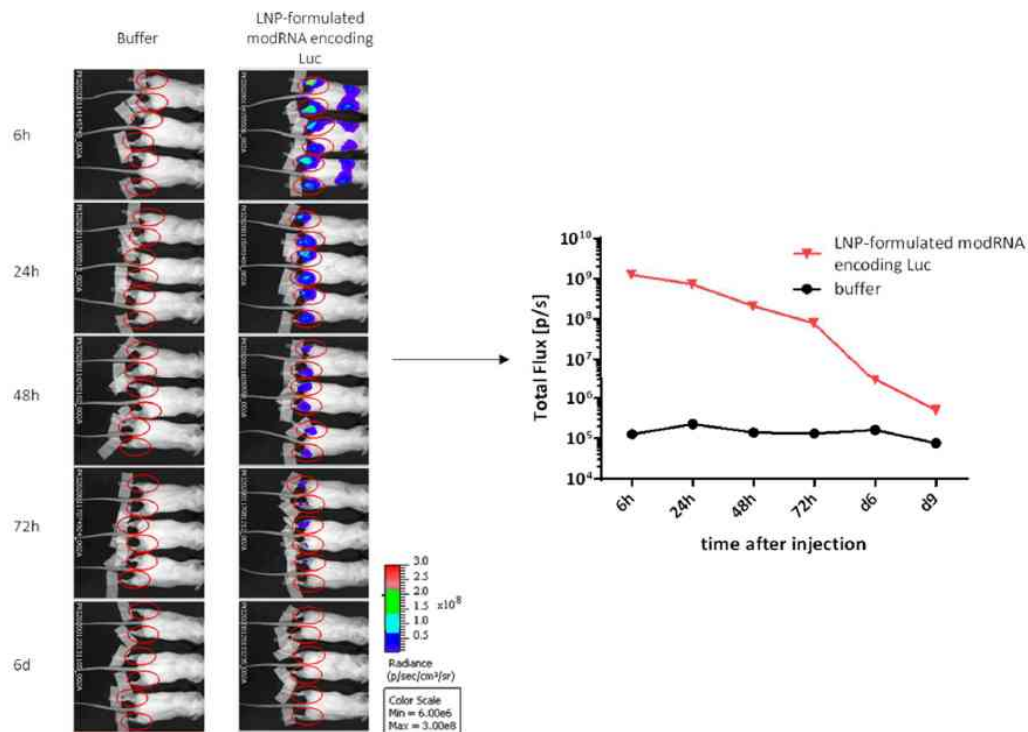
Pharmacokinetic studies have not been conducted with BNT162b2 and are generally not considered necessary to support the development and licensure of vaccine products for infectious diseases (WHO, 2005; WHO, 2014).

2.4.3.4. Distribution

In an in vivo study (R-20-0072; Tabulated Summary 2.6.5.5A), biodistribution was assessed using luciferase as a surrogate marker protein, with RNA encoding luciferase formulated like BNT162b2, with the identical lipid composition. The LNP-formulated luciferase-encoding modRNA was administered to BALB/c mice by IM injection of 1 µg each in the right and left hind leg (for a total of 2 µg). Using in vivo bioluminescence after injection of luciferin substrate, luciferase protein expression was detected at different timepoints at the site of injection and to a lesser extent, and more transiently, in the liver (Figure 2.4.3-2. Distribution to the liver is likely mediated by LNPs entering the blood stream. The luciferase expression at the injection sites dropped to background levels after 9 days. The repeat-dose toxicity study in rats showed no evidence of liver injury (Section 2.4.4.3).

The biodistribution of the antigen encoded by the RNA component of BNT162b2 is expected to be dependent on the LNP distribution and the results presented should be representative for the vaccine RNA platform, as the LNP-formulated luciferase-encoding modRNA had the same lipid composition.

Figure 2.4.3-2. Bioluminescence Emission in BALB/c Mice after IM Injection of an LNP Formulation of modRNA Encoding Luciferase



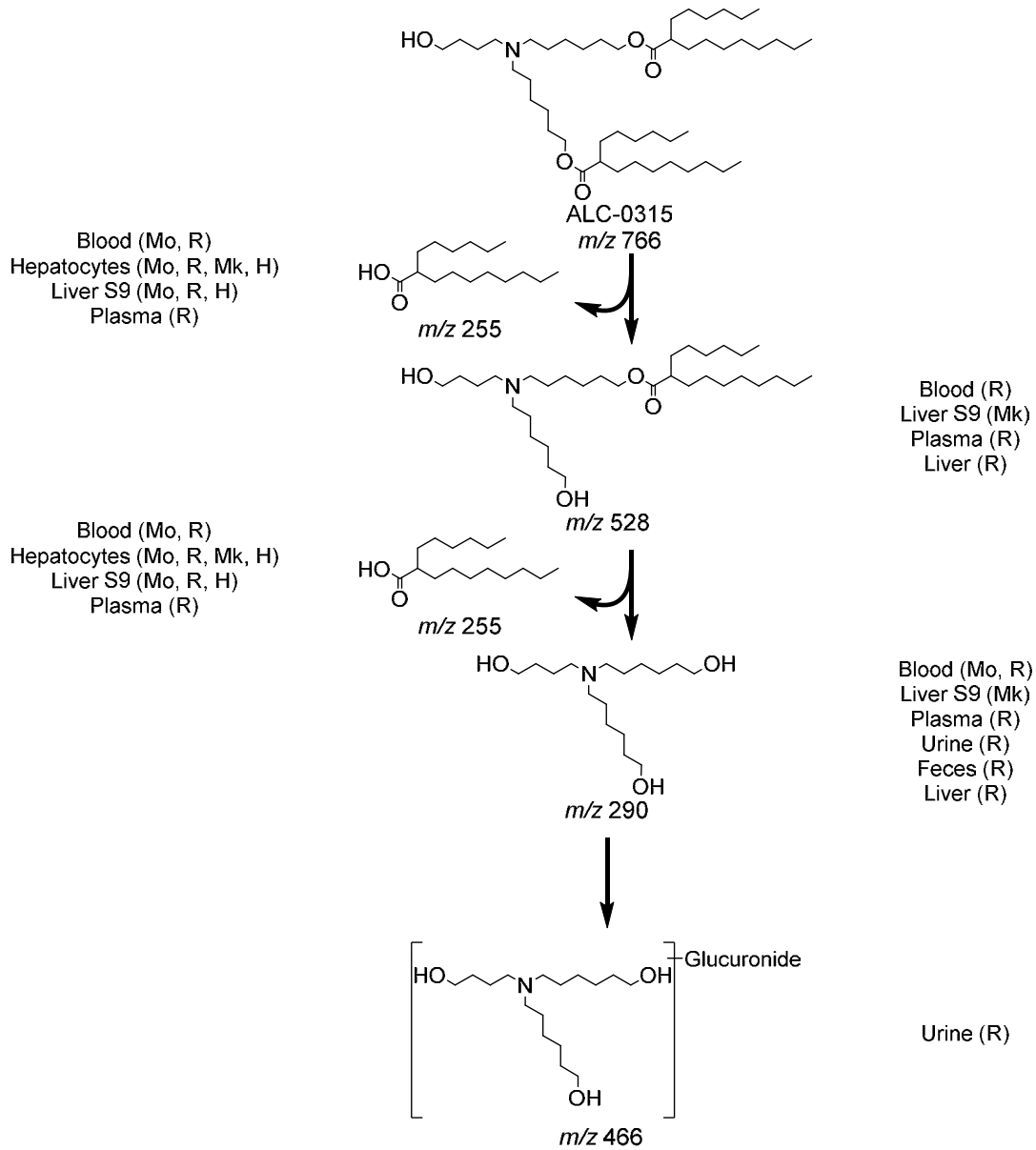
The distribution of a LNP with a comparable lipid composition to BNT162b2 but with a surrogate luciferase RNA (monitoring the ³H-CHE lipid label), was investigated in blood, plasma and selected tissues in male and female Wistar Han rats over 48 hours after a single IM injection at 50 µg mRNA/animal (Study 185350; Tabulated Summary 2.6.5.5B). The greatest mean concentration of LNP was found remaining in the injection site at each time point in both sexes. Outside the injection site, low levels of radioactivity were detected in most tissues, with the greatest levels in plasma observed 1-4 hours post-dose. Over 48 hours, the LNP distributed mainly to liver, adrenal glands, spleen and ovaries, with maximum concentrations observed at 8-48 hours post-dose. Total recovery (% of injected dose) of LNP, for combined male and female animals, outside of the injection site was greatest in the liver (up to 18%) and was much less in the spleen (≤1.0%), adrenal glands (≤0.11%) and ovaries (≤0.095%). The mean concentrations and tissue distribution pattern were broadly similar between the sexes.

2.4.3.5. Metabolism

Of the four lipids used as excipients in the LNP formulation, two are naturally occurring (cholesterol and DSPC) and will be metabolized and excreted like their endogenous counterparts. The in vitro metabolic stability of the two novel lipids, ALC-0315 (aminolipid) and ALC-0159 (PEG-lipid), were evaluated in mouse, rat, monkey, and human liver microsomes, S9 fractions, and hepatocytes. ALC-0315 and ALC-0159 were stable (>82% remaining) over 120 min in liver microsomes and S9 fractions and over 240 min in hepatocytes in all species and test systems (Studies 01049-20008, 01049-20009, 01049-20010, 01049-20020, 01049-20021, and 01049-20022; Tabulated Summaries 2.6.5.10A and 2.6.5.10B).

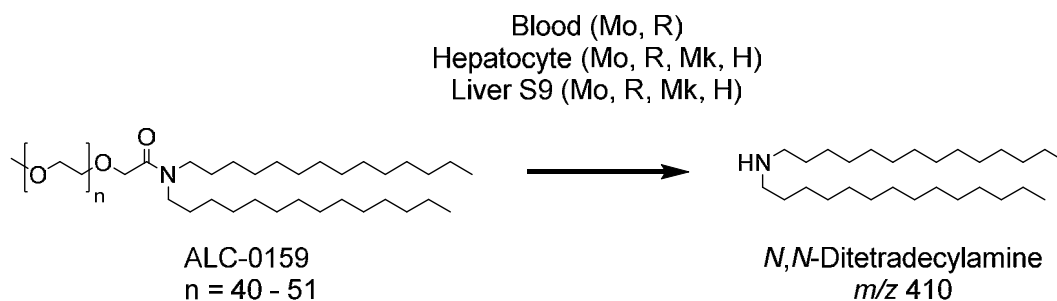
Further study of the metabolism of ALC-0315 and ALC-0159 in vitro and in vivo evaluating the plasma, urine, feces, and liver from the rat PK study (Section 2.4.3.3.2) determined ALC-0315 and ALC-0159 are metabolized slowly (Study PF-07302048_05Aug20_043725; Tabulated Summaries 2.6.5.9, 2.6.5.10C, and 2.6.5.10D). ALC-0315 and ALC-0159 underwent hydrolytic metabolism of the ester and amide functionalities, respectively, and this hydrolytic metabolism was observed across the species evaluated (Figure 2.4.3-3 and Figure 2.4.3-4).

Figure 2.4.3-3. Proposed Biotransformation Pathway of ALC-0315 in Various Species



Metabolism of ALC-0315 occurs via two sequential ester hydrolysis reactions, first yielding the monoester metabolite (m/z 528) followed by the doubly deesterified metabolite (m/z 290). Subsequent metabolism of the doubly deesterified metabolite resulted in a glucuronide metabolite (m/z 466), which was only observed in urine from the rat PK study. Additionally, 6-hexyldecanoic acid (m/z 255), the acid product of both hydrolysis reactions of ALC-0315, was identified.

Figure 2.4.3-4. Proposed Biotransformation Pathway of ALC-0159 in Various Species



The primary route of metabolism identified for ALC-0159 involves amide bond hydrolysis yielding *N,N*-ditetradecylamine (*m/z* 410).

The protein encoded by the RNA in BNT162b2 is expected to be proteolytically degraded like other endogenous proteins. RNA is degraded by cellular RNases and subjected to nucleic acid metabolism. Nucleotide metabolism occurs continuously within the cell, with the nucleoside being degraded to waste products and excreted or recycled for nucleotide synthesis. Therefore, no RNA or protein metabolism or excretion studies will be conducted.

2.4.3.6. Excretion

In the rat PK study ([Section 2.4.3.3.2](#)), there was no detectable excretion of ALC-0315 and ALC-0159 in urine after IV administration of LNPs containing surrogate luciferase RNA at 1 mg/kg. The percent excreted unchanged in feces was ~1% for ALC-0315 and ~50% for ALC-0159. Metabolites of ALC-0315 were detected in the urine of rats ([Figure 2.4.3-3](#)). No excretion studies have been conducted with BNT162b2 for the reasons described in [Section 2.4.3.5](#).

2.4.3.7. Pharmacokinetic Drug Interactions

No PK drug interaction studies have been conducted with BNT162b2.

2.4.4. TOXICOLOGY

2.4.4.1. Brief Summary

The nonclinical toxicity assessment of BNT162b2 (BioNTech code number BNT162, Pfizer code number PF-07302048) includes 2 GLP-compliant repeat-dose toxicity studies and a developmental and reproductive toxicity (DART) study in Wistar Han rats, outlined below in [Table 2.4.4-1](#). The nonclinical safety evaluation included 2 variants of BNT162b2: V8 and V9. BNT162b2 (V9), the candidate submitted for licensure, differs from BNT162b2 (V8) only in the presence of optimized codons to improve antigen expression, but the amino acid sequences of the encoded antigens are identical. Two GLP repeat-dose toxicity studies for BNT162b2 (V8) and BNT162b2 (V9), one study for each variant, have been completed. In both studies, the nonclinical toxicology findings were similar between BNT162b2 (V9) and BNT162b2 (V8). BNT162b2 (V9) was assessed for development and reproductive toxicity in rats.

The IM route of exposure was selected as it is the intended route of clinical administration. The selection of rats as the toxicology test species is consistent with the WHO guidance documents on nonclinical evaluation of vaccines ([WHO, 2005](#)), which recommend that vaccine toxicity studies be conducted in a species in which an immune response is induced by the vaccine. Generation of an immune response to BNT162b2 has been confirmed in rats in both repeat-dose toxicity studies and the DART study. The Wistar Han rat is used routinely for regulatory toxicity studies, and there is an extensive historical safety database on this strain of rat.

Table 2.4.4-1. Overview of Toxicity Testing Program

Study ^a	Study (Sponsor) No.	Group/ Dose, µg RNA	Total Volume (µL) ^b	No. of Animals/ Group	Study Status
Repeat-Dose Toxicity					
17-Day, 2 or 3 Dose (1 Dose/Week) IM Toxicity With a 3 Week Recovery Phase in Rats ^{c,d}	38166	Control ^e , 0	200 ^f	15/sex	Completed
		BNT162b2 (V8) ⁱ , 100	200 ^f	15/sex	
17-Day, 3 Dose (1 Dose/Week) IM Toxicity With a 3 Week Recovery Phase in Rats ^g	20GR142	Saline ^h , 0	60	15/sex	Completed
		BNT162b2 (V9) ⁱ , 30	60	15/sex	
Developmental and Reproductive Toxicity					
Combined Fertility and Developmental Study (Including Teratogenicity and Postnatal Investigations) by the IM route in Rats ^j	20256434 (RN9391 R58)	Saline ^h , 0	60	44 F	Completed
		BNT162b2 (V9) ⁱ , 30	60	44 F	

- a. All studies are GLP-compliant and were conducted in an OECD mutual acceptance of data-compliant member state.
- b. Doses were administered as 1 application at 1 site unless otherwise indicated.
- c. Study also evaluated the BNT162a1, BNT162b1, and BNT162c1 vaccine candidates.
- d. QW x 3 (Days 1, 8, 15) for BNT162a1, BNT162b1, and BNT162b2 (V8); QW x 2 (Days 1, 8) for BNT162c1.
- e. Phosphate buffered saline, 300 mM sucrose.
- f. One application (100 µL) at 2 sites for a total dose volume of 200 µL.
- g. Study also evaluated BNT162b3.
- h. Sterile saline (0.9% NaCl).
- i. BNT162b2 (V8) and BNT162b2 (V9) both encode the same amino acid sequence of the spike protein antigen with two prefusion conformation-stabilizing amino acids in the stalk.
- j. Study also evaluated BNT162b1 and BNT162b3.

Administration of BNT162b2 by IM injection to male and female Wistar Han rats once every week for a total of 3 weekly cycles of dosing was tolerated without evidence of systemic toxicity in GLP-compliant repeat-dose toxicity studies. Expected inflammatory responses to the vaccine were evident such as edema and erythema at the injection sites, transient elevation in body temperature, elevations in WBCs and acute phase reactants, and lower A:G ratios. A transient elevation in GGT was noted in animals vaccinated with BNT162b2 (V8) in Study 38166 without evidence of microscopic changes in the biliary system or other hepatobiliary biomarkers but was not recapitulated in Study 20GR142. Injection site reactions were common in all vaccine-administered animals and were greater after boost immunizations. Changes secondary to inflammation included slight and transient reduction in body weights and transient reductions in RETIC, PLT, and RBC mass parameters. All changes in clinical pathology parameters and acute phase proteins were reversed at the end of

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the recovery phase for BNT162b2 with the exception of higher RDW, higher globulins, and lower A:G ratios in animals administered BNT162b2 (V9). The higher RDW reflects prior RETIC increases. The higher A:G is due to low magnitude increases in globulins, which is an expected immune response to vaccine administration (Sellers et al, 2020).

Macroscopic pathology and organ weight changes were also consistent with immune activation and inflammatory response and included increased size of draining iliac lymph nodes and increased size and weight of spleen. Vaccine-related microscopic findings at the end of the dosing phase consisted of edema and inflammation in injection sites and surrounding tissues; increased cellularity in the draining (iliac) lymph nodes, bone marrow, and spleen; and hepatocyte vacuolation in the liver. Periportal vacuolation of hepatocytes was not associated with any microscopic evidence of hepatic injury or alterations in liver function tests and is interpreted to reflect hepatocyte uptake of the LNP lipids (Sedic et al, 2018). Microscopic findings at the end of the dosing phase were partially or completely recovered in all animals at the end of the recovery phase for BNT162b2. A robust immune response was elicited to the BNT162b2 antigen.

In the DART study, administration of BNT162b2 to female rats twice before the start of mating and twice during gestation at the human clinical dose (30 µg RNA/dosing day) was associated with nonadverse effects (body weight, food consumption, and localized effects in the injection site) after each dose administration. There were no effects of BNT162b2 administration on mating performance, fertility, or any ovarian or uterine parameters in the F0 female rats nor on embryo-fetal or postnatal survival, growth, or development in the F1 offspring through the end of lactation. A SARS-CoV-2 neutralizing antibody response to the vaccine was confirmed in F0 female rats prior to mating, at the end of gestation, and at the end of lactation and these neutralizing antibodies were also detectable in the F1 offspring (fetuses and pups).

2.4.4.2. Single-Dose Toxicity

A separate single-dose toxicity study with BNT162b2 has not been conducted.

2.4.4.3. Repeat-Dose Toxicity

2.4.4.3.1. Repeat-Dose Toxicity Study of Three LNP-Formulated RNA Platforms Encoding for Viral Proteins by Repeated Intramuscular Administration to Wistar Han Rats

The vaccine candidate BNT162b2 (V8), an LNP-formulated modified RNA vaccine expressing SARS-CoV-2 P2 S, was assessed in a GLP-compliant repeat-dose toxicity study in Wistar Han rats (Study 38166). This study also included assessment of 3 other LNP-formulated RNA vaccines, encoding either the SARS-CoV-2 P2 S or RBD antigens, which were not selected for licensure. For the purpose of this submission, only the study findings from the 100 µg BNT162b2 (V8) vaccine group are summarized; findings from the other vaccine candidates were generally similar.

Administration of BNT162b2 (V8) via IM injections once weekly for 3 administrations to male and female Wistar Han rats was tolerated without evidence of systemic toxicity. The

vaccine elicited a robust antigen-specific immune response and produced nonadverse macroscopic changes at the injection sites, spleen, and the draining lymph nodes; increased hematopoiesis in the bone marrow and spleen; periportal hepatocyte vacuolation; and clinical pathology changes consistent with an immune response. The findings in this study were fully recovered or showed evidence of ongoing recovery at the end of the 3-week recovery phase, and were consistent with those typically associated with the IM administration of LNP-encapsulated mRNA vaccines (Hassett et al, 2019).

Body weights were lower 24 hours after each BNT162b2 (V8) vaccine administration compared with predose values (down to 0.92x versus baseline) with evidence of weight gain (1.22x to 1.37x versus baseline) by the end of recovery. Body weight gain between the administrations was comparable to the buffer control group. There were no noteworthy effects on body weight at the end of the recovery phase. There were no effects on food consumption.

BNT162b2 (V8)-administered animals generally had higher body temperatures compared with buffer control animals at 4 and 24 hours postdose. Group mean temperatures in rats administered the BNT162b2 (V8) vaccine were higher, but within approximately 1°C of the group mean body temperature of buffer-administered animals. Individual rats administered BNT162b2 (V8) did not have body temperatures >40.0°C after administration.

Local reactions were observed in male and female animals dosed IM with BNT162b2 (V8). The incidence and severity of the reactions were higher after the second or third injections compared with the first injection. The majority of animals had very slight edema or rarely slight erythema after the first dose. After the second or third dose, the severity of edema and erythema increased up to moderate or rarely, severe grades. These observations resolved prior to the next injection or for recovery animals resolved during the 3-week recovery phase.

Most BNT162b2 (V8)-related changes in clinical pathology were consistent with an acute phase response and anticipated inflammation. Minor and variable alterations in other clinical pathology parameters were considered secondary effects of vaccination.

Expected immune responses to BNT162b2 (V8) were evident in hematology, such as elevations in mean neutrophil (up to 7.8x) eosinophil (up to 5.1x controls), basophil (1.47x controls), and LUC counts (up to 7.7x controls) and were highest on Day 17, 48 hours after the last injection. WBCs were higher (up to 2.2x controls) in the BNT162b2 (V8) vaccinated group on Day 17. PLT counts were slightly decreased on Day 17 (down to 0.66x controls). A transient reduction in RETIC counts (down to 0.28x controls) was only observed after the administration of the first dose on Day 4. Decreased RETICs were similarly observed in rats treated with the licensed LNP-siRNA pharmaceutical Onpattro™ (NDA # 210922) but have not been observed in humans treated with this biotherapeutic (Kozauer et al, 2018), suggesting this is a species-specific effect. A slight reduction in red blood cell mass (HGB down to 0.87x controls) was observed on Day 17. RETIC and RBC mass parameter decreases were likely secondary to the inflammation.

BNT162b2 (V8)-related changes in clinical chemistry included slightly higher GGT (a biomarker of biliary and not hepatocellular injury [Boone et al, 2005]) on Days 4 (up to 4.6x

controls) and 17 (up to 4.2x controls) without evidence of microscopic changes in the biliary system or other hepatobiliary biomarkers. Additionally, higher GGT was not observed in the second repeat-dose toxicity study (20GR142), conducted with the clinical candidate submitted for licensure. Albumin was slightly lower on Days 4 (down to 0.87x controls) and 17 (down to 0.89x controls) and globulin slightly higher on Day 17 (up to 1.2x controls). This resulted in the A:G ratio being slightly lower on Days 4 (down to 0.84x controls) and 17 (down to 0.76x controls). The effect on albumin and globulin were related to the vaccine-mediated inflammatory response as part of the negative and positive acute phase response, respectively (Sellers et al, 2020).

The acute phase proteins alpha-1-acid glycoprotein (up to 21x controls on Day 17) and alpha-2-macroglobulin (up to 217x controls on Day 17) were elevated in both males and females in the BNT162b2 (V8)-administered group on Days 4 and 17. Fibrinogen was higher in the vaccine-administered group (up to 3.1x controls), consistent with an acute phase response. Higher concentrations of acute phase proteins are an anticipated response to vaccination.

All changes in clinical pathology parameters and acute phase proteins were reversed at the end of the recovery phase.

Compared with the buffer control, there were no test-article related differences in the concentration of serum cytokines evaluated, in urinalysis parameters, or in ophthalmoscopic or auditory parameters.

BNT162b2 (V8)-related higher absolute and relative (to body) spleen weights (up to 1.62x controls) were evident and correlated with the macroscopic observation of increased spleen size and the increased hematopoiesis. This is likely secondary to immune responses induced by the BNT162b2 (V8) vaccine.

The most common macroscopic observation in the BNT162b2 (V8) group was a thickened injection site and/or induration noted for nearly all animals (16/20) at necropsy. This finding correlated with microscopic inflammation at the injection site. Macroscopic findings at the injection site were resolved at the end of the recovery phase. Enlarged spleen and iliac lymph nodes were noted in several animals in the BNT162b2 (V8)-administered group, which correlated microscopically to expansion of lymphoid and/or hematopoietic cells. The effects on the lymphoid organs are consistent with immune responses to the BNT162b2 (V8).

Vaccine-related microscopic findings at the end of dosing were evident in injection sites and surrounding tissues, in the draining (iliac) lymph nodes, bone marrow, spleen, and liver.

The inflammation at the injection site was characterized by infiltrates of macrophages, granulocytes, and lymphocytes into the muscle, and variably into the dermis and subcutis. Injection site inflammation was associated with moderate edema, mild myofiber degeneration, occasional muscle necrosis, and mild fibrosis. Injection site findings were consistent with an immune/inflammatory response to an IM vaccine administration.

In the draining (iliac) lymph node, increased cellularity of the follicular germinal centers and increased plasma cells (plasmacytosis) were variably present for all BNT162b2 (V8)-dosed animals. In addition, minimal to mild increases in the cellularity of bone marrow and

hematopoiesis in the spleen likely related to increased granulopoiesis and correlated with increased circulating neutrophils (which correlated with increased spleen size and weight) were present in BNT162b2 (V8)-dosed animals.

Vacuolation of hepatocytes (minimal to mild) in the portal regions of the liver were present for all BNT162b2 (V8)-dosed animals. The liver findings were not associated with changes in markers of hepatocyte injury (eg, AST or ALT). While GGT was elevated in vaccine-administered animals, it was not considered to be associated with the vacuolation of hepatocytes (Enmulat et al, 2010). The microscopic observation of liver vacuolation is believed to be associated with hepatocyte uptake of the LNP lipids (Section 2.4.3.4; Sedic et al, 2018).

Microscopic findings at the end of the dosing phase were partially or completely resolved in all animals at the end of the recovery phase. Inflammation at the injection site and surrounding tissues was less severe (minimal to mild) in animals administered BNT162b2 (V8) at the end of the 3-week recovery phase, indicating partial recovery. In the iliac lymph node, plasmacytosis was less severe, and macrophage infiltrates were present at the end of the 3-week recovery phase and reflect resolution of the inflammation noted at the end of the dosing phase.

All other observations in the bone marrow, spleen, and liver were fully resolved at the end of the 3-week recovery phase.

The immune response to the vaccine antigen was evaluated by S1-binding IgG and RBD-binding IgG ELISAs, and a SARS-CoV-2 S pseudotype neutralization (pVNT) assay on Days 17 and 38 (Section 2.4.2.1.4). The data demonstrate that BNT162b2 (V8) elicited a SARS-CoV-2 S-specific antibody response with high neutralizing activity.

In conclusion, administration of BNT162b2 (V8) by IM injection to male and female Wistar Han rats once every week for 3 doses, was tolerated at 100 µg RNA/dosing day without evidence of systemic toxicity.

2.4.4.3.2. 17-Day Intramuscular Toxicity Study of BNT162b2 (V9) in Wistar Han Rats with a 3-week Recovery

The vaccine candidate BNT162b2 (V9), an LNP-formulated modified RNA vaccine expressing SARS-CoV-2 P2 S, was assessed in a GLP-compliant repeat-dose toxicity study in Wistar Han rats (Study 20GR142). This study also included assessment of another LNP-formulated RNA vaccine candidate (BNT162b3) that will not be included in the licensure application. For the purpose of this submission, the study findings from the BNT162b2 (V9) vaccine are summarized; findings from the BNT162b3 vaccine candidate also tested in this study were generally similar. BNT162b2 (V9) was administered at 30 µg once weekly for 3 doses (Days 1, 8, and 15) followed by a 3-week recovery phase.

Administration of BNT162b2 (V9) via IM injections once weekly for 3 administrations to male and female Wistar Han rats was tolerated without evidence of systemic toxicity. The vaccine elicited a robust antigen-specific immune response and produced nonadverse macroscopic changes at the injection sites, spleen, and the draining lymph nodes; increased

hematopoiesis in the bone marrow and spleen; liver vacuolation; and clinical pathology changes consistent with an immune response. The findings in this study were either fully recovered or showed evidence of ongoing recovery at the end of the 3-week recovery phase, and were consistent with those typically associated with the IM administration of LNP-encapsulated mRNA vaccines ([Hassett et al, 2019](#)).

All animals administered BNT162b2 (V9) survived to scheduled necropsy. There were no test article-related clinical signs or body weight changes noted. Test article-related reduced mean food consumption was noted on Days 4 and 11 (down to 0.83x controls). Test article-related higher mean body temperature (maximum increase post each dose) compared with control animals was noted on Day 1 (up to 0.54°C), Day 8 (up to 0.98°C), and Day 15 (up to 1.03°C) postdose.

BNT162b2 (V9)-related injection site edema and erythema were noted on Days 1 (up to slight edema and very slight erythema), 8 (up to moderate edema and very slight erythema), and 15 (up to moderate edema and very slight erythema). The incidence and severity of the reactions were higher after the second or third injections compared with the first injection. Test article-related erythema and edema fully resolved prior to dose administration on Days 8 and 15. Injection site erythema and edema were fully resolved at the end of the recovery phase.

All clinical pathology changes (type and magnitude) were generally consistent with expected immune responses to the vaccine or secondary to inflammation.

There were higher WBCs (up to 2.95x controls), primarily involving neutrophils (up to 6.60x controls), monocytes (up to 3.30x controls), and LUC (up to 13.2x controls) and slightly higher eosinophils and basophils on Days 4 and 17. WBCs were higher on Day 17 as compared with Day 4. There were transiently lower RETICs on Day 4 (down to 0.27x controls) in both sexes and higher RETICs on Day 17 (up to 1.31x controls) in females only. Lower RBC mass parameters (down to 0.90x controls) were present on Days 4 and 17. All test article-related hematology and coagulation changes noted in the dosing phase were fully reversed after a 3-week recovery phase, with the exception of higher red cell distribution width (up to 1.21x controls) in animals administered BNT162b2 (V9). The higher RDW reflects prior reticulocyte increases.

There were lower A:G ratios (down to 0.82x) on Days 4 and 17. Higher fibrinogen levels were observed on Day 17 (up to 2.49x) when compared with control animals, consistent with an acute phase response. The acute phase proteins alpha-1-acid glycoprotein (up to 39x on Day 17) and alpha-2-macroglobulin (up to 71x on Day 17) were elevated in both males and females in the BNT162b2 (V9)-administered group on Days 4 and 17 with higher concentrations generally observed in males. All other changes in clinical pathology parameters were considered incidental. All test article-related clinical chemistry changes noted in the dosing phase were fully reversed after a 3-week recovery phase, except higher globulins (up to 1.08x controls) in animals administered BNT162b2 (V9) and lower A:G ratio (down to 0.91x controls) in females administered BNT162b2 (V9), reflecting vaccine-related immune response.

Test article-related higher group mean absolute and relative spleen weights (compared to body weight) were noted in males that had received BNT162b2 (V9) (up to 1.42x) and females (up to 1.59x) relative to control group means. There were no other test article-related changes in organ weights. At the end of the recovery phase, spleen weights were within normal limits.

Test article-related macroscopic findings included the observation of enlarged draining lymph nodes (2/20 animals) and pale/dark (5/20 animals) or firm (6/20 animals) injection sites in animals administered BNT162b2 (V9). These changes fully recovered, except for partial recovery of enlarged draining nodes, suggesting recovery in progress.

Test article-related microscopic pathology findings were observed at the injection site and in the draining (iliac) and inguinal lymph nodes, spleen, bone marrow, and liver for both vaccine candidates. All microscopic findings were nonadverse, as there was no evidence of systemic toxicity or clinical signs of illness or lameness.

At the end of the dosing phase, test article-related mixed cell inflammation (mild to moderate) and edema (mild to moderate) at the injection site were consistent with findings typically associated with the IM administration of LNP-encapsulated mRNA vaccines (Hassett et al, 2019). These findings correlated with macroscopic observations of abnormal color (dark/pale) and consistency (firm). At the end of the 3-week recovery phase, there was full recovery for injection site edema and partial recovery for injection site inflammation, suggesting recovery in progress.

At the end of the dosing phase, test article-related findings in the draining (iliac) and inguinal lymph nodes (up to moderately increased cellularity of plasma cells and germinal centers), spleen (minimally increased cellularity of hematopoietic cells and germinal centers), and the bone marrow (minimal increased cellularity of hematopoietic cells) were present. These changes are secondary to immune activation and/or inflammation at the injection site. The presence of plasma cells (interpreted as plasmablasts) in the draining (iliac) and inguinal lymph nodes is consistent with a robust immunological response to the vaccines. These observations correlated with macroscopic observations of abnormal size (enlarged) in the lymph nodes and spleen and increased spleen weights. At the end of the 3-week recovery phase, full recovery of increased cellularity of hematopoietic cells in the spleen and bone marrow, with partial recovery (recovery in progress) of increased cellularity of plasma cells and germinal centers in the draining and inguinal lymph nodes, and increased cellularity of the germinal centers in the spleen.

At the end of the dosing phase, the test article-related microscopic finding of minimal periportal hepatocyte vacuolation was not associated with hepatocellular damage or alterations in liver function tests. The liver vacuolation is believed to be associated with hepatocyte uptake of the LNP lipids (Section 2.4.3.4; Sedic et al, 2018). At the end of 3-week recovery phase, this finding was completely recovered.

Administration of 3 once weekly doses of BNT162b2 (V9) elicited SARS-CoV-2 neutralizing antibody responses in males and females at the end of the dosing (Day 17) and recovery phases (Day 21) of the study. SARS-CoV-2 neutralizing antibody responses were

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not observed in animals prior to vaccine administration or in saline-administered control animals.

In conclusion, administration of BNT162b2 (V9) at 30 µg RNA/dosing day via IM injections weekly for 3 administrations to male and female Wistar Han rats was tolerated without evidence of systemic toxicity. Dosing of BNT162b2 (V9) produced changes consistent with an inflammatory response and immune activation. The findings in this study are consistent with those typically associated with the IM administration of LNP-encapsulated mRNA vaccines.

2.4.4.4. Genotoxicity

No genotoxicity studies are planned for BNT162b2 as the components of the vaccine construct are lipids and RNA and are not expected to have genotoxic potential (WHO, 2005).

2.4.4.5. Carcinogenicity

Carcinogenicity studies with BNT162b2 have not been conducted as the components of the vaccine construct are lipids and RNA and are not expected to have carcinogenic or tumorigenic potential. Carcinogenicity testing is generally not considered necessary to support the development and licensure of vaccine products for infectious diseases (WHO, 2005).

2.4.4.6. Reproductive and Developmental Toxicity

Reproductive and developmental toxicity assessments were made with BNT162b2 (V9) (Study 20256434). BNT162b2 was administered by IM injection at the human clinical dose (30 µg RNA/dosing day) to 44 female Wistar Han rats (F0) 21 and 14 days prior to mating with untreated males and on GD 9 and 20, for a total of 4 dosing days. A separate control group of 44 F0 females received saline by the same route and regimen.

Following completion of a mating phase with untreated males, 22 rats/group underwent caesarean-section on GD 21 and were submitted to routine embryo-fetal development evaluations. The remaining 22 rats/group were allowed to litter and development of the offspring was observed until PND 21.

There were no BNT162b2-related deaths during the study. IM administration of BNT162b2 before and during gestation to female Wistar rats resulted in nonadverse clinical signs and macroscopic findings localized to the injection site as well as transient, nonadverse body weight and food consumption effects after each dose administration. These maternal findings are all consistent with administration of a vaccine and an inflammatory/immune response.

There were no BNT162b2-related effects on any mating or fertility parameters. There were no BNT162b2-related effects on any ovarian, uterine, or litter parameters, including embryo-fetal survival, growth, or external, visceral, or skeletal malformations, anomalies, or variations. There were no effects of BNT162b2 administration on postnatal offspring (F1) development, including postnatal growth, physical development (pinna unfolding and eye

opening), reflex ontogeny (pre-weaning auditory and visual function tests), macroscopic observations, and survival.

All F0 females administered BNT162b2 developed SARS-CoV-2 neutralizing antibodies and these antibodies were also detectable in all fetuses and pups from the caesarean and littering groups, respectively. The animals in the saline control group did not exhibit an immune response to BNT162b2.

In conclusion, administration of BNT162b2 to female rats twice before the start of mating and twice during gestation at the human clinical dose was associated with nonadverse effects (body weight, food consumption, and effects localized to the injection site) after each dose administration. However, there were no effects of BNT162b2 administration on mating performance, fertility, or any ovarian or uterine parameters in the F0 female rats nor on embryo-fetal or postnatal survival, growth, or development in the F1 offspring. An immune response was confirmed in F0 female rats following administration of each vaccine candidate and these responses were also detectable in the F1 offspring (fetuses and pups).

Macroscopic and microscopic evaluation of male and female reproductive tissues from the repeat-dose toxicity studies with BNT162b2 showed no evidence of toxicity.

2.4.4.7. Local Tolerance

Local tolerance of IM administration of BNT162b2 was evaluated by injection site observations and macroscopic and microscopic examination of injection sites in the repeat-dose toxicity studies and is described in [Section 2.4.4.3](#).

2.4.4.8. Other Toxicity Studies

2.4.4.8.1. Phototoxicity

Phototoxicity studies with BNT162b2 have not been conducted.

2.4.4.8.2. Antigenicity

Immunogenicity was evaluated as part of the primary pharmacodynamic studies ([Section 2.4.2.1](#)). Serology data from the repeat-dose toxicity studies shows a robust antigen-specific immune response to BNT162b2.

2.4.4.8.3. Immunotoxicity

Stand-alone immunotoxicity studies with BNT162b2 have not been conducted. However, immunotoxicological endpoints were collected as part of the repeat-dose toxicity studies; there were no adverse effects observed and no significant effects on measured cytokines.

2.4.4.8.4. Mechanistic Studies

Mechanistic studies with BNT162b2 have not been conducted.

2.4.4.8.5. Dependence

Dependence studies with BNT162b2 have not been conducted.

2.4.4.8.6. Studies on Metabolites

Stand-alone studies with administration of metabolites of BNT162b2 have not been conducted.

2.4.4.8.7. Studies on Impurities

Stand-alone studies with administration of impurities of BNT162b2 have not been conducted.

2.4.4.8.8. Other Studies

No other studies with BNT162b2 evaluated in this submission have been conducted.

2.4.4.9. Target Organ Toxicity

Based on data from the GLP repeat-dose toxicity studies ([Section 2.4.4.3](#)), administration of BNT162b2 was well tolerated without any evidence of systemic toxicity. BNT162b2 administration was associated with local reactogenicity at the injection site and expected inflammatory responses, including increases in lymphoid cells in draining lymph nodes and spleen. Microscopic findings within injection sites, which were partially reversed by the end of recovery, support this conclusion. The liver finding was reversible, not associated with changes in markers of hepatocyte injury and not considered adverse. The elevated levels of GGT in [Study 38166](#) were not recapitulated in [Study 20GR142](#) and were not associated with hepatobiliary changes microscopically. Elevated GGT was not attributed to the hepatocyte vacuolation ([Enmulat et al, 2010](#)).

2.4.5. INTEGRATED OVERVIEW AND CONCLUSIONS

The nonclinical program demonstrates that BNT162b2 is immunogenic in mice, rats, and nonhuman primates, and the toxicity studies support the licensure of this vaccine. Preclinical assessments in mice and nonhuman primates demonstrate that BNT162b2 elicits a rapid antibody response with measurable SARS-CoV-2 neutralizing titers after a single dose and substantial increases in titers after a second dose that exceed titers in sera from SARS-CoV-2/COVID-19-recovered patients. A Th1-dominant T cell response was evident in both mice and nonhuman primates. In a SARS-CoV-2 rhesus challenge model, BNT162b2 provided complete protection in the lungs, as determined by lack of detectable viral RNA, and there was no evidence of vaccine-elicited disease enhancement.

An IV rat PK study, using an LNP with the identical lipid composition as BNT162b2, demonstrated that the novel lipid excipients in the LNP formulation, ALC-0315 and ALC-0159, distribute from the plasma to the liver. While there was no detectable excretion of either lipid in the urine, the percent of dose excreted unchanged in feces was ~1% for ALC-0315 and ~50% for ALC-0159. Further studies indicated metabolism played a role in the elimination of ALC-0315. Biodistribution was assessed using luciferase expression as a surrogate reporter formulated like BNT162b2, with the identical lipid composition. After IM injection of the LNP-formulated RNA encoding luciferase in BALB/c mice, luciferase protein expression was demonstrated at the site of injection 6 hours post dose and was not detected after 9 days. Luciferase was detected to a lesser extent in the liver; expression was present at 6 hours after injection and was not detected by 48 hours after injection. After IM administration of a radiolabeled LNP-mRNA formulation containing ALC-0315 and ALC-0159 to rats, the percent of administered dose was also greatest at the injection site. Outside of the injection site, total recovery of radioactivity was greatest in the liver and much lower in the spleen, with very little recovery in the adrenal glands and ovaries. The metabolism of ALC-0315 and ALC-0159 was evaluated in blood, liver microsomes, S9 fractions, and hepatocytes from mice, rats, monkeys, and humans. The *in vivo* metabolism was examined in rat plasma, urine, feces, and liver samples from the PK study. Metabolism of ALC-0315 and ALC-0159 appears to occur slowly *in vitro* and *in vivo*. ALC-0315 and ALC-0159 are metabolized by hydrolytic metabolism of the ester and amide functionalities, respectively, and this hydrolytic metabolism is observed across the species evaluated.

Administration of BNT162b2 by IM injection to male and female Wistar Han rats once every week for a total of 3 weekly cycles of dosing was tolerated without evidence of systemic toxicity in GLP-compliant repeat-dose toxicity studies. Expected immune responses to the vaccine were evident such as edema and erythema at the injection sites, transient elevation in body temperature, elevations in WBCs and acute phase reactants, and decreased A:G ratios. Injection site reactions were common in all vaccine-administered animals and were greater after boost immunizations. Changes secondary to inflammation included slight and transient reductions in body weights and transient reductions in RETIC, PLT, and RBC mass parameters. All changes in hematology parameters and acute phase proteins were similar to control at the end of the recovery phase for BNT162b2 with the exception of higher RDW and lower A:G ratios in animals administered BNT162b2 (V9). Macroscopic pathology and organ weight changes were also consistent with immune activation and inflammatory response and included increased size of draining iliac lymph nodes and increased size and

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weight of spleen. Vaccine-related microscopic findings at the end of dosing for BNT162b2 were evident in injection sites and surrounding tissues, in the draining iliac lymph nodes, bone marrow, spleen, and liver. Microscopic findings at the end of the dosing phase were partially (recovery in progress) or completely recovered in all animals at the end of the recovery phase for BNT162b2. A robust immune response was elicited to the BNT162b2 vaccine antigen.

Administration of BNT162b2 to female rats twice before the start of mating and twice during gestation at the human clinical dose (30 µg RNA/dosing day) was associated with nonadverse effects (body weight, food consumption and effects localized to the injection site) after each dose administration. There were no effects of BNT162b2 administration on mating performance, fertility, or any ovarian or uterine parameters in the F0 female rats nor on embryo-fetal or postnatal survival, growth, or development in the F1 offspring. An immune response was confirmed in F0 female rats following administration of BNT162b2 and this response was also detectable in the F1 offspring (fetuses and pups).

In summary, the nonclinical package summarized above supports the BLA of BNT162b2 administered twice by IM injection at a dose of 30 µg RNA.

2.4.6. LIST OF LITERATURE REFERENCES

Barry MA, May S, Weaver EA. Imaging luciferase-expressing viruses. *Methods Mol Biol* 2012;797:79-87.

Boone L, Meyer D, Cusick P, et al. Selection and interpretation of clinical pathology indicators of hepatic injury in preclinical studies. *Vet Clin Pathol* 2005;34(3):182-8.

Cai Y, Zhang J, Xiao T, et al. Distinct conformational states of SARS-CoV-2 spike protein. *Science* 2020;10.1126/science.abd4251.

Chen C-Y, Tran DM, Cavedon A, et al. Treatment of Hemophilia A Using Factor VIII Messenger RNA Lipid Nanoparticles. *Mol Ther Nucleic Acids* 2020;20:534-44.

Elia U, Ramishetti S, Dammes N, et al. Design of SARS-CoV-2 RBD mRNA Vaccine Using Novel Ionizable Lipids. *bioRxiv* 2020.10.15.341537.

Ennulat D, Magid-Slav M, Rehm S, et al. Diagnostic performance of traditional hepatobiliary biomarkers of drug-induced liver injury in the rat. *Toxicol Sci* 2010;116(2):397-412.

Fukuchi M, Saito R, Maki S, et al. Visualization of activity-regulated BDNF expression in the living mouse brain using non-invasive near-infrared bioluminescence imaging. *Mol Brain* 2020;13(1):122.

Hassett KJ, Benenato KE, Jacquinet E et al. Optimization of lipid nanoparticles for intramuscular administration of mRNA vaccines. *Molecular Therapy Nucleic Acids* 2019;15:1-11.

Jeon YH, Choi Y, Kang JH, et al. In vivo monitoring of DNA vaccine gene expression using firefly luciferase as a naked DNA. *Vaccine* 2006;24(16):3057-62.

Jiang S, Hyllyer C, Du L. Neutralizing antibodies against SARS-CoV-2 and other human coronaviruses. *Science and society. Trends Immunol* 2020;41(5)(May):355-9.

Ke Z, Oton J, Qu K, et al. Structures, conformations and distributions of SARS-CoV-2 spike protein trimers on intact virions. *Nature* 2020;10.1038/s41586-020-2665-2.

Kim JY, Ko JH, Kim Y, et al. Viral load kinetics of SARS-CoV-2 infection in first two patients in Korea. *J Korean Med Sci* 2020;35(7)(Feb):e86.

Kozauer NA, Dunn WH, Unger EF, et al. CBER multi-discipline review of Onpattro. NDA 210922. 10 Aug 2018. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/210922Orig1s000MultiR.pdf. 02 Aug 2020.

Munster VJ, Feldmann F, Williamson BN, et al. Respiratory disease in rhesus macaques inoculated with SARS-CoV-2. *Nature* 2020 (May). Available from: <https://doi.org/10.1101/2020.03.21.001628>. Accessed: 24 Sep 2020.

Pallesen J, Wang N, Corbett KS, et al. Immunogenicity and structures of a rationally designed prefusion MERS-CoV spike antigen. *Proc Natl Acad Sci USA* 2017;114(35):E7348-57.

Pardi N, Hogan MJ, Pelc RS, et al. Zika virus protection by a single low-dose nucleoside-modified mRNA vaccination. *Nature* 2017;543(7644):248-51.

Pardi N, Parkhouse K, Kirkpatrick E, et al. Nucleoside-modified mRNA immunization elicits influenza virus hemagglutinin stalk-specific antibodies. *Nat Comm* 2018;9(1)(08):3361.

Sahin U, Karikó K, Türeci Ö. mRNA-based therapeutics - developing a new class of drugs. *Nat Rev Drug Discov* 2014;13(10):759-80.

Sedic M, Senn J, Lynn A, et al. Safety Evaluation of Lipid Nanoparticle–Formulated Modified mRNA in the Sprague- Dawley Rat and Cynomolgus Monkey. *Vet Path* 2018;55(2):341-54.

Sellers RS, Nelson K, Bennet B, et al. Scientific and regulatory policy committee points to consider*: approaches to the conduct and interpretation of vaccine safety studies for clinical and anatomic pathologists. *Toxicol Pathol* 2020;48(2):257-76.

Singh DK, Ganatra SR, Singh B, et al. SARS-CoV-2 infection leads to acute infection with dynamic cellular and inflammatory flux in the lung that varies across nonhuman primate species. *bioRxiv* 2020:06.05.136481. Accessed: 24 Sep 2020.

Truong B, Allegri G, Liu X-B, et al. Lipid nanoparticle-targeted mRNA therapy as a treatment for the inherited metabolic liver disorder arginase deficiency. *Proc Natl Acad Sci USA* 2019;116(42):21150-9.

US Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research. Development and licensure of vaccines to prevent COVID-19. In: *Guidance for industry*. Rockville, MD: Food and Drug Administration; 2020: 21 pages.

World Health Organization. WHO guidelines on nonclinical evaluation of vaccines. Annex 1. In: *World Health Organization. WHO technical report series, no. 927*. Geneva, Switzerland; World Health Organization; 2005:31-63.

World Health Organization. Annex 2. Guidelines on the nonclinical evaluation of vaccine adjuvants and adjuvanted vaccines. In: *WHO technical report series no. 987*. Geneva, Switzerland: World Health Organization; 2014: p. 59-100.

Wrapp D, Wang N, Corbett KS, et al. Cryo-EM structure of the 2019-nCoV spike in the prefusion conformation. *Science* 2020;367(6483):1260-3.

Yong CY, Ong HK, Yeap SK, et al. Recent advances in the vaccine development against middle east respiratory syndrome-coronavirus. *Front Microbiol* 2019;10:1781.

Zakhartchouk AN, Sharon C, Satkunarajah M, et al. Immunogenicity of a receptor-binding domain of SARS coronavirus spike protein in mice: implications for a subunit vaccine. *Vaccine* 2007;25(1):136-43.

Zhou M, Zhang X, Qu J. Coronavirus disease 2019 (COVID-19): a clinical update. *Front Med* 2020(Apr):1-10.

Zost S, Gilchuk P, Chen R, et al. Rapid isolation and profiling of a diverse panel of human monoclonal antibodies targeting the SARS-CoV-2 spike protein. *BioRxiv* posted May 13, 2020, www.biorxiv.org/content/10.1101/2020.05.12.091462v1.

Zou L, Ruan F, Huang M, et al. SARS-CoV-2 viral load in upper respiratory specimens of infected patients. *N Engl J Med* 2020;382(12)(03):1177-9.

Board Members and fellow citizens.

I know you can't answer questions during this time but I'd like to make this more interactive. I have been here in December, March and this is my third time speaking at these meetings.

By a show of hands how many of you looked at the ¹[11,000 pages of evidence](#) I shared last time I was here?

Only one of you... Chairman of the board said we are not doing this.

I'd like to remind you that in the ²[mission statement for this board](#) that states: "In addition, the Board serves as the primary advocate and representative of the citizens of the Commonwealth..." So essentially you are the people's advocates.

I want to speak on another topic today and that is the lack of data on vaccine injuries and deaths.

Are you aware that since ³[1986 Vaccine Manufacturers](#) are not liable for injury or death? (This does not incentivize them to make vaccines safer.)

It's time Vaccine Manufacturers become liable again.

Have any of you examined ⁴[vaccine safety](#)?

Have you seen the studies that compare the health of the vaccinated to the unvaccinated?

⁵[National Health Federation Study](#)

⁶[Children's Health Defense Study Slides](#)

Are you aware of what ⁷[VAERS](#) is? The vaccine adverse events reporting system.

How is that the deaths and injuries have been ignored? There are an enormous amount of deaths. (This system is underreported and is estimated to be only 10% of the actual injuries and deaths)

¹ [11,000 Pages of Evidence Filed in Landmark 5G Case Against the FCC, Hearing Set for Jan. 25 • Children's Health Defense \(childrenshealthdefense.org\)](#)

² [Mission, Roles, Priorities and Functions - Commissioner \(virginia.gov\)](#)

³ [H.R.5546 - 99th Congress \(1985-1986\): National Childhood Vaccine Injury Act of 1986 | Congress.gov | Library of Congress](#)

⁴ [VaccineSafety-Version-1.0-October-2-2017-1.pdf \(icandecide.org\)](#)

⁵ [National Health Federation \(rallycongress.net\)](#)

⁶ [Fully Vaccinated vs. Unvaccinated — Part 1 • Children's Health Defense \(childrenshealthdefense.org\)](#)

⁷ [Vaccine Adverse Events Reporting System \(VAERS\) – MCH Data Connect \(harvard.edu\)](#)

I have made copies of the ⁸[VAERS data](#) so that you all can have it. (I would like this entered into public record)

Are you aware that Cancer is NEVER looked at and long-term studies are never done on Vaccines aka Biologics?

(Attached document 2.4 Nonclinical Overview Pfizer Document on page 29 look at 2.4.4.5. Carcinogenicity, you'll see it clearly states, "Carcinogenicity testing is generally not considered necessary to support the development and licensure of vaccine products for infectious diseases (WHO, 2005)

Have you seen the side effects from the [Pfizer data](#) that's been released?

(From this there are two in particular that I will attach to the email for ease of finding as there are now over 300 uploaded documents, 5.3.6 Adverse Events Reports beginning on page 30 through page 38 lists 8 pages of adverse events single spaced!)

Have you heard of SADS; ⁹[Sudden Adult Death Syndrome](#)?

Have any of you watched the ¹⁰[film Vaxxed](#)?

(Have you heard of William Thompson the whistleblower from the CDC?)

What about the docu-series ¹¹[The Truth about Vaccines](#)?

(Dr. Stanley Plotkin is the "godfather" of Vaccines, in his 9 hour [Deposition](#) in court he admits he is agnostic and the number of aborted fetal cells used to make vaccines astonished me as a Christian)

How about ¹²[Senator Johnson and the Covid 19 public hearings](#) that took place in Washington, DC?

What about the ¹³[Global Covid Summit](#) with incredible doctors like Peter McCullough, Dr. Robert Malone (inventor of the MRNA technology) and many more. ¹⁴[Letter for Doctors](#)

⁸ [COVID Vaccine Data \(openvaers.com\)](#)

⁹ [The Latest Tragedy: Sudden Adult Death Syndrome - The Post & Email \(thepostemail.com\)](#)

¹⁰ [Vaxxed: From Cover-Up to Catastrophe \(2016\) - IMDb](#)

¹¹ [The Truth About Vaccines 10-Day Docu-Series](#)

¹² [LIVE: Sen. Ron Johnson holds forum with people who claim 'adverse' reactions to COVID-19 vaccine - YouTube](#)

¹³ [EPISODE 267: THE REAL GLOBAL COVID SUMMIT - The HighWire](#)

¹⁴ [Letter to take to your doctor - Global Covid Summit](#)

Before you allow the VA school immunization lists to mimic the CDC schedule isn't it time vaccine manufacturers are liable again and we examine ¹⁵[vaccine safety](#)?

Thanks for your time.

I was not able in 2 minutes to remark on the fact that the majority of people who have taken this Covid 19 “vaccine” have done so without fully informed consent. Informed consent includes showing the vaccine insert and being made aware of all ingredients and potential side effects. I hope we can all agree that this one being under the [Emergency Use Authorization](#) (EUA) has made it different from any other in history. As the data shows in VAERS as well.

Sincerely,

Doris Knick

healersporch@yahoo.com

¹⁵ [1-PAGE-INTRO-VAX-SAFETY.pdf \(icandecide.org\)](#)



COMMONWEALTH of VIRGINIA

Department of Health
P O BOX 2448
RICHMOND, VA 23218

Colin M. Greene, MD, MPH
State Health Commissioner

TTY 7-1-1 OR
1-800-828-1120

MEMORANDUM

DATE: August 4, 2022

TO: Virginia State Board of Health

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

SUBJECT: Exempt Final Stage for Regulations Governing School Immunizations (12VAC5-110)

The Regulations for the Immunization of School Children clarify immunization requirements for attendance at a public or private elementary, middle or secondary school, child care center, nursery school, family day care home, or developmental center as required by § 32.1-46 of the Code of Virginia.

Chapter 1223 of the 2020 Acts of Assembly added language to § 32.1-46 that created an exemption to the Administrative Process Act. The exemption process requires the Department of Health to provide a Notice of Intended Regulatory Action (NOIRA) and provide for a 60-day public comment period prior to the Board's adoption of the regulations. The NOIRA was posted on the Town Hall website on April 6, 2022 and the public comment period concluded on June 24, 2022. A total of 26 comments were received. Of those comments, 11 opposed vaccine mandates, 10 expressed concerns over the Human papillomavirus (HPV) vaccine requirement, 2 provided no explanation, 1 opposed chemicals in children, 1 misunderstood the action, and 1 supported the action. Appendix A provides the details on the comments received related to this action.

The proposed amendments included in this action are necessary to conform to changes in the Code of Virginia as a result of Chapter 1223 of the 2020 Acts of Assembly. The amendments include:

- Updates 12VAC5-110-10 to
 - Include the term “Adequately Immunized” in the definition of “Adequate Immunization”
 - Amend the definition of “Immunization Schedule” in 12VAC5-110-10 to reference the 2021 Recommended Immunization Schedules for Children and

Adolescents Aged 18 Years or Younger developed and published by the Centers for Disease Control and Prevention (CDC), the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP).

- Updates the purpose in 12VAC5-110-20 of the regulations such that it no longer contains specific vaccines.
- Amends the language in 12VAC5-110-50 to reference the exemption to the Administrative Process Act, requirement for a NOIRA, and a 60 day public comment period
- Updates 12VAC5-110-70 to
 - Amend the varicella requirement to clarify that children shall receive two properly spaced doses of varicella vaccine and that the first dose shall be administered at age 12 months or older.
 - Amend the HPV requirement to clarify that there shall be two doses of properly spaced HPV vaccine, regardless of gender, and that the first dose shall be administered before the child enters the 7th grade.
 - Add a requirement for rotavirus to state that children shall have two or three properly spaced doses of rotavirus vaccine, depending on the manufacturer, for children up to eight months of age
 - A requirement for hepatitis A vaccine has been added to state that children shall have two properly spaced doses of hepatitis A vaccine and the first dose shall be administered at age 12 months or older.
 - Add a requirement for meningococcal conjugate vaccine to state that children shall have two properly spaced doses of meningococcal conjugate vaccine, that the first dose shall be administered prior to entry to seventh grade, and that the second dose shall be administered prior to entry to twelfth grade.
- Updates 12VAC5-110-90 to
 - Clarify exclusion language so as to not use a term defined to mean something else in the regulations (immunization schedule)
 - Amend subsection H to clarify update HPV requirements
- Amends Documents Incorporated by Reference to incorporate the most recent version of the Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger

If this regulatory action is approved by the Board of Health, the regulatory package will be submitted to the Virginia Regulatory Town Hall website for the Executive Branch Review process, which includes the Office of the Attorney General, the Department of Planning and Budget, the Secretary of Health and Human Resources, and the Governor. At the conclusion of that review, the action will be effective following its publication in the Virginia Register.



townhall.virginia.gov

Exempt Action: Final Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-110
VAC Chapter title(s)	Regulations for the Immunization of School Children
Action title	Amend Regulations to Conform to Chapter 1223 of the 2020 Acts of Assembly
Final agency action date	
Date this document prepared	August 4, 2022

This information is required for executive branch review pursuant to Executive Order 19 (2022) (EO 19), any instructions or procedures issued by the Office of Regulatory Management (ORM) or the Department of Planning and Budget (DPB) pursuant to EO 19. In addition, this information is required by the Virginia Registrar of Regulations pursuant to the Virginia Register Act (§ 2.2-4100 et seq. of the Code of Virginia). Regulations must conform to the Regulations for Filing and Publishing Agency Regulations (1 VAC 7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*.

Brief Summary

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

This amendment to the Regulations for the Immunization of School Children is necessary to maintain conformity with the Code of Virginia following language added in Chapter 1223 of the 2020 General Assembly Regular Session. As a result of that action, the list of minimum requirements for school required immunization in § 32.1-46 was amended to include additional vaccine requirements. This amendment to the regulations will bring them into compliance with the list specified in the Code of Virginia.

Prior to this Final Exempt Action, the Virginia Department of Health (VDH) published a Notice of Intended Regulatory Action followed by a 60-day public comment period, as required by § 32.1-46 subsection C. VDH received 26 comments. Twenty-four were in opposition to the action (11 generally for choice and against mandates, 10 concerns over HPV vaccine, 1 provided no explanation, 1 minimize chemicals in

children, and 1 misunderstood action), one appeared to be for the action, and one was categorized as N/A because no comment was left and the title was "protect our children" which could go either way.

The proposed amendments seek to update the Regulations for the Immunization of School Children in order to adhere to the minimum immunization requirements specified in § 32.1-46. The proposed amendments are listed below and are consistent with language added to the Code of Virginia as a result of Chapter 1223 of the 2020 Regular Session.

- Update 12VAC5-110-10 to
 - Include the term “Adequately Immunized” in the definition of “Adequate Immunization”
 - Amend the definition of “Immunization Schedule” in 12VAC5-110-10 to reference the 2021 Recommended Immunization Schedules for Children and Adolescents Aged 18 Years or Younger developed and published by the Centers for Disease Control and Prevention (CDC), the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP).
- Update the purpose in 12VAC5-110-20 of the regulations such that it no longer contains specific vaccines.
- Amend the language in 12VAC5-110-50 to reference the exemption to the Administrative Process Act, requirement for a NOIRA, and a 60 day public comment period.
- Update 12VAC5-110-70 to
 - Amend the varicella requirement to clarify that children shall receive two properly spaced doses of varicella vaccine and that the first dose shall be administered at age 12 months or older.
 - Amend the HPV requirement to clarify that there shall be two doses of properly spaced HPV vaccine, regardless of gender, and that the first dose shall be administered before the child enters the 7th grade.
 - Add a requirement for rotavirus to state that children shall have two or three properly spaced doses of rotavirus vaccine, depending on the manufacturer, for children up to eight months of age.
 - A requirement for hepatitis A vaccine has been added to state that children shall have two properly spaced doses of hepatitis A vaccine and the first dose shall be administered at age 12 months or older.
 - Add a requirement for meningococcal conjugate vaccine to state that children shall have two properly spaced doses of meningococcal conjugate vaccine, that the first dose shall be administered prior to entry to seventh grade, and that the second dose shall be administered prior to entry to twelfth grade.
- Update 12VAC5-110-90 to
 - Clarify exclusion language so as to not use a term defined to mean something else in the regulations (immunization schedule).
 - Amend subsection H to clarify update HPV requirements.
- Amend Documents Incorporated by Reference to incorporate the most recent version of the Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger.

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, internal staff review, petition for rulemaking, periodic review, or board decision). For purposes of executive branch review, “mandate” has the same meaning as defined in the ORM procedures, “a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part.”

Chapter 1223 of the 2020 General Assembly Regular Session requires the Virginia Department of Health to update the Regulations for the Immunization of School Children to conform school immunization requirements to the minimum requirements specified in § 32.1-46.

Statement of Final Agency Action

Provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

Office of Regulatory Management
Economic Review Form

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-110
VAC Chapter title(s)	Regulations for the Immunization of School Children
Action title	Amend Regulations to Conform to Chapter 1223 of the 2020 Acts of Assembly
Date this document prepared	August 11, 2022

Cost Benefit Analysis

Table 1a: Costs and Benefits of the Proposed Changes (Primary Option)

(1) Direct Costs & Benefits	<ul style="list-style-type: none"> Conform regulations to language in Section 32.1-46 of the Code of Virginia. Direct Costs: none anticipated Direct Benefits: Reduce confusion to regulated community by ensuring that the Regulations for the Immunization of School Children are consistent with requirements in the Code of Virginia Update definitions and terms used in the regulations Direct Costs: none anticipated Direct Benefits: Increase clarity of the regulations so that terms used are properly defined and only used as defined 		
(2) Quantitative Factors	Estimated Dollar Amount	Present Value	
Direct Costs	(a) \$0	(c) 0	
Direct Benefits	(b) \$0	(d) 0	
(3) Benefits-Costs Ratio	N/A	(4) Net Benefit	N/A

(5) Indirect Costs & Benefits	There are no anticipated indirect costs or benefits for the proposed amendments.
(6) Information Sources	N/A
(7) Optional	

Table 1b: Costs and Benefits under the Status Quo (No change to the regulation)

(1) Direct Costs & Benefits	<ul style="list-style-type: none"> Section 32.1-46 of the Code of Virginia states that the Board of Health’s regulations “shall at a minimum require” and then lists a series of immunization requirements. At this time, the regulations are out of compliance with the Code of Virginia <p>Direct Costs: \$0</p> <p>Direct Benefits: There are no direct benefits identified</p> <ul style="list-style-type: none"> Currently, there are terms used that are not clearly defined, require updates, or are used in multiple ways throughout the regulations. <p>Direct Costs: \$0</p> <p>Direct Benefits: There are no direct benefits identified</p>		
(2) Quantitative Factors	Estimated Dollar Amount	Present Value	
Direct Costs	(a) \$0	(c) 0	
Direct Benefits	(b) \$0	(d) 0	
(3) Benefits-Costs Ratio	N/A	(4) Net Benefit	N/A
(5) Indirect Costs & Benefits	There are no anticipated indirect costs or benefits for the proposed amendments.		

(6) Information Sources	N/A
(7) Optional	

Table 1c: Costs and Benefits under an Alternative Approach

(1) Direct Costs & Benefits	<ul style="list-style-type: none"> • There are no alternatives to this action as it is simply to get the regulations in compliance with the language in the Code of Virginia. <p>Direct Costs: N/A</p> <p>Direct Benefits: N/A</p>		
(2) Quantitative Factors	Estimated Dollar Amount	Present Value	
Direct Costs	(a) N/A	(c) N/A	
Direct Benefits	(b) N/A	(d) N/A	
(3) Benefits-Costs Ratio	N/A	(4) Net Benefit	N/A
(5) Indirect Costs & Benefits	N/A		
(6) Information Sources	N/A		
(7) Optional			

Impact on Local Partners

Table 2: Impact on Local Partners

(1) Direct Costs & Benefits	No direct cost to local partners such as school divisions as these requirements already exist in the Code of Virginia. The benefit is increased clarity for partners and constituents to know immunization requirements.
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(2) Quantitative Factors	Estimated Dollar Amount
Direct Costs	(a) \$0
Direct Benefits	(b) \$0
(3) Indirect Costs & Benefits	No anticipated indirect costs as this is an action to get into compliance with the Code of Virginia. The indirect benefit is increased clarity for partners and constituents to know immunization requirements.
(4) Information Sources	N/A
(5) Assistance	N/A
(6) Optional	

Economic Impacts on Families

Table 3: Impact on Families

(1) Direct Costs & Benefits	No direct impact on families as these amendments are already required by the Code of Virginia. Benefit is increased clarity for families to know what current school immunization requirements are in Virginia.
(2) Quantitative Factors	Estimated Dollar Amount
Direct Costs	(a) \$0
Direct Benefits	(b) \$0
(3) Indirect Costs & Benefits	No indirect impact on families as these amendments are already required by the Code of Virginia. Benefit is increased clarity for families to know what current school immunization requirements are in Virginia.
(4) Information Sources	N/A

(5) Optional	
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Impacts on Small Businesses

Table 4: Impact on Small Businesses

(1) Direct Costs & Benefits	No direct cost or benefits to small businesses.
(2) Quantitative Factors	Estimated Dollar Amount
Direct Costs	(a) \$0
Direct Benefits	(b) \$0
(3) Indirect Costs & Benefits	No indirect cost or benefits to small businesses.
(4) Alternatives	No alternatives possible as this action is to get into compliance with the Code of Virginia.
(5) Information Sources	N/A
(6) Optional	

Changes to Number of Regulatory Requirements

Table 5: Total Number of Requirements

Chapter number	Number of Requirements			
	Initial Count	Additions	Subtractions	Net Change
12VAC5-110	52	4	0	4

1 **Project 7086 - NOIRA**

2 **Department Of Health**

3 **Regulations to Conform to Legislation Enacted by the 2020 General Assembly**

4 **12VAC5-110-10. Definitions.**

5 The following words and terms when used in this chapter shall have the following meanings
6 unless the context clearly indicates otherwise:

7 "Adequate immunization" or "Adequately Immunized" means the immunization requirements
8 prescribed under 12VAC5-110-70.

9 "Admit" or "admission" means the official enrollment or reenrollment for attendance at any
10 grade level, whether full-time or part-time, of any student by any school.

11 "Admitting official" means the school principal or his designated representative if a public
12 school; if a nonpublic school or child care center, the principal, headmaster or director of the
13 school or center.

14 "Board" means the State Board of Health.

15 "Commissioner" means the State Health Commissioner.

16 "Compliance" means the completion of the immunization requirements prescribed under
17 12VAC5-110-70.

18 "Conditional enrollment" means the enrollment of a student for a period of 90 days contingent
19 upon the student having received at least one dose of each of the required vaccines and the
20 student possessing a plan, from a physician or local health department, for completing his
21 immunization requirements within the ensuing 90 calendar days. If the student requires more than
22 two doses of hepatitis B vaccine, the conditional enrollment period, for hepatitis B vaccine only,
23 shall be 180 calendar days.

24 "Documentary proof" means an appropriately completed copy of the most current version of
25 Form MCH 213G signed by a physician or his designee, registered nurse, or an official of a local
26 health department. A copy of the immunization record signed or stamped by a physician or his
27 designee, registered nurse, or an official of a local health department indicating the dates of
28 administration including month, day, and year of the required vaccines, shall be acceptable in lieu
29 of recording these dates on Form MCH 213G, as long as the record is attached to Form MCH
30 213G and the remainder of Form MCH 213G has been appropriately completed. A printout of an
31 immunization record from the provider's electronic health record can be accepted without a
32 signature or stamp. For a new student transferring from an out-of-state school, any immunization
33 record, which contains the exact date (month/day/year) of administration of each of the required
34 doses of vaccines, is signed by a physician or his designee or registered nurse, and complies
35 fully with the requirements prescribed under 12VAC5-110-70 shall be acceptable.

36 "Immunization" means the administration of a product licensed by the FDA to confer protection
37 against one or more specific pathogens.

38 "Immunization ~~schedules~~ schedule" means the ~~2017~~ 2022 Recommended Immunization
39 Schedules for Children and Adolescents Aged 18 Years or Younger developed and published by
40 the Centers for Disease Control and Prevention (CDC), the Advisory Committee on Immunization
41 Practices (ACIP), the American Academy of Pediatrics (AAP), and the American Academy of
42 Family Physicians (AAFP).

43 "Physician" means any person licensed to practice medicine in any of the 50 states or the
44 District of Columbia.

45 "School" means:

- 46 1. Any public school from kindergarten through grade 12 operated under the authority of
47 any locality within this Commonwealth;
- 48 2. Any private or religious school that offers instruction at any level or grade from
49 kindergarten through grade 12;
- 50 3. Any private or religious nursery school or preschool, or any private or religious child
51 care center required to be licensed by this Commonwealth;
- 52 4. Any preschool classes or Head Start classes operated by the school divisions within
53 this Commonwealth; and
- 54 5. Any family day home or developmental center.

55 "Student" means any person who seeks admission to a school, or for whom admission to a
56 school is sought by a parent or guardian, and who will not have attained the age of 20 years by
57 the start of the school term for which admission is sought.

58 "Twelve months of age" means the 365th day following the date of birth. For the purpose of
59 evaluating records, vaccines administered up to four days prior to the first birthday (361 days
60 following the date of birth) will be considered valid.

61 **12VAC5-110-20. Purpose.**

62 This chapter is designed to ensure that all students attending any school public or private
63 elementary, middle or secondary school, child care center, nursery school, family day care home,
64 or developmental center in the Commonwealth, are adequately immunized and protected against
65 diphtheria, pertussis, tetanus, poliomyelitis, rubeola, rubella, mumps, haemophilus influenzae
66 type b, hepatitis B, varicella, pneumococcal, and human papillomavirus disease as appropriate
67 for the age of the student vaccine preventable diseases as specified in this chapter.

68 **12VAC5-110-50. Application of the Administrative Process Act.**

69 ~~The provisions of the Virginia Administrative Process Act (§ 2.2-4000 et seq. of the Code of~~
70 ~~Virginia) shall govern the adoption, amendment, modification and revision of this chapter, and the~~
71 ~~conduct of all proceedings and appeals hereunder. The Regulations for the Immunization of~~
72 ~~School Children are exempt from the requirements of Article 2 (§ 2.2-4006 et seq.) of the~~
73 ~~Administrative Process Act (§ 2.2-4000 et seq.). However, the Department of Health shall (i)~~
74 ~~provide a Notice of Intended Regulatory Action and (ii) provide for a 60-day public comment period~~
75 ~~prior to the Board's adoption of the regulations.~~

76 **12VAC5-110-70. Immunization requirements.**

77 Every student enrolling in a school shall provide documentary proof of adequate immunization
78 with the prescribed number of doses of each of the vaccines and toxoids listed in the following
79 subdivisions, as appropriate for the child's age according to the immunization schedules. Spacing,
80 minimum ages, and minimum intervals shall be in accordance with the immunization schedules.
81 A copy of every student's immunization record shall be on file in his school record.

82 1. Diphtheria Toxoid. A minimum of four properly spaced doses of diphtheria toxoid. One
83 dose shall be administered on or after the fourth birthday and prior to entering
84 kindergarten.

85 2. Tetanus Toxoid. A minimum of four properly spaced doses of tetanus toxoid. One dose
86 shall be administered on or after the fourth birthday and prior to entering kindergarten.

87 3. Pertussis Vaccine. A minimum of four properly spaced doses of pertussis vaccine. One
88 dose shall be administered on or after the fourth birthday. A booster dose shall be
89 administered prior to entering the seventh grade.

90 4. Poliomyelitis Vaccine. A minimum of four doses of poliomyelitis vaccine with one dose
91 administered on or after the fourth birthday and prior to entering kindergarten.

92 5. Measles (Rubeola) Vaccine. One dose of live measles vaccine administered at age 12
93 months or older, and a second dose administered prior to entering kindergarten.

94 6. Rubella Vaccine. A minimum of one dose of rubella virus vaccine administered at age
95 12 months or older.

96 7. Mumps Vaccine. One dose of mumps virus vaccine administered at age 12 months or
97 older and a second dose administered prior to entering kindergarten.

98 8. Haemophilus Influenzae Type b (Hib) Vaccine. A complete series of Hib vaccine (i.e.,
99 up to a maximum of four doses of vaccine as appropriate for the age of the child and the
100 age at which the immunization series was initiated). The number of doses administered
101 shall be in accordance with current immunization schedule recommendations. Attestation
102 by the physician or his designee, registered nurse, or an official of a local health
103 department on that portion of Form MCH 213G pertaining to Hib vaccine shall mean that
104 the child has satisfied the requirements of this section. This section shall not apply to
105 children older than 60 months of age or for admission to any grade level, kindergarten
106 through grade 12.

107 9. Hepatitis B Vaccine. A minimum of three doses of hepatitis B vaccine for all children.
108 The FDA has approved a two-dose schedule only for adolescents 11 through 15 years of
109 age and only when the Merck brand (RECOMBIVAX HB) Adult Formulation Hepatitis B
110 vaccine is used. The two RECOMBIVAX HB adult doses must be separated by a minimum
111 of four months. The two dose schedule using the adult formulation must be clearly
112 documented in the Hepatitis B section on Form MCH 213G.

113 10. Varicella (Chickenpox) Vaccine. ~~All children born on and after January 1, 1997, shall~~
114 ~~be required to have one dose of chickenpox vaccine~~ Two properly spaced doses of
115 varicella vaccine. The first dose shall be administered on or after at age 12 months of age
116 or older and a second dose administered prior to entering kindergarten.

117 11. Pneumococcal Conjugate Vaccine (PCV). A complete series of PCV (i.e., up to a
118 maximum of four doses of vaccine as appropriate for the age of the child and the age at
119 which the immunization series was initiated). The number of doses administered shall be
120 in accordance with current immunization schedule recommendations. Attestation by the
121 physician or his designee, registered nurse, or an official of a local health department on
122 that portion of Form MCH 213G pertaining to PCV vaccine shall mean that the child has
123 satisfied the requirements of this section. This section shall not apply to children older than
124 60 months of age or for admission to any grade level, kindergarten through grade 12.

125 12. Human Papillomavirus (HPV) Vaccine. ~~Three~~ Two doses of properly spaced HPV
126 vaccine ~~for females, effective October 1, 2008.~~ The first dose shall be administered before
127 the child enters the ~~sixth~~ seventh grade.

128 13. Rotavirus Vaccine. Two or three properly spaced doses of rotavirus vaccine,
129 depending on the manufacturer, for children up to eight months of age.

130 14. Hepatitis A Vaccine. Two properly spaced doses of hepatitis A vaccine (HAV). The
131 first dose shall be administered at age 12 months or older, and a second dose
132 administered prior to entering kindergarten.

133 15. Meningococcal Conjugate Vaccine. Two properly spaced doses of meningococcal
134 conjugate vaccine (MenACWY). The first dose shall be administered prior to entry to
135 seventh grade. The second dose shall be administered prior to entry to twelfth grade.

136 **12VAC5-110-90. Responsibilities of admitting officials.**

137 A. Procedures for determining the immunization status of students. Each admitting official or
138 his designee shall review, before the first day of each school year, the school medical record of
139 every new student seeking admission to his school, and that of every student enrolling in grade

140 six for compliance with the requirements prescribed in 12VAC5-110-70. Such review shall
141 determine into which one of the following categories each student falls:

142 1. Students whose immunizations are adequately documented and complete in
143 conformance with 12VAC5-110-70. Students with documentation of existing immunity to
144 mumps, measles, rubella, or varicella as defined in 12VAC5-110-80 B shall be considered
145 to be adequately immunized for such disease.

146 2. Students who are exempt from the immunization requirements of 12VAC5-110-70
147 because of medical contraindications or religious beliefs provided for by 12VAC5-110-80.

148 3. Students whose immunizations are inadequate according to the requirements of
149 12VAC5-110-70.

150 4. Students without any documentation of having been adequately immunized.

151 B. Notification of deficiencies. Upon identification of the students described in subdivisions A
152 3 and 4 of this section, the admitting official shall notify the parent or guardian of the student:

153 1. That there is no, or insufficient, documentary proof of adequate immunization in the
154 student's school records.

155 2. That the student cannot be admitted to school unless he has documentary proof that
156 he is exempted from immunization requirements pursuant to 12VAC5-110-70.

157 3. That the student may be immunized and receive certification by a licensed physician,
158 registered nurse, or an official of a local health department.

159 4. How to contact the local health department to receive the necessary immunizations.

160 C. Conditional enrollment. Any student whose immunizations are incomplete may be admitted
161 conditionally if that student provides documentary proof at the time of enrollment of having
162 received at least one dose of the required immunizations accompanied by a schedule for
163 completion of the required doses within 90 calendar days, during which time that student shall
164 complete the immunizations required under 12VAC5-110-70. If the student requires more than
165 two doses of hepatitis B vaccine, the conditional enrollment period, for hepatitis B vaccine only,
166 shall be 180 calendar days. If a student is a homeless child or youth and does not have
167 documentary proof of necessary immunizations or has incomplete immunizations and is not
168 exempted from immunization as described in 12VAC5-110-80, the school administrator shall
169 immediately admit such student and shall immediately refer the student to the local school division
170 liaison, who shall assist in obtaining the documentary proof of, or completing, immunizations. The
171 admitting official should examine the records of any conditionally enrolled student at regular
172 intervals to ensure that such a student remains on schedule with his plan of completion.

173 D. Exclusion. The admitting official shall, at the end of the conditional enrollment period,
174 exclude any student who is not in compliance with the immunization requirements under 12VAC5-
175 110-70 and who has not been granted an exemption under 12VAC5-110-80 until that student
176 provides documentary proof that his immunization ~~schedule has~~ requirements have been
177 completed, unless documentary proof that a medical contraindication developed during the
178 conditional enrollment period is submitted.

179 E. Transfer of records. The admitting official of every school shall be responsible for sending
180 a student's immunization records or a copy thereof, along with his permanent academic or
181 scholastic records, to the admitting official of the school to which a student is transferring within
182 10 days of his transfer to the new school.

183 F. Report of student immunization status. Each admitting official shall, within 30 days of the
184 beginning of each school year or entrance of a student, or by October 15 of each school year, file
185 with the State Health Department through the health department for his locality, a report
186 summarizing the immunization status of the students in his school as of the first day of school.
187 This report shall be filed using the web-enabled reporting system or on the most current version

188 of Form SIS, the Student Immunization Status Report, and shall contain the number of students
189 admitted to that school with documentary proof of immunization, the number of students who have
190 been admitted with a medical or religious exemption and the number of students who have been
191 conditionally admitted.

192 G. Immunization records shall be open to inspection by health department officials.


193 H. Each admitting official shall ensure that the parent or guardian of a ~~female~~ child to be
194 enrolled in the ~~sixth~~ seventh grade receives educational materials describing the link between the
195 human papillomavirus and cervical cancer. Materials shall be approved by the board and provided
196 to the parent or guardian prior to the child's enrollment in the ~~sixth~~ seventh grade.

197 Documents Incorporated by Reference (12VAC5-110)

198 ~~[Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or](#)~~
199 ~~[Younger, United States 2017, Centers for Disease Control and Prevention, U.S. Department of](#)~~
200 ~~[Health and Human Services, effective January 1, 2017](#)~~

201 ~~[Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or](#)~~
202 ~~[Younger, United States 2022, Centers for Disease Control and Prevention, U.S. Department of](#)~~
203 ~~[Health and Human Services.](#)~~

Commenter	Title	Comment	Date/ID
Erin Grzeda	No!	No	5/7/22 2:16 pm CommentID:121925
Virginians For Children First	HPV vaccine has made you all culpable criminal child endangerment and medical malpractice	When Gardasil first came out, 41 states considered this requirement in 2006- 24 took it to bill - ONE STATE ADOPTED IT- VIRGINIA! Today 3 states and DC have a "requirement that isn't required"- WHY? Colonial Heights, Fauquier County- 13 news media sources- MY FORMER PEDIATRICIAN - ALL REPORTED IT AS REQUIRED. Norm Oliver didn't care- and it seems Dr. Greene doesn't care either since I spoke at the VDH with all of this information last month- and STILL it will be on the list of requirements next year. A BILLION invested by MERCK strictly for the HPV vaccine production under Northam. Marshall Vogt over and over saying "he feels the requirement that isn't required is necessary?" WHY? IT IS NOT COMMUNICABLE IN SCHOOL. period. and if you cannot make sure that parents are ALL GETTING THE ACCURATE INFORMATION from the doctors, counties, VDH, mainstream media, etc. YOU are responsible for every child whose parent got the FALSE information - and trustingly vaccinated their child who then suffered neurological damage as the Vaccine contains Sarin - but since it is supposed to "cook off" doesn't have to be included in the ingredient list. A nerve gas- and neurological side effects like guillian-barre syndrome. small fiber neuropathy, CFS, etc are not a coincidence. DO YOUR JOB. 3 states and DC in 16 years! Read this study by THE NEW ENGLAND JOURNAL OF MEDICINE- https://www.nejm.org/doi/full/10.1056/nejmsr1003547 AND https://www.oatext.com/the-expanding-cocktail-of-harmful-ingredients-in-human-papillomavirus-vaccines.php ? fbcclid=IwAR3zoAdm7X4PfDEBYu_iXAkXiXxyk7oqxHRdMZigr4kgCdxuCymBulkWuNw 47 states can see the absolute insanity of "requiring" a vaccine for an STD. WHY CAN'T VIRGINIA? Anne Taydus- Vp strategy and advocacy Virginians for Children First	5/7/22 3:38 pm CommentID:121926
Matthew McNeill	Immunization	I refer all questions about the safety and veracity of vaccines and immunizations to the thorough and complete work done and completed by Robert Kennedy Jr. I would like to minimize the amount of chemicals injected into our kids!	5/7/22 4:09 pm CommentID:121927
Rosie	NO MORE forced vaccinations	My child's body MY CHOICE!	5/7/22 4:17 pm CommentID:121928
Lisa Cacciatore	No medical mandates	Stop the medical mandates. Make schools great again!!! Take all the excess out, back to academics	5/7/22 4:44 pm CommentID:121929
Anonymous	HPV vaccine	The HPV vaccine has injured many children and many have died. If you mandate this then you should be held responsible for any injuries and DEATHS due to the vaccine mandate.	5/7/22 5:09 pm CommentID:121931
Doris	Common Sense NOT Conformity	For far too long Vaccine injuries have been ignored! When are you going to make Vaccine Manufacturers liable again?!? What about true informed consent and showing the inserts with death listed on it?!? How about LONG TERM Safety studies?!? Why is CANCER NEVER looked at in terms of vaccines? HPV has been proven to regulate itself. It is not deadly but these jabs have been proven to be. Just look at the VAERS data. Look at VAXXED one and two documentary of the willful ignorance of the CDC and WHO. You are no longer trusted in the eyes of MILLIONS. Common sense is needed not conformity. Conformity with who CA, DC and VA who are the only states who've added HPV to the list of mandatory injections. This is ridiculous. Who protects the people from these captured agencies?	5/7/22 6:06 pm CommentID:121932
Anonymous	No!!	Why do children need a vaccine against an STD? It's ludicrous. Aside from that, medical freedom is a MUST and no parent should be required to inject their child with something. The list of vaccines required have grown over the years and we now see more autism and other issues for children. I see more young women having a hard time conceiving when they want a family. Vaccine manufacturers are not held liable for damages and we all know Big Pharma is only out for profit. So are many of those making these decisions. The safety of our citizens, both children and adults, has been sold out for personal gain. Shame on you if you allow it to continue. You will reap what you sow.	5/8/22 11:45 am CommentID:121935
Anonymous	No mandates for children	A child's body should not be force injected with anything that carries no liability against it's manufacturer and hasn't been properly researched (meaning long term studies with an actual control group of non-vaccinated children). HPV should never have been added to the list of mandatory vaccines after so many reactions and side effects were seen. Parents should be the ones making the final decisions for what medical procedures are done to their child.	5/8/22 2:03 pm CommentID:121936
Anonymous	HPV	Remove the HPV mandate as far too many children and young adults have been seriously & permanently injured from this shot for an illness that is NOT easily transmissible through school attendance (unless the schools are pushing/permitting rampant underage sexual activity). I personally know of a girl who nearly died of Crohn's disease brought on right after the HPV shot and has had much of her intestines removed and now deals with complications of the j-pouch the doctors created in a attempt to fix the damage caused by the HPV shot. She can never be normal again because of the damage from this shot! Giving this to any child is the same as playing Russian roulette! There are MANY medical reports documenting the serious dangers with the HPV shot. This should not be mandated for any child!	5/9/22 6:08 am CommentID:121939
Anonymous	HPV Vaccine	Check out this official government medical report on the HPV shot's serious side effect! This is just one of the serious side effects of the HPV shot. Getting this shot is like playing Russian roulette - are you willing to damage your child or any other child with this shot for an illness NOT transmitted during normal school activity?? https://pubmed.ncbi.nlm.nih.gov/29889622/	5/9/22 6:16 am CommentID:121940
Kambra Russell	NO!!!!	There should never be more vaccines added to the schedule! Parents know what's best for their children!!! It should always be the choice of the parents! Sexually transmitted disease vaccines should never be added! Experimental MRNA vaccines should never be added!! Parents should always be allowed to opt-out of everything!!!!!!!	5/10/22 6:40 am CommentID:121946
Melissa McKinley	No! Absolutely not!	It is not the school nor the governments place to have any decisions is the health and well-being of a child. According to Virginia law, it's the parents right to choose what is best for their child!! No to unnecessary vaccines!	5/10/22 7:00 am CommentID:121947
Macaria	No forced	I do not want the government to make medical choices for my children. I am against forced vaccinations. I have	5/10/22 7:49 am

Suddarth	vaccines	zero faith in the medical community.	CommentID:121948
Jamie Hinkle	No to medical mandates of any kind	I do not agree with any updates to the current schedule of vaccines which would mandate/ add HPV, COVID etc. Given the recent conversations regarding, "my body, my choice," the government needs to pay attention. The people want less mandates. We want medical freedom and to have informed consent. VDH and the CDC should be reexamining every vaccine that is on the current schedule. Looking at the cases of vaccine injury and stopping the push with a "one size fits all approach." I do not want anyone telling me what shots my kids need to have in order to go to school, fit into society, especially those which are resulting in long term damage or short term efficacy. NO to mandated shots.	5/10/22 7:54 am CommentID:121949
Crystal	No.	How many teens will live with long term side effects from HPV vaccine because of limited information already? Chronic fatigue, POTS, etc. enough. HPV is not nor should it ever be required!!	5/10/22 8:06 am CommentID:121950
Veronica Farr	No vaccine mandates	No vaccine mandates!!!!	5/10/22 8:39 am CommentID:121951
Priscilla Bayes	No to Vaccine Mandates	Parents should be the one to decide what goes into the bodies of their children NOT THE GOVERNMENT! No changes are necessary and this needs to stop. We are a country founded on freedom and choice. Stop the madness!	5/10/22 6:38 pm CommentID:121992
Kristen Kelly	No to any type of medical mandates	No to any type of medical mandates	5/10/22 10:37 pm CommentID:122004
Anna Marquez	Vaccines	No to mantory vaccines .	5/11/22 1:38 pm CommentID:122008
Anonymous	No more vaccine mandates	Where there is risk there must be choice and informed consent. Medical decisions should be confidential. There is no reason any citizen should know another person's medical treatments unless they are part of that person's Healthcare team.	5/13/22 11:50 am CommentID:122026
Medical Freedom	Medical Freedom	Where there is risk, there must be choice.	5/18/22 9:43 pm CommentID:122062
Anonymous	No mandatory vaccines	Medical freedom for all	5/22/22 8:47 pm CommentID:122077
Tired of tyranny	Vaccines	There are only certain vaccines that I can see have a history of being tested and true. I do believe that there is a huge difference between vaccines given in terms of the # and boosters, from back in the 70's to the 90's to now. I would like to see what can be done to accommodate some of the concerns made by parents. While I understand polio, for instance, should be a required vaccine, the flu shot shouldn't be. The current covid vaccine simply has too much medical controversy to be required at this point in time.	5/31/22 8:31 am CommentID:122119
Virginia Chapter Children's Health Defense	Protect Our Children	 <p>Children's Health Defense VIRGINIA CHAPTER</p>	
Virginia Chapter Children's Health Defense	Protect Our Children		6/23/22 5:24 pm CommentID:122161



COMMONWEALTH of VIRGINIA

Department of Health
P O BOX 2448
RICHMOND, VA 23218

Colin M. Greene, MD, MPH
State Health Commissioner

TTY 7-1-1 OR
1-800-828-1120

MEMORANDUM

DATE: August 8, 2022

TO: State Board of Health

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

SUBJECT: Proposed Regulations – Sexual Assault Survivor Treatment and Transfer –
Promulgation of New Regulation to Implement Chapter 725 of the 2020 Acts of
Assembly

Enclosed for your review are proposed Sexual Assault Survivor Treatment and Transfer Regulations.

Chapter 725 of the 2020 Acts of Assembly created Article 8 of Chapter 5 of Title 32.1 of the Code of Virginia, which requires the State Board of Health to promulgate regulations to effectuate the act, specifically the standards for review and approval of sexual assault survivor transfer plans, pediatric sexual assault survivor transfer plans, sexual assault survivor treatment plans, and pediatric sexual assault survivor treatment plans. As the requirement to have such plans extends to hospitals, clinics, and physician's offices, there is no existing regulatory chapter that would best fit this mandate. This regulatory action would create a new regulatory chapter for these standards. When the NOIRA was published for this regulatory action, no comments were received.

The State Board of Health is requested to approve the proposed regulations. Should the Board of Health approve them, they will be submitted to the Office of the Attorney General to begin the Executive Branch review process. Following Executive Branch review and approval, the proposed amendments will be submitted to the Virginia Register of Regulations and the Virginia Regulatory Town Hall website for publication with a 60-day comment period. Following the close of that public comment period, VDH will draft the final amendments.



townhall.virginia.gov

Proposed Regulation Agency Background Document

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-416
VAC Chapter title(s)	Sexual Assault Survivor Treatment and Transfer Regulation
Action title	Promulgation of New Regulation to Implement Chapter 725 of the 2020 Acts of Assembly
Date this document prepared	August 8, 2022

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

Brief Summary

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

Chapter 725 (2020 Acts of Assembly) creates Article 8 of Chapter 5 of Title 32.1 of the Code of Virginia, which requires the Board to promulgate regulations to effectuate the act, specifically the standards for review and approval of sexual assault survivor transfer plans, pediatric sexual assault survivor transfer plans, sexual assault survivor treatment plans, and pediatric sexual assault survivor treatment plans. As the requirement to have such plans extends to hospitals, clinics, and physician's offices, there is no already existing regulatory chapter that would best fit this mandate, so the Virginia Board of Health 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.

"Board" means the Virginia Board of Health.

"EMTALA" means the Emergency Medical Treatment and Labor Act (42 USC § 1395dd et seq.).

"PERK" means physical evidence recovery kit.

"PSAS" means pediatric sexual assault survivor.

"SAFE" means sexual assault forensic examiner.

"SAS" means a sexual assault survivor.

"STI" means sexually transmitted infection.

"VDH" means the Virginia Department of Health.

Mandate and Impetus

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

Chapter 725 (2020 Acts of Assembly) creates Article 8 of Chapter 5 of Title 32.1 of the Code of Virginia, which requires the Board to promulgate regulations to effectuate the act. Specifically, subsection A of § 32.1-162.15:4 of the Code of Virginia requires the Board to adopt regulations to establish standards for review and approval of SAS treatment plans. Section 32.1-162.15:5 of the Code of Virginia requires the Board to adopt regulations to establish standards for review and approval of SAS transfer plans and PSAS transfer plans. Subsection B of § 32.1-162.15:6 of the Code of Virginia requires the Board to adopt regulations to establish standards for the review and approval of PSAS treatment plans; subsection C of that same statute requires the Board to adopt regulations to establish standards for review and approval of PSAS transfer plans.

Legal Basis

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

Subsection A of § 32.1-162.15:4 of the Code of Virginia requires the Board to adopt regulations to establish standards for review and approval of SAS treatment plans. Section 32.1-162.15:5 of the Code of Virginia requires the Board to adopt regulations to establish standards for review and approval of SAS transfer plans and PSAS transfer plans. Subsection B of § 32.1-162.15:6 of the Code of Virginia requires the Board to adopt regulations to establish standards for the review and approval of PSAS treatment plans; subsection C of that same statute requires the Board to adopt regulations to establish standards for review and approval of PSAS transfer plans. More generally, pursuant to § 32.1-12 of the Code of Virginia, the Board

has the authority to make, adopt, promulgate and enforce such regulations and provide for reasonable variances and exemptions therefrom as may be necessary to carry out the provisions of Title 32.1 of the Code of Virginia and other laws of the Commonwealth administered by it, the State Health Commissioner, or the Department of Health.

Purpose

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

The rationale or justification for the regulatory change is that Chapter 725 (2020 Acts of Assembly) requires the Board to promulgate regulations for the treatment and transfer of survivors of sexual assault (adult and pediatric). The regulatory change is essential to protect the health, safety, and welfare of citizens because it sets minimum standards for treatment services and transfer services specific to survivors of sexual assault and appropriate handling of evidence collected. The goals of the regulatory change and the problems it is intended to solve is to ensure that there are more robust, planned health care services for survivors of sexual assault throughout the Commonwealth and that there is clarity for patients about where to go to receive treatment services.

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.

Part I General Information

12VAC5-416-10. Definitions

Adds definitions for administrator, anonymous physical evidence recovery kit or anonymous PERK, applicant, approved pediatric transfer facility, approved pediatric treatment facility, approved plan, assent, board, clinic, commissioner, DCLS, department, directed plan of correction, emergency contraception, EMTALA, follow-up health care, forensic medical examination, health care professional, hospital, inspector, legal representative, OLC, pediatric health care facility, physician’s office, physical evidence recovery kit or PERK, plan of correction, proposed plan, PSAS, PSAS transfer plan, PSAS transfer services, PSAS treatment plan, PSAS treatment services, rape crisis center, regulant, SAS, sexual assault forensic examiner or SAFE, SAS transfer plan, SAS transfer services, SAS treatment plan, SAS treatment services, STI, transfer hospital, transportation services, and treatment hospital.

12VAC5-416-20. Plans required.

Requires hospitals to develop and submit for approval a SAS transfer plan or SAS treatment plan and prohibits providing SAS transfer or treatment services without an approved plan. Requires pediatric health care facilities to develop and submit for approval a PSAS transfer plan or PSAS treatment plan and prohibits PSAS transfer or treatment services without an approved plan.

12VCA5-416-30. Request for plan approval.

Creates the process by which hospitals and pediatric health care facilities submit proposed plans for VDH’s review, including the timeline for submission and approval and the process to correct unacceptable plans.

12VAC5-416-40. Review and renewal of plan approval.

Requires hospitals and pediatric health care facilities to triennially review approved plans for any needed changes and creates the process by which hospitals and pediatric health care facilities submit revised plans for VDH’s review, including the timeline for submission and approval and the process to correct unacceptable plans.

12VAC5-416-50. Change notification.

Requires hospitals and pediatric health care facilities to give advance notice to VDH before switching from transfer to treatment or vice versa and requires submission of the new plan with that advance notice.

12VAC5-416-60. Complaints.

Requires VDH to investigate complaints arising from alleged noncompliance, including criteria for determining whether on-site investigation is needed and for records to be provided upon request. Requires VDH to notify the hospital or pediatric health care facility—and the complainant, if known—of the outcome and requires the hospital or pediatric health care facility to submit a plan of correction for violations cited.

12VAC5-416-70. Inspections.

Permits VDH to combine hospital inspections and requires VDH to provide a written inspection report to the hospital. Permits hospitals to redact patient names and addresses and requires hospitals to provide requested records to VDH.

12VAC5-416-80. Plan of correction; directed plan of correction.

Creates the process for plans of correction and creates minimum standards for plans of corrections. Describes the criteria for when a directed plan of correction may be required.

12VAC5-416-90. Allowable variances.

Creates a variance process by which a hospital or pediatric health care facility with an approved plan may request modification of regulatory requirements.

12VAC5-416-100. Violations of this chapter.

Describes the enforcement options available to the State Health Commissioner if a hospital or pediatric health care facility violated the regulatory chapter or enabling statutes.

Part II SAS Treatment Plan12VAC5-416-110. Minimum standards for SAS treatment plan.

Requires hospitals providing SAS treatment services to meet the minimum standards established for SAS treatment plans.

12VAC5-416-120. Staffing and education.

Requires hospitals to have a sexual assault forensic examiner available in person during hours of operation and that emergency department staff receive annual training.

12VAC5-416-130. Informed consent.

Requires hospitals to obtain informed consent and document informed consent.

12VAC5-416-140. Documentation.

Requires hospitals to document findings of the forensic medical examination.

12VAC5-416-150. Medical history.

Requires hospitals to document specific information about the alleged sexual assault and minimum information for medical history.

12VAC5-416-160. Physical examination, laboratory testing, and evidence collection.

Describes standards for conducting a physical examination of a SAS and requires all necessary laboratory testing be conducted.

12VAC5-416-170. Chain of custody.

Requires hospitals to maintain chain of custody, specifies the minimum information to label on specimens, requires hospitals to document specific information when transferring evidence, and permits hospitals to store evidence in a secure location.

12VAC5-416-180. Prophylaxis and contraception.

Requires hospitals to provide specific oral and written information about STIs and emergency contraception, requires provision of or arrangements for prophylaxis for STIs unless medically contraindicated or consent is refused, requires provision or arrangements for emergency contraception unless medically contraindicated or consent is refused or the hospital is operated under the auspices of a religious institution objecting to emergency contraception on religious grounds.

12VAC5-416-190. Anonymous PERK.

Requires hospitals to make minimum disclosures to SASs about PERKs if the SAS chooses not to report to law enforcement and requires hospitals to ensure PERKs are forwarded to DCLS.

12VAC5-416-200. Medical advocacy services.

Requires hospitals to have an memorandum of understanding (MOU) with at least one rape crisis center, to triennially review the MOU, to have policies and procedures for mandatory reporting, and to provide oral and written information about medical advocacy services.

12VAC5-416-210. Discharge and follow-up health care.

Requires hospitals to provide oral and written discharge instructions and contact information and hours of operation for local advocacy programs. Describes what may be included in follow-up health care.

12VAC5-416-220. Reporting requirements.

Requires hospitals to annually report the total number of SASs to whom a forensic medical examination was provided and the total number of PERKS offered and completed.

Part III PSAS Treatment Plan12VAC5-416-230. Minimum standards for PSAS treatment plan.

Requires pediatric health care facilities providing PSAS treatment services to meet the minimum standards established for PSAS treatment plans.

12VAC5-416-240. Pediatric staffing.

Requires pediatric health care facilities to have a sexual assault forensic examiner available in person during hours of operation.

12VAC5-416-250. Informed assent and consent for treatment.

Requires pediatric health care facilities to exercise all reasonable and necessary efforts to obtain informed assent from the PSAS, subject to certain age and capacity limits. Requires pediatric health care facilities to obtain informed consent and document informed assent and consent.

12VAC5-416-260. Documentation.

Requires pediatric health care facilities to document findings of the forensic medical examination.

12VAC5-416-270. Medical history.

Requires pediatric health care facilities to document specific information about the alleged sexual assault and minimum information for medical history.

12VAC5-416-280. Physical examination, laboratory testing, and evidence collection.

Describes standards for conducting a physical examination of a PSAS and requires all necessary laboratory testing be conducted.

12VAC5-416-290. Chain of custody.

Requires pediatric health care facilities to maintain chain of custody, specifies the minimum information to label on specimens, requires pediatric health care facilities to document specific information when transferring evidence, and permits pediatric health care facilities to store evidence in a secure location.

12VAC5-416-300. Prophylaxis and contraception.

Requires pediatric health care facilities to provide specific oral and written information about STIs and emergency contraception, requires provision of or arrangements for prophylaxis for STIs unless medically contraindicated or consent is refused, requires provision or arrangements for emergency contraception unless medically contraindicated or consent is refused or the pediatric health care facility is operated under the auspices of a religious institution objecting to emergency contraception on religious grounds.

12VAC5-416-310. Anonymous PERK.

Requires pediatric health care facilities to make minimum disclosures to PSASs about PERKs if the PSAS chooses not to report to law enforcement and requires hospitals to ensure PERKs are forward to DCLS.

12VAC5-416-320. Medical advocacy services.

Requires pediatric health care facilities to have a memorandum of understanding (MOU) with at least one rape crisis center, to triennially review the MOU, to have policies and procedures for mandatory reporting, and to provide oral and written information about medical advocacy services.

12VAC5-416-330. Discharge and follow-up health care.

Requires pediatric health care facilities to provide oral and written discharge instructions and contact information and hours of operation for local advocacy programs. Describes what may be included in follow-up health care.

12VAC5-416-340. Approved pediatric treatment facilities with limited capacity.

Requires pediatric health care facilities with limited capacity to make certain adjustments to their treatment plans and requires pediatric health care facilities that are not open 24/7 to share that information publicly, including with signage.

PART IV SAS Transfer Plan

12VAC5-416-350. Minimum requirements for SAS transfer plan.

Requires hospitals providing SAS transfer services to meet the minimum standards established for SAS transfer plans.

12VAC5-416-360. Screening.

Requires hospitals to provide appropriate screening and have mandatory reporting procedures.

12VAC5-416-370. Acute injuries.

Requires hospitals to screen, treat, and stabilize acute injuries before transfer.

12VAC5-416-380. Transfer coordination.

Requires hospitals to coordinate transfer with the receiving facility, ensure a qualified staff member is available to provide treatment, and to provide information about emergency contraception and the patient's medical record.

PART V PSAS Transfer Plan

12VAC5-416-390. Minimum requirements for PSAS transfer plan.

Requires pediatric health care facilities providing PSAS transfer services to meet the minimum standards established for PSAS transfer plans.

12VAC5-416-400. Screening.

Requires pediatric health care facilities to provide appropriate screening and have mandatory reporting procedures. Prohibits pediatric health care facilities from turning away a patient for screening on the basis they arrived close to—but not after—close of business.

12VAC5-416-410. Acute injuries.

Requires pediatric health care facilities to screen, treat, and stabilize acute injuries before transfer. Requires pediatric health care facilities to contact child protective services or local law enforcement if the patient is in danger.

12VAC5-416-420. Transfer coordination.

Requires pediatric health care facilities to coordinate transfer with the receiving facility, ensure a qualified staff member is available to provide treatment, and to provide the patient’s medical record to the receiving facility.

12VAC5-416-430. Required transfer disclosures.

Requires pediatric health care facilities to discuss transfer with the PSAS’s legal representative and to provide information about emergency contraception and the patient’s medical record.

Documents Incorporated by Reference (12VAC5-416)

Lists documents incorporated by reference in 12VAC5-416-180 and 12VAC5-416-300.

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 in implementing the mandates of Chapter 725 (2020 Acts of Assembly) is increased transparency about what facilities can provide sexual assault treatment services and what facilities can provide transfer services and more consistent care across the Commonwealth for patients who are SASs or PSASs. The primary advantages to the agency or Commonwealth is new data about the availability of sexual assault treatment services and transfer service to drive policy making decisions. There are no primary disadvantages to the public, the agency, or the Commonwealth.

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.

Hospitals that provide transfer services to SASs and PSASs are required to comply with EMTALA. The proposed regulation requires these hospitals to have procedures for mandatory reporting to adult and child protective services (12VAC5-416-360(B) and 12VAC5-416-400(C)), to communicate with the receiving hospital to ensure a SAFE is available to provide treatment services (12VAC5-416-380(B) and 12VAC5-416-420(B)), to provide information to patients about emergency contraception and a copy of their record (12VAC5-416-380(C) and 12VAC5-416-430(C)), to contact child protective services or local law enforcement as appropriate (12VAC5-416-410(C) and (D)), and to minimize undue burdens and loss of forensic evidence (12VAC-416-420(C)). These more restrictive requirements arise from the fact that the patient has experienced an alleged sexual assault. Alerting the appropriate protective services, and potentially law enforcement, when a crime is alleged to have taken place is often a state mandatory requirement for most if not all health care professionals. The preservation of evidence is also critical to the investigation or prosecution of any crime. The information about emergency contraception is mandated to be provided pursuant to Chapter 725 (2020 Acts of Assembly). Chapter 725 (2020 Acts of Assembly) also requires a SAFE to conduct forensic medical examinations, so ensuring the treating facility has a SAFE available to perform that function is necessary.

Agencies, Localities, and Other Entities Particularly Affected

Consistent with § 2.2-4007.04 of the Code of Virginia, identify any other state agencies, localities, or other entities particularly affected by the regulatory change. Other entities could include local partners such as tribal governments, school boards, community services boards, and similar regional organizations. “Particularly affected” are those that are likely to bear any identified disproportionate material impact which would not be experienced by other agencies, localities, or entities. “Locality” can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulation or regulatory change are most likely to occur. If no agency, locality, or entity is particularly affected, include a specific statement to that effect.

Other State Agencies Particularly Affected

Virginia Commonwealth University Health System Authority

Localities Particularly Affected

Chesapeake Hospital Authority

Other Entities Particularly Affected

General hospitals, special hospitals, and outpatient surgical hospitals licensed pursuant to Article 1 (§ 32.1-123 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia; pediatric health care facilities as defined by § 32.1-162.15:2 of the Code of Virginia.

Economic Impact

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

Impact on State Agencies

<p><i>For your agency:</i> projected costs, savings, fees, or revenues resulting from the regulatory change, including:</p> <ul style="list-style-type: none"> 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. 	<p>There are no projected savings, fees, or revenues resulting from the regulatory change. VDH projects a one-time cost of \$283,696 in Year 1, a one-time cost of \$692,391 in Year 2, and an on-going cost of \$582,391. These amounts will support the hiring of three FTEs to review and approve initial plans and revised plans, conduct statewide travel for complaints, and the development of the mandated training for staff in hospital emergency departments who provide care to SASs and PSASs</p> <p>VDH could not absorb the costs identified above with existing resources, so VDH received an appropriation of \$283,696 for SFY2023 and an appropriation of \$567,391 for SFY2024, both from the general fund, to hire the necessary FTEs. VDH did not receive appropriations to cover the cost of</p>
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	<p>developing the mandated training, and is planning on asking for an appropriation from the general fund to cover this cost in the upcoming 2023 General Assembly session.</p>
<p><i>For other state agencies:</i> projected costs, savings, fees, or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.</p>	<p>In 2019, the hospital operated by Virginia Commonwealth University Health System Authority had a forensic nursing program that treated SASs; VDH is unsure if this also includes PSASs.</p> <p>Virginia Commonwealth University Health System Authority will likely incur some costs resulting from this regulatory change. The projected costs for transferring or treating patients include the development of policies and procedures that meet the minimums described in this regulatory action. The hospital that Virginia Commonwealth University Health System Authority operates has an emergency department, so it already has policies and procedures about transfers, as that is part of the requirements under EMTALA; it also already at least provides treatment for SASs. For its existing policies and procedures, VDH is estimating it would cost \$1,250 one time to amend their policies to conform to the regulatory minimums. It may be the case that no amendments are needed if the policies and procedures meet or exceed the proposed regulatory minimums, in which case no cost is expected to be incurred.</p> <p>There may be some recordkeeping and administrative costs because Chapter 725 (2020 Acts of Assembly) mandates that hospitals that treat SASs file annual reports with VDH. VDH estimates these costs are not likely to exceed \$2,500 per year.</p> <p>Virginia Commonwealth University Health System Authority likely will not have savings or fees. It may have some revenue resulting from providing care to SASs, though this is difficult to project due to the complexity of health care financing involving a multitude of reimbursement rates from Medicaid and third party insurance carriers, as well as any charity care conditions it has on its certificates of public need.</p>
<p><i>For all agencies:</i> Benefits the regulatory change is designed to produce.</p>	<p>The benefits the regulatory change is designed to produce is increased knowledge of and awareness of what hospitals and pediatric health care facilities can provide treatment services or transfer services for SASs and PSASs. It also creates minimum standards for those services so that care for this patient population is more consistent throughout the Commonwealth.</p>

Impact on Localities

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

<p>Projected costs, savings, fees, or revenues resulting from the regulatory change.</p>	<p>In 2019, the hospital operated by Chesapeake Hospital Authority did not have a forensic nursing program, so VDH assumes it may not have been treating SASs and PSASs, beyond what is required for stabilization by EMTALA.</p> <p>Chesapeake Hospital Authority will likely incur some costs resulting from this regulatory change. The projected costs for transferring or treating patients include the development of policies and procedures that meet the minimums described in this regulatory action. The hospital that Chesapeake Hospital Authority operates has an emergency department, so it already has policies and procedures about transfers, as that is part of the requirements under EMTALA. For its existing policies and procedures if it opts to transfer SASs and/or PSASs, VDH is estimating it would cost \$1,250 one time to amend their policies to conform to the regulatory minimums. It may be the case that no amendments are needed, if the policies and procedures exceed the regulatory minimums, in which case no cost is expected to be incurred. If Chesapeake Hospital Authority decides that its hospital should instead treat SASs and/or PSASs, VDH is estimating it would cost \$5,000 to develop these policies and procedures.</p> <p>Chesapeake Hospital Authority likely will not have savings or fees. It may have some revenue resulting from providing care (even it is just stabilizing care under EMTALA) to SASs and PSASs, though this is difficult to project due to the complexity of health care financing involving a multitude of reimbursement rates from Medicaid and third party insurance carriers, as well as any charity care conditions it has on its certificates of public need.</p>
<p>Benefits the regulatory change is designed to produce.</p>	<p>The benefits the regulatory change is designed to produce is increased knowledge of and awareness of what hospitals and pediatric health care facilities can provide treatment services or transfer services for SASs and PSASs. It also creates minimum standards for those services so that care for this patient population is more consistent throughout the Commonwealth.</p>

Impact on Other Entities

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

<p>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.</p>	<p>The entities likely to be affected by the regulatory change are hospitals and pediatric health care facilities, as defined by Code of Virginia § 32.1-162.15:2.</p>
<p>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:</p> <ul style="list-style-type: none"> 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. 	<p>There are currently 170 hospitals licensed pursuant to Article 1 (§ 32.1-123 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia; this includes the hospitals operated by the Virginia Commonwealth University Health System Authority and Chesapeake Hospital Authority that were already discussed above.</p> <p>Currently, there is no accurate count of how many pediatric health care facilities there are in the Commonwealth. Based on data collected by the Healthcare Workforce Data Center in the Department of Health Professions, there are 21,257 employed physicians in the Commonwealth and there are 6,017 that are board certified in either pediatrics or family medicine. VDH does not have data about the patient populations served or where these patients are seen by the 21,257 employed physicians, as physicians do not need to be board certified in pediatrics or family medicine to potentially treat PSASs outside of a hospital setting. VDH estimates that it is likely that most pediatric health care facilities that are not hospitals would be considered small businesses.</p>
<p>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:</p> <ul style="list-style-type: none"> 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. 	<p>VDH anticipates that roughly one-sixth of inpatient hospitals will choose to treat patients and the remaining inpatient hospitals will transfer patients, based on data collected by the Joint Commission on Health Care in 2019.</p> <p>VDH anticipates that most outpatient surgical hospitals and pediatric health care facilities will opt to transfer patients rather than treat them.</p> <p>a) The projected costs for transferring or treating patients would include the development of policies and procedures that meet the minimums described in this regulatory action. The inpatient hospitals that have emergency departments should already have policies and procedures about transfers, as that is part of the requirements under the federal Emergency Medical Treatment and Labor Act (EMTALA). To the extent that a hospital or pediatric health care facility does not have any existing policies or procedures about transfer or treatment of SASs and/or PSASs, VDH is estimating it would cost \$5,000 one-time to</p>

	<p>develop. For those that do have existing policies, VDH is estimating it would cost \$1,250 one-time to amend their policies to conform to the regulatory minimums. It may be the case that no amendments are needed, if the policies and procedures exceed the regulatory minimums, in which case no cost is expected to be incurred.</p> <p>There will be some recordkeeping and administrative costs for hospitals that are treating SASs because Chapter 725 (2020 Acts of Assembly) mandates that those hospitals file annual reports with VDH. VDH estimates these costs are not likely to exceed \$2,500 per year.</p> <p>b) There are no projected costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change.</p> <p>c) The projected costs for equipment or services for hospitals and non-hospital pediatric health care facilities that choose to transfer patients should be zero. Hospitals and non-hospital pediatric health care facilities that choose to treat patients are not anticipated to have any costs related to equipment, but would have ensure it has at least one sexual assault forensic examiner available. If this person is not already a part of the staff, that person would have to be hired or put on contract.</p> <p>e) The mandates of Chapter 725 (2020 Acts of Assembly) go into effect on July 1, 2023. Hospitals and pediatric health care facilities have known these mandates were coming since the passage of Chapter 725 (2020 Acts of Assembly). Additionally, VDH built in some regulatory flexibility in that hospitals and pediatric health care facilities that were already treating or transferring SASs and PSASs prior to July 1, 2023 can continue to do so while VDH reviews their initial plan submission, to avoid disruption to care in the their communities.</p>
<p>Benefits the regulatory change is designed to produce.</p>	<p>The benefits the regulatory change is designed to produce is increased knowledge of and awareness of what hospitals and pediatric health care facilities can provide treatment services or transfer services for SASs and PSASs. It also creates minimum standards for those services so that care for this patient population is more consistent throughout the Commonwealth.</p>

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 legislation required the Board to adopt regulations governing the treatment and transfer of SASs and PSASs, and the least burdensome method to accomplish the purpose of this action is to promulgate the regulation.

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

Regulatory Flexibility Analysis

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

In developing the proposed regulations, the Board considered that pediatric health care facilities likely consist primarily of small businesses. Providing a small business exemption would result in the overwhelming number of pediatric health care facilities being exempt from the requirements, just as establishing performance standards or less stringent requirements specific to small business would have the effect of lowered standards and requirements for a large majority of those to whom this regulatory chapter applies. Chapter 725 (2020 Acts of Assembly) does not give the Board the discretion to exempt small businesses from the requirements.

Additionally, as these standards and requirements are aimed at ensuring both adequate care to SASs and PSASs as well as evidence for potential criminal prosecution, the Board cannot lower these standards without potentially endangering patients or jeopardizing the administration of justice. Further, Chapter 725 (2020 Acts of Assembly) also prescribes the content of transfer and treatment plans, the requirement that hospitals and pediatric health care facilities submit them for approval, VDH's timeline for reviewing and approving submitted plans, and the reporting requirements for hospitals. Consequently, there are no other alternative regulatory methods to minimizing the adverse impact on small businesses that the Board could utilize without being inconsistent with the principles of justice and the public health, safety, and welfare in accomplishing the objectives of the legislative mandates.

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

**Periodic Review and
Small Business Impact Review Report of Findings**

If you are using this form to report the result of a periodic review/small business impact review that is being conducted as part of this regulatory action, and was announced during the NOIRA stage, indicate whether the regulatory change meets the criteria set out in EO 19 and the ORM procedures, e.g., is necessary for the protection of public health, safety, and welfare; minimizes the economic impact on small businesses consistent with the stated objectives of applicable law; and is clearly written and easily understandable. In addition, as required by § 2.2-4007.1 E and F of the Code of Virginia, discuss the agency’s consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation; (3) the complexity of the regulation; (4) the extent to 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.

No periodic review/small business impact review was announced during the NOIRA stage and thus, no results are being reported. There is a continued need for the regulation, as no legislation has passed that repeals the mandate for this regulation. VDH has received no complaints or comments concerning the regulation. The regulation is appropriately detailed to describe both the processes applicable to hospitals and pediatric health care facilities and the minimum standards for treatment and transfer, without crossing into scope of practice issues or criminal law enforcement. VDH is not aware of any overlap, duplication, or conflict involving this regulation and federal or state law or regulation. This is a new regulatory chapter, and the technology, economic conditions, or other factors in the area affected by the regulation have not demonstrably changed since the passage of Chapter 725 (2020 Acts of Assembly). VDH cannot lessen the standards to minimize the economic impact of regulation on small businesses because it would likely frustrate the administration of justice and the health, safety, and welfare of SASs and PSASs to lower standards for adequate medical care to and for the collection, documentation, and preservation of evidence.

Public Comment

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

No comment was received.

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 Board 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 **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 this stage of this regulatory action.

Detail of Changes

List all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Use all tables that apply, but delete inapplicable tables.

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

New chapter-section number	New requirements to be added to VAC	Other regulations and laws that apply	Change, intent, rationale, and likely impact of new requirements
416-10	<p style="text-align: center;">Part I General Information</p> <p><u>12VAC5-416-10. Definitions.</u></p> <p><u>The following words and terms when used in this regulation shall have the following meanings unless the context clearly indicates otherwise:</u></p> <p><u>"Administrator" means the person appointed by the governing body as having responsibility for the overall management of a hospital or pediatric health care facility. Job titles may include chief executive officer, director, executive director, office manager, or business manager.</u></p> <p><u>"Anonymous physical evidence recovery kit" or "anonymous PERK" has the same meaning as in § 19.2-11.5 of the Code of Virginia.</u></p> <p><u>"Applicant" means a hospital or pediatric health care facility that does not have an approved plan.</u></p>	None	<p>CHANGE: The Board is proposing to promulgate this section.</p> <p>INTENT: The intent of these new requirements is to provide definitions for terms used in the regulation.</p> <p>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 applicants and regulators.</p> <p>LIKELY IMPACT: The likely impact of these new requirements is improved clarity for applicants and regulators.</p>

	<p><u>"Approved pediatric transfer facility" means a pediatric health care facility for which a PSAS transfer plan has been approved pursuant to this chapter</u></p> <p><u>"Approved _____ pediatric treatment facility" means a pediatric health care facility for which a PSAS treatment plan has been approved pursuant to this chapter.</u></p> <p><u>"Approved plan" means a SAS treatment plan, PSAS treatment plan, SAS transfer plan, or PSAS transfer plan that has been approved pursuant to this chapter.</u></p> <p><u>"Assent" means the expressed willingness of an individual to participate in an activity.</u></p> <p><u>"Board" means the State Board of Health.</u></p> <p><u>"Clinic" means an outpatient establishment, facility, or department of a hospital where patients are given medical diagnosis, treatment, or advice, including of a specialist nature. This includes a clinic operated by a local health department, but does not include a clinic directly maintained or operated by the federal government.</u></p> <p><u>"Commissioner" means the State Health Commissioner.</u></p> <p><u>"DCLS" means the Division of Consolidated Laboratory Services of the Virginia Department of General Services.</u></p> <p><u>"Department" means the Department of Health.</u></p> <p><u>"Directed plan of correction" means a plan prescribed by the department that details specific corrective actions for cited violations in inspection findings that shall be taken by the regulant to achieve specific outcomes within specific timeframes.</u></p>		
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	<p><u>"Emergency contraception"</u> means medication approved by the U.S. Food and Drug Administration that can significantly reduce the risk of pregnancy if taken within 72 hours after sexual assault.</p> <p><u>"EMTALA"</u> means the Emergency Medical Treatment and Labor Act (42 USC § 1395dd et seq.)</p> <p><u>"Follow-up health care"</u> means any physical examination, laboratory tests to determine the presence of STIs, or appropriate medications, including HIV prophylaxis, provided to a SAS or PSAS by a health care professional within 90 days after the date on which treatment or transfer services pursuant to this chapter are first provided.</p> <p><u>"Forensic medical examination"</u> means health care services provided to a SAS or PSAS that include medical history, physical examination, laboratory testing, assessment for drug-facilitated or alcohol-facilitated sexual assault, collection of evidence in accordance with the requirements of Chapter 1.2 (§ 19.2-11.5 et seq.) of Title 19.2 of the Code of Virginia, discharge and follow-up health care planning necessary to ensure the health, safety, and welfare of the SAS or PSAS, and the collection and preservation of evidence that may be used in a criminal proceeding.</p> <p><u>"Health care professional"</u> means any person (i) licensed, certified, or registered by a health regulatory board of the Department of Health Professions or (ii) holding a multistate licensure privilege to practice nursing or an applicant</p>		
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	<p><u>for licensure, certification or registration.</u></p> <p><u>"Hospital" means any hospital licensed by the department pursuant to Article 1 (§ 32.1-123 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia.</u></p> <p><u>"Inspector" means an individual employed by the department and designated by the commissioner to conduct inspections, investigations, or evaluations.</u></p> <p><u>"Legal representative" means a PSAS's parent, guardian, or any person who by order of a court of component jurisdiction has legal custody of the PSAS.</u></p> <p><u>"OLC" means the Office of Licensure and Certification of the department.</u></p> <p><u>"Pediatric health care facility" means a hospital, clinic, or physician's office that provides health care services to pediatric patients.</u></p> <p><u>"Physician's office" means the office of one or more physicians, surgeons, or nurse practitioners with autonomous practice privileges. A physician's office does not mean a hospital as defined in § 32.1-123 of the Code of Virginia or a facility directly maintained or operated by the federal government.</u></p> <p><u>"Physical evidence recovery kit" or "PERK" has the same meaning as in § 19.2-11.5 of the Code of Virginia.</u></p> <p><u>"Plan of correction" means a plan developed by a regulant and approved by the department that is the regulant's written response to inspection findings and details corrective actions to cited violations, who is responsible for implementing corrective actions, how the regulant will prevent</u></p>		
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	<p><u>reoccurrence, and specifies the date by which the regulant will correct those deficiencies.</u></p> <p><u>"Proposed plan" means a SAS treatment plan, PSAS treatment plan, SAS transfer plan, or PSAS transfer plan that has been submitted pursuant to this chapter to the Department.</u></p> <p><u>"PSAS" means a pediatric survivor of sexual assault who is less than 18 years of age.</u></p> <p><u>"PSAS transfer plan" means a plan for the transfer of a PSAS to an approved pediatric treatment facility that includes PSAS transfer services and the written agreement of an approved pediatric treatment facility to accept transfer.</u></p> <p><u>"PSAS transfer services" means an appropriate medical examination and such stabilizing treatment as may be necessary prior to the transfer of a PSAS from an approved pediatric transfer facility to an approved pediatric treatment facility in accordance with the provisions of a PSAS transfer plan approved by the department.</u></p> <p><u>"PSAS treatment plan" means a plan for the treatment of a PSAS at an approved pediatric treatment facility that includes PSAS treatment services and the storage, retention, and dissemination of photographic evidence.</u></p> <p><u>"PSAS treatment services" means a forensic medical examination and other health care services provided to a PSAS by an approved pediatric treatment facility in accordance with this chapter.</u></p> <p><u>"Rape crisis center" has the same meaning as ascribed in 34 USC § 12291(a)(25).</u></p> <p><u>"Regulant" means a treatment hospital, transfer</u></p>		
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	<p><u>hospital, approved pediatric treatment facility, or approved pediatric transfer facility that has a PSAS treatment plan, PSAS transfer plan, SAS treatment plan, or SAS transfer plan approved by the department.</u></p> <p><u>"SAS" means a survivor of sexual assault who is 18 years of age or older.</u></p> <p><u>"Sexual assault forensic examiner" or "SAFE" means a sexual assault nurse examiner, physician, physician assistant, nurse practitioner, or registered nurse who has completed training that meets or is substantially similar to the Sexual Assault Nurse Examiner Education Guidelines established by the International Association of Forensic Nurses or its successor.</u></p> <p><u>"SAS transfer plan" means a plan for the transfer of a SAS to a treatment hospital that includes SAS transfer services and the written agreement of a treatment hospital to accept transfer.</u></p> <p><u>"SAS transfer services" means an appropriate medical examination and such stabilizing treatment as may be necessary prior to the transfer of a SAS from a transfer hospital to a treatment hospital in accordance with the provisions of a SAS transfer plan approved by the department.</u></p> <p><u>"SAS treatment plan" means a plan for the treatment of a SAS at a treatment hospital that includes SAS treatment services and the storage, retention, and dissemination of photographic evidence.</u></p> <p><u>"SAS treatment services" means a forensic medical examination and other health care services provided to a SAS by a treatment hospital in accordance with this chapter.</u></p>		
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	<p><u>"STI" means sexually transmitted infection.</u></p> <p><u>"Transfer hospital" means a hospital with a SAS transfer plan approved by the department.</u></p> <p><u>"Transportation service" means transportation provided to a SAS or PSAS who is transferred from a transfer hospital, treatment hospital, approved pediatric treatment facility, or approved pediatric transfer facility to a treatment hospital or approved pediatric treatment facility pursuant to a SAS transfer plan or PSAS transfer plan approved in accordance with this chapter.</u></p> <p><u>"Treatment hospital" means a hospital with a SAS treatment plan approved by the department to provide SAS treatment services to a SAS who presents with a complaint of sexual assault within the previous seven days or who have disclosed past sexual assault by a specific individual and were in the care of that individual within the previous seven days.</u></p>		
<p>416-20</p>	<p><u>12VAC5-416-20. Plans required.</u></p> <p><u>A. A hospital shall:</u></p> <p><u>1. Develop either a:</u></p> <p><u>a. SAS treatment plan that meets the requirements of Part II (12VAC5-416-110 et seq.) of this chapter; or</u></p> <p><u>b. SAS transfer plan that meets the requirements of Part IV (12VAC5-416-350 et seq.) of this chapter; and</u></p> <p><u>2. Submit any such plan to the department as specified by 12VAC5-416-30.</u></p>	<p>None</p>	<p>CHANGE: The Board is proposing to promulgate this section.</p> <p>INTENT: The intent of these new requirements is that hospitals and pediatric health care facilities know that they must develop and submit plans for VDH's approval and to address hospitals and pediatric health care facilities that are already providing treatment and transfer of SASs and PSASs prior to July 1, 2023.</p> <p>RATIONALE: The rationale of these new requirements is that hospitals and pediatric health care facilities should be directed to where the</p>

	<p><u>B. A hospital may not provide SAS treatment services or SAS transfer services unless the department has granted approval of the proposed plan, except that a hospital may provide SAS treatment services or SAS transfer services prior to approval of its initial proposed plan if the hospital was providing one or more of these services on or before July 1, 2023.</u></p> <p><u>C. A pediatric health care facility shall:</u></p> <ol style="list-style-type: none"> <u>1. Develop either a:</u> <ol style="list-style-type: none"> <u>a. PSAS treatment plan that meets the requirements of Part III (12VAC5-416-230 et seq.) of this chapter; or</u> <u>b. PSAS transfer plan that meets the requirements of Part V (12VAC5-416-390 et seq.) of this chapter; and</u> <u>2. Submit any such plan to the department as specified by 12VAC5-416-30.</u> <p><u>D. A pediatric health care facility may not provide PSAS treatment services or PSAS transfer services unless the department has granted approval of the proposed plan, except that a pediatric health care facility may provide PSAS treatment services or PSAS transfer services prior to approval of its initial proposed plan if the pediatric health care facility was providing one or more of these services on or before July 1, 2023.</u></p> <p>Statutory Authority <u>§§ 32.1-12, 32.1-162.15:4, 32.1-162.15:5, and 32.1-162.15:6 of the Code of Virginia.</u></p>		<p>minimum plan standards and plan submission process are located within the regulations and to grant some flexibility to hospitals and pediatric health care facilities already providing treatment and transfer of SASs and PSASs prior to July 1, 2023.</p> <p>LIKELY IMPACT: The likely impact of these new requirements is improved clarity for applicants and regulants and reduced or eliminated interruptions in the provision of care for hospitals and pediatric health care facilities that are already providing treatment and transfer of SASs and PSASs prior to July 1, 2023.</p>
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<p>416-30</p>	<p><u>12VAC5-416-30. Request for plan approval.</u></p> <p><u>A. An applicant shall transmit to the OLC its proposed plan by electronic mail or postal mail no sooner than 60 calendar days before the applicant's desired effective date for the proposed plan.</u></p> <p><u>B. The OLC shall consider a proposed plan submission to be complete when all components of the proposed plan are included in the submission. The OLC may deny approval to an applicant whose proposed plan has been incomplete for more than 180 calendar days.</u></p> <p><u>C. An applicant may withdraw a proposed plan at any time prior to the OLC's determination of whether to approve the proposed plan by notifying the OLC in writing of its intent to withdraw.</u></p> <p><u>D. The OLC shall notify the applicant of the outcome of its review in writing no more than 30 calendar days after receipt of the proposed plan. If the OLC denies approval of the proposed plan, the OLC shall provide a written statement setting forth the reasons for denial.</u></p> <p><u>E. The OLC shall grant the administrator or his designee the opportunity to revise and resubmit a proposed plan that the OLC initially determines to be unacceptable. The administrator or his designee shall resubmit the proposed plan to the OLC no more than 15 calendar days after the OLC has notified the administrator or his designee pursuant to subsection D.</u></p> <p>Statutory Authority <u>§§ 32.1-12, 32.1-162.15:4, 32.1-162.15:5, and 32.1-162.15:6 of the Code of Virginia.</u></p>	<p>None</p>	<p>CHANGE: The Board is proposing to promulgate this section.</p> <p>INTENT: The intent of these new requirements is to describe the plan submission and review process.</p> <p>RATIONALE: The rationale for these new requirements is that a clear process for plan submission and review process will set reasonable expectations for applicants and VDH staff.</p> <p>LIKELY IMPACT: The likely impact of these new requirements is improved clarity for applicants and VDH staff.</p>
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<p>416-40</p>	<p><u>12VAC5-416-40. Review and renewal of plan approval.</u></p> <p><u>A. A regulant shall:</u></p> <p> <u>1. Review its approved plan or plans at least triennially with the administrator or his designee and appropriate clinical staff; and</u></p> <p> <u>2. Document in writing the triennial review process and any recommendations for updates.</u></p> <p><u>B. If a regulant determines that pursuant to subsection A that an update is needed to an approved plan, it shall submit the proposed plan to the OLC in writing no less than 60 days in advance of the proposed plan's implementation date.</u></p> <p><u>C. The OLC shall notify the regulant of the outcome of its review in writing no more than 30 calendar days after receipt of the proposed plan. If the OLC denies approval of the proposed plan, the OLC shall provide a written statement setting forth the reasons for denial.</u></p> <p><u>D. The OLC shall grant the administrator or his designee the opportunity to revise and resubmit a proposed plan that the OLC initially determines to be unacceptable. The administrator or his designee shall resubmit the proposed plan to the OLC no more than 15 calendar days after the OLC has notified the administrator or his designee pursuant to subsection C of this section.</u></p> <p>Statutory Authority <u>§§ 32.1-12, 32.1-162.15:4, 32.1-162.15:5, and 32.1-162.15:6 of the Code of Virginia.</u></p>	<p>None</p>	<p>CHANGE: The Board is proposing to promulgate this section.</p> <p>INTENT: The intent of these new requirements is to ensure that the plans utilized by hospitals and pediatric health care facilities are up to date with clinical standards and regulatory minimums.</p> <p>RATIONALE: The rationale for these requirements is that both clinical standards and regulatory minimums do change over time and routine regular review of plans will prevent the hospitals and pediatric health care facilities from using out of date standards.</p> <p>LIKELY IMPACT: The likely impact of these requirements is hospitals and pediatric health care facilities are using current clinical standards and meeting regulatory minimums.</p>
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<p>416-50</p>	<p><u>12VAC5-416-50. Change notification.</u></p> <p><u>A. A treatment hospital proposing to transition to a transfer hospital shall:</u></p> <ol style="list-style-type: none"> <u>1. Notify the OLC in writing no less than 60 calendar days in advance of transitioning to a transfer hospital; and</u> <u>2. Submit a SAS transfer plan with its notification.</u> <p><u>B. A transfer hospital proposing to transition to a treatment hospital shall:</u></p> <ol style="list-style-type: none"> <u>1. Notify the OLC in writing no less than 60 calendar days in advance of transitioning to a treatment hospital; and</u> <u>2. Submit a SAS treatment plan with its notification.</u> <p><u>C. An approved pediatric treatment facility proposing to transition to an approved pediatric transfer facility shall:</u></p> <ol style="list-style-type: none"> <u>1. Notify the OLC in writing no less than 60 calendar days in advance of transitioning to an approved pediatric transfer facility; and</u> <u>2. Submit a PSAS transfer plan with its notification.</u> <p><u>D. An approved pediatric transfer facility proposing to transition to an approved pediatric treatment facility shall:</u></p> <ol style="list-style-type: none"> <u>1. Notify the OLC in writing no less than 60 calendar days in advance of transitioning to an approved pediatric treatment facility; and</u> 	<p>None</p>	<p>CHANGE: The Board is proposing to promulgate this section.</p> <p>INTENT: The intent of these requirements is to create a process by which a hospital or pediatric health care facility may transition from transfer to treatment or vice versa.</p> <p>RATIONALE: The rationale for these requirements is that since hospitals and pediatric health care facilities have discretion to choose to treat or transfer, there needs to be a process to do so that allows VDH to review and approve the new plans.</p> <p>LIKELY IMPACT: The likely impact of these new requirements is improved clarity for regulants and VDH staff.</p>
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	<p><u>2. Submit a PSAS treatment plan with its notification.</u></p>		
<p>416-60</p>	<p><u>12VAC5-416-60. Complaints.</u></p> <p><u>A. The OLC shall investigate complaints regarding alleged violations of this chapter or Article 8 (§ 32.1-162.15:2 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia. The OLC shall determine if an investigation requires an on-site inspection. In making this determination, the OLC shall consider several factors, to include:</u></p> <ol style="list-style-type: none"> <u>1. If the complainant has first-hand knowledge of the alleged incident;</u> <u>2. The regulatory history of the regulant or applicant, including the number of substantiated prior complaints;</u> <u>3. If the OLC has recently inspected the regulant or applicant, and if the incident would have been observed during the prior inspection; and</u> <u>4. The nature of the complaint, including degree of potential serious harm to SASs, PSASs, or other patients.</u> <p><u>B. The OLC may request records from a regulant or applicant to assist in making a determination pursuant to subsection A. The regulant or applicant shall provide the requested records no more than 5 business days after the OLC makes the request.</u></p> <p><u>C. When the investigation is complete, the OLC shall notify the complainant, if known, and the regulant or applicant in</u></p>	<p>None</p>	<p>CHANGE: The Board is proposing to promulgate this section.</p> <p>INTENT: The intent of these new requirements is to give VDH the flexibility to determine whether a complaint warrants an on-site inspection and to describe what happens after an investigation is complete.</p> <p>RATIONALE: The rationale for these new requirements is encouraging efficient and effective use of agency resources in responding to complaints and set expectations about what complainants and regulants after an inspection.</p> <p>LIKELY IMPACT: The likely impact of these new requirements is a more adaptive and efficient complaint process.</p>

	<p><u>writing of the findings of the investigation.</u></p> <p><u>D. For any violation cited during a complaint investigation, the administrator or his designee shall submit a plan of correction in accordance with 12VAC5-416-80.</u></p> <p>Statutory Authority <u>§§ 32.1-12, 32.1-162.15:4, 32.1-162.15:5, 32.1-162.15:6, and 32.1-162.15:10 of the Code of Virginia.</u></p>		
<p>416-70</p>	<p><u>12VAC5-416-70. Inspections.</u></p> <p><u>A. The OLC may combine an inspection of a treatment hospital or transfer hospital with an inspection conducted pursuant to § 32.1-126 of the Code of Virginia.</u></p> <p><u>B. A regulant or applicant shall make available to the inspector any requested records and shall allow access to interview the agents, employees, contractors, and any person under the regulant's or applicant's control, direction, or supervision.</u></p> <p><u>1. Upon request of the inspector after the inspector's arrival:</u></p> <p><u>a. The treatment hospital or transfer hospital shall provide to the inspector a list of all SASs it treated or transferred in the previous 12 months; and</u></p> <p><u>b. The approved pediatric treatment facility or approved pediatric transfer facility shall provide to the inspector a list of all PSASs it treated or</u></p>	<p>None</p>	<p>CHANGE: The Board is proposing to promulgate this section.</p> <p>INTENT: The intent of these new requirements is describe what responsibilities a regulant or applicant has when an inspection takes place.</p> <p>RATIONALE: The rationale for these new requirements is to set expectations about what applicants and regulants should do during inspection and ensure the privacy of patients.</p> <p>LIKELY IMPACT: The likely impact of these new requirements is improved clarity for applicants and regulants.</p>

	<p><u>transferred in the previous 12 months.</u></p> <p><u>2. If copies of records are removed from the premises, the regulant or applicant may redact names and addresses of patients contained in such records prior to removal.</u></p> <p><u>3. The inspector shall inform the regulant or applicant that it may redact names and addresses of patients prior to the inspector removing copies of records from the premises.</u></p> <p><u>C. The OLC shall provide a written inspection report to the administrator. If the OLC cites one or more violations in the written inspection report, the administrator or his designee shall submit a plan of correction in accordance with 12VAC5-416-80.</u></p>		
<p>416-80</p>	<p><u>12VAC5-416-80. Plan of correction; directed plan of correction.</u></p> <p><u>A. Upon receipt of a written inspection report, the administrator or his designee shall prepare a written plan of correction addressing each violation cited at the time of inspection.</u></p> <p><u>B. The administrator shall submit to the OLC a written plan of correction no more than 15 working days after receipt of the inspection report. The plan of correction shall contain for each violation cited:</u></p> <p><u>1. A description of the corrective action or actions to be taken and the position title of the</u></p>	<p>None</p>	<p>CHANGE: The Board is proposing to promulgate this section.</p> <p>INTENT: The intent of these new requirements is to create a plan of correction process, including what the consequences of an unacceptable plan of correction are.</p> <p>RATIONALE: The rationale for these new requirements is set expectations about what applicants and regulants should do after inspection if violations are found.</p> <p>LIKELY IMPACT: The likely impact of these new requirements is improved clarity for applicants and regulants.</p>

	<p><u>employees to implement the corrective action;</u></p> <p><u>2. The expected correction date, not to exceed 45 working days from the exit date of the inspection; and</u></p> <p><u>3. A description of the measures implemented to prevent a recurrence of the violation.</u></p> <p><u>C. A regulant or applicant shall ensure that the person responsible for the validity of the plan of correction signs, dates, and indicates their title on the plan of correction.</u></p> <p><u>D. The OLC shall:</u></p> <p><u>1. Notify the administrator or his designee if the OLC determines any item in the plan of correction is unacceptable; and</u></p> <p><u>2. Grant the administrator or his designee an opportunity to revise and resubmit a plan of correction that the OLC initially determines to be unacceptable. If the administrator or his designee revises and resubmits the plan of correction, the revision is due to the OLC no more than 15 working days after the OLC has notified the administrator or his designee pursuant to subdivision 1 of this subsection.</u></p> <p><u>E. The department may impose a directed plan of correction when a regulant or applicant:</u></p> <p><u>1. Has one or more violations that warrant directing the regulant or</u></p>		
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	<p><u>applicant to take specific actions; or</u></p> <p><u>2. Has been cited for the same violation in the most recent prior inspection.</u></p> <p><u>F. Upon request of the OLC, a regulant or applicant shall produce evidence that all or part of a plan of correction or directed plan of correction has been implemented. The OLC may conduct an inspection to verify any portion of a plan of correction or directed plan of correction.</u></p> <p><u>G. The administrator or his designee shall ensure the plan of correction or directed plan of correction is implemented and monitored so that compliance is maintained.</u></p> <p>Statutory Authority <u>§§ 32.1-12, 32.1-25, 32.1-162.15:4, 32.1-162.15:5, and 32.1-162.15:6 of the Code of Virginia.</u></p>		
<p>416-90</p>	<p><u>12VAC5-416-90. Allowable variances.</u></p> <p><u>A. The commissioner may authorize a variance only to a specific standard or requirement of this chapter, not to regulations of another agency or to any standards or requirements in federal, state, or local laws. A variance shall:</u></p> <ol style="list-style-type: none"> <u>1. Require advance written approval from the commissioner;</u> <u>2. Not be extended to general applicability; and</u> <u>3. Not endanger the health, safety, or well-being of SASs, PSASs, other patients, or the public.</u> <p><u>B. A regulant may request a variance at any time. The</u></p>	<p>None</p>	<p>CHANGE: The Board is proposing to promulgate this section.</p> <p>INTENT: The intent of these new requirements is to permit the commissioner to grant variances if warranted and to create a clear process by which variances may be requested or modified.</p> <p>RATIONALE: The rationale for these new requirements is to permit the commissioner to address unforeseen circumstances that complicate a regulant's compliance with a requirement in this chapter.</p> <p>LIKELY IMPACT: The likely impact of these new requirements is reduced likelihood of confusion on how a regulant may request</p>

	<p><u>request for a variance shall describe in writing:</u></p> <ol style="list-style-type: none"> <u>1. How compliance with the current standard or requirement is economically burdensome and constitutes impractical hardship unique to the regulant; and</u> <u>2. Proposed alternatives to meet the purpose of the standard or requirement that will ensure the health, safety, and well-being of SASs, PSASs, other patients, and the public.</u> <p><u>C. The regulant may withdraw a request for a variance at any time by notifying the OLC in writing.</u></p> <p><u>D. The commissioner shall notify the regulant in writing of the commissioner's decision on the variance request. If granted, the commissioner may attach conditions to a variance that, in the sole judgment of the commissioner, protects the health, safety, and well-being of SASs, PSASs, other patients, and the public.</u></p> <p><u>E. The commissioner may rescind or modify a variance if:</u></p> <ol style="list-style-type: none"> <u>1. The impractical hardship unique to the regulant changes or no longer exists;</u> <u>2. Additional information becomes known that alters the basis for the original decision, including if the regulant failed to comply with the standard or requirement prior to receiving a variance;</u> <u>3. The regulant fails to meet any conditions</u> 		<p>a variance and clarity on what the commissioner's authority is in regards to granting or modifying a variance.</p>
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	<p><u>attached to the variance:</u> <u>or</u></p> <p>4. <u>Results of the variance jeopardize the health, safety, or well-being of SASs, PSASs, other patients, and the public.</u></p> <p>F. <u>If a variance is denied, expires, or is rescinded, the commissioner or his designee shall enforce the standard or requirement to which the variance was granted.</u></p> <p>G. <u>The administrator shall develop and document procedures for monitoring the implementation of any variance.</u></p>		
<p>416-100</p>	<p><u>12VAC5-416-100. Violations of this chapter.</u></p> <p>A. <u>A hospital or pediatric health care facility may not violate the provisions of this chapter or Article 8 (§ 32.1-162.15:2 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia.</u></p> <p>B. <u>The commissioner may:</u></p> <p>1. <u>For each violation of subsection A of this section by a hospital:</u></p> <p>a. <u>Deny, revoke, or suspend the license to operate the hospital in accordance with the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia);</u></p> <p>b. <u>Refer the hospital for criminal prosecution pursuant to subsection A of § 32.1-27 of the Code of Virginia; or</u></p> <p>c. <u>Petition an appropriate court for an injunction, mandamus, or other</u></p>	<p>None</p>	<p>CHANGE: The Board is proposing to promulgate this section.</p> <p>INTENT: The intent of these new requirements is to describe the consequences for violating the regulatory requirements or enabling statutes.</p> <p>RATIONALE: The rationale for these new requirements is that applicants and regulants should be informed of the consequences for violations so as to discourage violations.</p> <p>LIKELY IMPACT: The likely impact of these new requirements is improved clarity for applicants and regulants.</p>

	<p><u>appropriate remedy or imposition of a civil penalty against the _____ hospital pursuant to subsection B or C of § 32.1-27 of the Code of Virginia; and</u></p> <p><u>2. For each violation of subsection A of this section by a pediatric health care facility:</u></p> <p><u>a. Report the health care professionals involved in the violation to the appropriate health regulatory board in the Department of Health Professions;</u></p> <p><u>b. Refer the pediatric health care facility for criminal prosecution pursuant to subsection A of § 32.1-27 of the Code of Virginia; or</u></p> <p><u>c. Petition an appropriate court for an injunction, mandamus, or other appropriate remedy or imposition of a civil penalty against the pediatric health care facility pursuant to subsection B or C of § 32.1-27 of the Code of Virginia.</u></p> <p><u>C. If the commissioner determines that a violation of subsection A of this section by a hospital jeopardizes the health or safety of patients, the commissioner may immediately revoke, suspend, or deny a license. Suspension of a license shall in all cases be for an indefinite time.</u></p>		
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	<p><u>D. Upon receipt of a completed application and a nonrefundable service charge prescribed by § 32.1-130, the commissioner may issue a new license to the hospital that has had its license revoked if the commissioner determines that:</u></p> <ol style="list-style-type: none"><u>1. The conditions upon which revocation was based have been corrected; and</u><u>2. The hospital is in compliance with this chapter, Article 8 (§ 32.1-162.15:2 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia, and all other applicable state and federal law and regulations.</u> <p><u>E. Upon receipt of a completed application, the commissioner may partially or completely restore a suspended license to the hospital if the commissioner determines that:</u></p> <ol style="list-style-type: none"><u>1. The conditions upon which suspension was based have been completely or partially corrected; and</u><u>2. The interests of the public will not be jeopardized by resumption of operation.</u> <p><u>F. The hospital shall submit evidence relevant to subdivisions D 1, D 2, E 1, and E 2 of this section that is satisfactory to the commissioner or his designee. The commissioner or his designee may conduct an inspection prior to making a determination.</u></p> <p><u>G. The commissioner may not require an additional fee for restoring a license pursuant to subsection E of this section.</u></p>		
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<p>416-110</p>	<p style="text-align: center;"><u>Part II</u> <u>SAS Treatment Plan</u></p> <p><u>12VAC5-416-110. Minimum requirements for SAS treatment plan.</u></p> <p><u>A treatment hospital shall ensure that its SAS treatment plan meets the minimum standards established in Part II (12VAC5-416-110 et seq.) of this chapter and includes the provision of a forensic medical examination to a SAS when ordered by a health care professional and with the consent of the SAS.</u></p>	<p>None</p>	<p>CHANGE: The Board is proposing to promulgate this section.</p> <p>INTENT: The intent of these new requirements is to broadly describe what must be included in the plan.</p> <p>RATIONALE: The rationale for these new requirements is to ensure that applicants and regulants are incorporating all regulatory minimums when developing their plans.</p> <p>LIKELY IMPACT: The likely impact of these new requirements is improved clarity for applicants and regulants.</p>
<p>416-120</p>	<p><u>12VAC5-416-120. Staffing and education.</u></p> <p><u>A. A treatment hospital shall ensure that at least one SAFE is available during all hours of operation in person.</u></p> <p><u>B. A treatment hospital shall ensure that health care professionals providing services in its emergency department annually complete training developed and made available by the department on the topics of:</u></p> <ol style="list-style-type: none"> <u>1. Sexual assault;</u> <u>2. Detection of sexual assault;</u> <u>3. Provision of services for SASs and PSASs; and</u> <u>4. Collection of evidence in cases involving alleged sexual assault.</u> <p><u>C. If the training specified in subsection B is not available, a treatment hospital shall substitute the training for continuing education provided by the treatment hospital or by third</u></p>	<p>None</p>	<p>CHANGE: The Board is proposing to promulgate this section.</p> <p>INTENT: The intent of these new requirements is to ensure that adequately trained staff are available to provide treatment services.</p> <p>RATIONALE: The rationale for these new requirements is that providing treatment services should only be done or directed by someone who has been trained to provide that specialty care and to provide some flexibility to hospitals if training is not available from VDH.</p> <p>LIKELY IMPACT: The likely impact of these new requirements is adequate treatment services and improved clarity for applicants and regulants.</p>

	<p><u>parties on the same topics identified in this subsection.</u></p>		
<p>416-130</p>	<p><u>12VAC5-416-130. Informed consent.</u></p> <p><u>A. Except as provided in § 54.1-2970.1 of the Code of Virginia, a treatment hospital shall obtain informed consent from the SAS for:</u></p> <ol style="list-style-type: none"> <u>1. Medical evaluation and treatment, including the administration of prophylaxis and emergency contraception, the need for follow-up care, and medical advocacy services and counseling;</u> <u>2. Reporting the alleged crime;</u> <u>3. Performing a forensic medical examination;</u> <u>4. Photodocumentation;</u> <u>5. Evidence collection; and</u> <u>6. Transferal of evidence to law enforcement.</u> <p><u>B. In obtaining informed consent for evidence collection, a treatment hospital shall inform the SAS that the ability to collect viable evidence declines as time elapses.</u></p> <p><u>C. Except as provided in § 54.1-2970.1 of the Code of Virginia, a treatment hospital shall obtain informed consent in writing from the SAS to the maximum extent practicable, provided that if it cannot obtain informed consent in writing, it shall:</u></p> <ol style="list-style-type: none"> <u>1. Obtain oral informed consent from the SAS; and</u> <u>2. Document in the SAS's medical records why informed written</u> 	<p>None</p>	<p>CHANGE: The Board is proposing to promulgate this section.</p> <p>INTENT: The intent of these new requirements is to ensure informed consent is obtained and documented in conformity with recommendations from the American College of Emergency Physicians.</p> <p>RATIONALE: The rationale for these new requirements is that informed consent creates trust between patients and their health care providers and reduces risk.</p> <p>LIKELY IMPACT: The likely impact of these new requirements is patients feeling empowered to make decisions about their care.</p>

	<p><u>consent was not obtained.</u></p> <p><u>D. A treatment hospital shall maintain documentation of compliance with this section in the SAS's medical records.</u></p>		
416-140	<p><u>12VAC5-416-140. Documentation.</u></p> <p><u>A treatment hospital shall ensure that all findings of the forensic medical examination are comprehensively and objectively documented.</u></p>	None	<p>CHANGE: The Board is proposing to promulgate this section.</p> <p>INTENT: The intent of these new requirements is to ensure the findings are complete.</p> <p>RATIONALE: The rationale for these new requirements is that inadequately documented findings may compromise any future criminal investigation or prosecution.</p> <p>LIKELY IMPACT: The likely impact of these new requirements is improved clarity for applicants and regulants.</p>
416-150	<p><u>12VAC5-416-150. Medical history.</u></p> <p><u>A. A treatment hospital shall document specific information related to the alleged sexual assault, including:</u></p> <ol style="list-style-type: none"> <u>1. Time, date, and place of the alleged sexual assault;</u> <u>2. The SAS's ability to give consent to the reported sexual activity;</u> <u>3. Alleged use of force, threats of force, weapons, coercion, drugs, or alcohol to facilitate the sexual assault;</u> <u>4. Types or means of the alleged sexual assault;</u> <u>5. Number of alleged assailants;</u> 	None	<p>CHANGE: The Board is proposing to promulgate this section.</p> <p>INTENT: The intent of these new requirements is to describe the minimum medical history and alleged sexual assault information to be captured for SASs in conformity with recommendations from the American College of Emergency Physicians.</p> <p>RATIONALE: The rationale for these new requirements is that inadequately documented findings may compromise any future criminal investigation or prosecution.</p> <p>LIKELY IMPACT: The likely impact of these new requirements is improved</p>

	<p><u>6. The occurrence of penetration of any body part with a penis, finger, or other object;</u></p> <p><u>7. Whether the SAS voided, removed or inserted a tampon, douched, wiped or cleaned the genital area, bathed, showered, gargled, brushed teeth, smoked, ate, drank, chewed gum, changed clothes, or took medications after the alleged sexual assault;</u></p> <p><u>8. Whether the SAS bit an alleged assailant or was bitten by the alleged assailant; and</u></p> <p><u>9. Any other relevant information as determined by the health care professional who is providing care.</u></p> <p><u>B. To the maximum extent practicable, a treatment hospital shall ensure that:</u></p> <p><u>1. Information documented pursuant to subsection A includes direct quotations from the SAS describing the alleged sexual assault; and</u></p> <p><u>2. Information solicited pursuant to subsection A is through the use of open-ended, non-leading questions that encourage free narrative from the SAS.</u></p> <p><u>C. A treatment hospital shall document the SAS's medical history, including:</u></p> <p><u>1. Use of contraceptives and which type the SAS uses;</u></p> <p><u>2. Last menstrual period, if applicable;</u></p>		<p>chances that criminal investigation or prosecution is successful and improved clarity for applicants and regulants.</p>
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	<p><u>3. Last consensual intercourse;</u></p> <p><u>4. Pregnancy status, if applicable;</u></p> <p><u>5. History of anogenital surgery; and</u></p> <p><u>6. Any other relevant information as determined by the health care professional who is providing care.</u></p>		
<p>416-160</p>	<p><u>12VAC5-416-160. Physical examination, laboratory testing, and evidence collection.</u></p> <p><u>A. A treatment hospital shall ensure that health care professionals conducting the forensic medical examination or collecting the PERK:</u></p> <ol style="list-style-type: none"> <u>1. Are specially educated and clinically trained to perform these tasks;</u> <u>2. Clearly document all findings; and</u> <u>3. Prevent cross contamination of evidence by changing gloves whenever cross contamination could occur.</u> <p><u>B. A treatment hospital shall ensure that in conducting a forensic medical examination:</u></p> <ol style="list-style-type: none"> <u>1. A clean sheet is placed on the floor to be a barrier for the collection paper before the SAS undresses;</u> <u>2. A SAS is permitted to remove and place each piece of clothing being collected in a separate paper bag; and</u> <u>3. A health care professional:</u> <ol style="list-style-type: none"> <u>a. Conducts an appropriate</u> 	<p>None</p>	<p>CHANGE: The Board is proposing to promulgate this section.</p> <p>INTENT: The intent of these new requirements is to ensure that the collection of evidence for a PERK is complete and done in conformity with recommendations from the American College of Emergency Physicians.</p> <p>RATIONALE: The rationale for these new requirements is that improper evidence collection can jeopardize or destroy the potential for criminal investigation or prosecution.</p> <p>LIKELY IMPACT: The likely impact of these new requirements is improved chances that criminal investigation or prosecution is successful and improved clarity for applicants and regulants.</p>

	<p>evaluation _____ to determine the SAS's risk of infection or STIs, including HIV, resulting from the alleged _____ sexual assault;</p> <p>b. Documents the presence of any physical _____ injury, biological evidence, or foreign debris;</p> <p>c. Photographs and recovers any trace evidence, including sand, soil, leaves, grass, and biological secretions;</p> <p>d. Documents the location on the body from which trace evidence _____ is collected;</p> <p>e. _____ Performs appropriate photodocumentation of collection sites and injuries before evidence collection;</p> <p>f. Recovers debris, moist secretions, and dry secretions in accordance with best practices; and</p> <p>g. Documents the location, size, and complete description of any trauma, including bite _____ marks, strangulation injuries, or areas of point tenderness, including _____ those occurring around the mouth, _____ breasts, thighs, wrists, upper arms, legs, back, and _____ anogenital region.</p> <p>C. If drug-facilitated or alcohol-facilitated sexual assault</p>		
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	<p><u>is suspected, a treatment hospital shall ensure that blood or urine or both are collected with the consent of the SAS.</u></p> <p><u>D. A treatment hospital shall ensure that health care professionals performing a forensic medical examination conduct all necessary laboratory testing.</u></p> <p>Statutory Authority <u>§§ 32.1-12 and 32.1-162.15:4 of the Code of Virginia.</u></p>		
<p>416-170</p>	<p><u>12VAC5-416-170. Chain of custody.</u></p> <p><u>A. A treatment hospital shall ensure that the chain of custody is maintained for all samples collected during the forensic medical examination.</u></p> <p><u>B. A treatment hospital shall ensure that all specimens are properly sealed, initialed, and labeled with:</u></p> <ol style="list-style-type: none"> <u>1. The name of the treatment hospital;</u> <u>2. The SAS's name and patient identification number;</u> <u>3. Date and time of specimen collection;</u> <u>4. Description and location of the body part of the origin of the specimen;</u> <u>5. The name and signature of the person collecting the specimen; and</u> <u>6. Any other information that may be required by law.</u> <p><u>C. A treatment hospital shall ensure that all transfers in the custody of evidence are documented in a written record of:</u></p> <ol style="list-style-type: none"> <u>1. The name, title, and signature of the person</u> 	<p>None</p>	<p>CHANGE: The Board is proposing to promulgate this section.</p> <p>INTENT: The intent of these new requirements is to ensure that chain of custody is maintained in conformity with recommendations from the American College of Emergency Physicians and local law enforcement.</p> <p>RATIONALE: The rationale for these new requirements is that mishandling evidence or breaking the chain of custody can jeopardize or destroy the potential for criminal investigation or prosecution.</p> <p>LIKELY IMPACT: The likely impact of these new requirements is improved chances that criminal investigation or prosecution is successful and improved clarity for applicants and regulants.</p>

	<p><u>receiving the evidence;</u> <u>and</u> <u>2. Date and time of transfer.</u></p> <p><u>D. A treatment hospital may designate a secured location to store evidence and maintain chain of custody, provided the treatment hospital has consulted with local law enforcement on the location, security, and policies and procedures for storage.</u></p>		
<p>416-180</p>	<p><u>12VAC5-416-180. Prophylaxis and contraception.</u></p> <p><u>A. A treatment hospital shall provide appropriate oral and written information regarding:</u></p> <p><u>1. The possibility of infection or STIs, including HIV resulting from the alleged sexual assault;</u></p> <p><u>2. Accepted medical procedures and medications for the prevention or treatment of infection or STIs;</u></p> <p><u>3. The indications, contraindications, and potential risks of medical procedures or medications for the prevention or treatment of infection or STIs;</u></p> <p><u>4. The possibility of pregnancy resulting from the alleged sexual assault;</u></p> <p><u>5. Medically and factually accurate oral and written information about emergency contraception;</u></p> <p><u>6. The indications, contraindications, and potential risks associated with the use of emergency contraception; and</u></p>	<p>None</p>	<p>CHANGE: The Board is proposing to promulgate this section.</p> <p>INTENT: The intent of these new requirements is to describe the information to be provided to a patient and the care to be provided or arranged for with regard to STIs and emergency contraception, subject to certain exclusions.</p> <p>RATIONALE: The rationale for these new requirements is that treatment for STIs and emergency contraception are often clinically indicated for alleged sexual assaults and patients should be provided adequate information to make informed choices. Also, VDH recognizes that some hospitals may object to emergency contraceptive on religious grounds and has provided an exception.</p> <p>LIKELY IMPACT: The likely impact of these new requirements is patients feeling empowered to make decisions about their care.</p>

	<p><u>7. The availability of emergency contraception for SASs.</u></p> <p><u>B. Unless the prophylaxis is medically contraindicated or the SAS refuses to consent to the administration of prophylaxis, the treatment hospital shall provide, or arrange for, the administration to a SAS of prophylaxis for STIs in accordance with the:</u></p> <p><u>1. Sexually Transmitted Infections Treatment Guidelines, July 2021 (U.S. Centers for Disease Control and Prevention); and</u></p> <p><u>2. Recommendations for Providing Quality Sexually Transmitted Diseases Clinical Services, January 2020 (U.S. Centers for Disease Control and Prevention).</u></p> <p><u>C. Unless emergency contraceptive is medically contraindicated or the SAS refuses to consent to the administration of emergency contraceptive, the treatment hospital shall provide, or arrange for, the administration to a SAS of emergency contraceptive.</u></p> <p><u>D. The provisions of subsection C of this section may not apply to a treatment hospital operated under the auspices of a religious institution objecting to the administration or arrangement of administration for emergency contraceptive on religious grounds.</u></p>		
<p>416-190</p>	<p><u>12VAC5-416-190. Anonymous PERK.</u></p> <p><u>A. If a SAS who undergoes a forensic medical examination elects not to report the offense to law enforcement, the treatment hospital shall ensure that the</u></p>	<p>None</p>	<p>CHANGE: The Board is proposing to promulgate this section.</p> <p>INTENT: The intent of these new requirements is to describe what a hospital must do when a patient</p>

	<p><u>health care professional informs the SAS:</u></p> <ol style="list-style-type: none"> <u>1. The PERK will be forwarded to DCLS for storage as an anonymous PERK;</u> <u>2. The anonymous PERK will be stored by DCLS;</u> <u>3. The SAS has the right to object to the destruction of the anonymous PERK;</u> <u>4. How the SAS can have the anonymous PERK released to a law enforcement agency at a later date; and</u> <u>5. The rights of the SAS pursuant to § 19.2-11.11 of the Code of Virginia.</u> <p><u>B. The treatment hospital shall ensure that the health care professional forwards the anonymous PERK to DCLS in accordance with the policies and procedures established by DCLS.</u></p>		<p>declines to report the offense to law enforcement.</p> <p>RATIONALE: The rationale for these new requirements is that patients should be adequately informed about what happens next to their PERK and their ability to change their mind in the future.</p> <p>LIKELY IMPACT: The likely impact of these new requirements is improved clarity for patients about what will happen to their PERK and for applicants and regulants about their obligations.</p>
<p>416-200</p>	<p><u>12VAC5-416-200. Medical advocacy services.</u></p> <p><u>A. A treatment hospital shall:</u></p> <ol style="list-style-type: none"> <u>1. Enter into a memorandum of understanding with at least one rape crisis center; and</u> <u>2. Adopt procedures to ensure compliance with mandatory reporting requirements pursuant to §§ 63.2-1509 and 63.2-1606 of the Code of Virginia.</u> <p><u>B. A treatment hospital shall review its memorandums of understanding with rape crisis centers at least triennially and shall document the outcome of this review in writing.</u></p>	<p>None</p>	<p>CHANGE: The Board is proposing to promulgate this section.</p> <p>INTENT: The intent for these new requirements is to meet the statutory requirements for memoranda of understanding (MOUs) with rape crisis centers and provision of information to patients about medical advocacy, and to ensure the MOUs are regularly reviewed.</p> <p>RATIONALE: The rationale for these new requirements is that Chapter 725 (2020 Acts of Assembly) mandates these MOUs, that regular review ensures the MOU continues to serve the</p>

	<p><u>C. A treatment hospital shall provide written and oral information to the SAS about medical advocacy services provided by a rape crisis center with which the hospital has entered into a memorandum of understanding pursuant to this section.</u></p>		<p>purposes of legislation and the contracting parties, and that patients are adequately informed of non-hospital services that may be of assistance.</p> <p>LIKELY IMPACT: The likely impact of these new requirements is improved clarity for patients about what community resources are available and for applicants and regulants about their obligations.</p>
<p>416-210</p>	<p><u>12VAC5-416-210. Discharge and follow-up health care.</u></p> <p><u>A. A treatment hospital shall ensure that a SAS is provided with oral and written medical discharge instructions that include:</u></p> <ol style="list-style-type: none"> <u>1. A summary of the examination, which includes:</u> <ol style="list-style-type: none"> <u>a. Evidence collected;</u> <u>b. Tests conducted;</u> <u>c. Medication prescribed or provided;</u> <u>d. Information provided during the examination; and</u> <u>e. Treatment received;</u> <u>2. Medication doses to be taken, if any;</u> <u>3. Recommended examinations and laboratory tests to determine the presence or absence of STIs;</u> <u>4. Follow-up care related to HIV prophylaxis;</u> <u>5. Any other follow-up health care appointments needed or scheduled; and</u> <u>6. Referrals.</u> 	<p>None</p>	<p>CHANGE: The Board is proposing to promulgate this section.</p> <p>INTENT: The intent of these new requirements is to meet the statutory requirements for follow-up health care.</p> <p>RATIONALE: The rationale for these new requirements is that care for patients who have experienced an alleged sexual assault does not end after the initial hospital encounter and adequate instructions and follow-up care should be provided.</p> <p>LIKELY IMPACT: The likely impact of these new requirements is improved clarity for patients about what next steps they need to take for their care and for applicants and regulants about their obligations.</p>

	<p><u>B. A treatment hospital shall provide to a SAS contact information and the hours of operation for local advocacy programs.</u></p> <p><u>C. A treatment hospital shall inform a SAS in writing that the SAS is not required to disclose the alleged sexual assault to other health care professionals to receive follow-up health care.</u></p> <p><u>D. The follow-up health care appointments that a treatment hospital may schedule or recommend to a SAS include:</u></p> <ol style="list-style-type: none"> <u>1. For patients with evidence of acute trauma, a short-term follow-up appointment to reexamine and document the development of visible findings and photograph areas of injury, and an exam two to four weeks later to document resolution of findings or healing of injuries; and</u> <u>2. For all patients, a repeat examination for STIs in accordance with the policies and procedures of the treatment hospital and with best practices.</u> <p>Statutory Authority <u>§§ 32.1-12 and 32.1-162.15:4 of the Code of Virginia.</u></p>		
<p>416-220</p>	<p><u>12VAC5-416-220. Reporting requirements.</u></p> <p><u>A treatment hospital shall report to the department by December 1 of each year:</u></p> <ol style="list-style-type: none"> <u>1. The total number of SASs to whom a forensic medical examination was provided; and</u> 	<p>None</p>	<p>CHANGE: The Board is proposing to promulgate this section.</p> <p>INTENT: The intent of these new requirements is to meet the statutory requirements for hospital reporting.</p> <p>RATIONALE: The rationale for these new requirements is that the regulations should</p>

	<p><u>2. The total number of PERKs offered and completed.</u></p>		<p>be in conformity with the enabling statutes.</p> <p>LIKELY IMPACT: The likely impact of these new requirements is improved clarity for applicants and regulants about their obligations and increased knowledge about treatment services.</p>
416-230	<p>Part III PSAS Treatment Plan <u>12VAC5-416-230. Minimum requirements for PSAS treatment plan.</u> <u>An approved pediatric treatment facility shall ensure that its PSAS treatment plan meets the minimum standards established in Part III (12VAC5-416-230 et seq.) of this chapter and includes the provision of a forensic medical examination to a PSAS when ordered by a health care professional and with the assent of the PSAS and consent of the PSAS's legal representative.</u></p>	None	<p>CHANGE: The Board is proposing to promulgate this section.</p> <p>INTENT: The intent of these new requirements is to broadly describe what must be included in the plan.</p> <p>RATIONALE: The rationale for these new requirements is to ensure that applicants and regulants are incorporating all regulatory minimums when developing their plans.</p> <p>LIKELY IMPACT: The likely impact of these new requirements is improved clarity for applicants and regulants.</p>
416-240	<p><u>12VAC5-416-240. Pediatric staffing.</u> <u>An approved pediatric treatment facility shall ensure that at least one SAFE is available during all hours of operation in person.</u></p>	None	<p>CHANGE: The Board is proposing to promulgate this section.</p> <p>INTENT: The intent of these new requirements is to ensure that adequately trained staff are available to provide treatment services.</p> <p>RATIONALE: The rationale for these new requirements is that providing treatment services should only be done or directed by someone who has been trained to provide that specialty care.</p> <p>LIKELY IMPACT: The likely impact of these new requirements is adequate treatment services and</p>

			improved clarity for applicants and regulants.
416-250	<p><u>12VAC5-416-250. Informed assent and consent for treatment.</u></p> <p><u>A. An approved pediatric treatment facility:</u></p> <ol style="list-style-type: none"> <u>1. Shall ensure that all necessary _____ and reasonable efforts are made to obtain informed assent of PSASs who are six years of age or older prior to and during treatment, unless the attending health care professional reasonably believes that the PSAS lacks the developmental and linguistic capacity to give informed assent;</u> <u>2. May obtain informed assent of PSASs who are less than six years of age prior to and during treatment, if the attending health care professional reasonably believes that the PSAS has the developmental and linguistic capacity to give informed assent; and</u> <u>3. Shall ensure that the attending health care professional documents in the PSAS's medical record the informed assent or the attending health _____ care professional's judgment that the PSAS lacks the developmental _____ and linguistic capacity to give informed assent.</u> <p><u>B. Except as provided in § 54.1-2970.1 of the Code of Virginia, an approved pediatric health care facility shall obtain informed consent from the PSAS's legal representative for:</u></p>	None	<p>CHANGE: The Board is proposing to promulgate this section.</p> <p>INTENT: The intent of these new requirements is to ensure informed assent and consent is obtained and documented, subject to certain age and capacity restrictions.</p> <p>RATIONALE: The rationale for these new requirements is that informed assent and consent creates trust between patients and their health care providers and reduces risk.</p> <p>LIKELY IMPACT: The likely impact of these new requirements is patients and their legal representatives feeling empowered to make decisions about the patient's care.</p>

	<p><u>1. Medical evaluation and treatment, including the administration of prophylaxis and emergency contraception, the need for follow-up care, and medical advocacy services and counseling;</u></p> <p><u>2. Reporting the alleged crime;</u></p> <p><u>3. Performing a forensic medical examination;</u></p> <p><u>4. Photodocumentation;</u></p> <p><u>5. Evidence collection; and</u></p> <p><u>6. Transferal of evidence to law enforcement.</u></p> <p><u>C. In obtaining informed consent for evidence collection, an approved pediatric treatment facility shall inform the PSAS and the PSAS's legal representative that the ability to collect viable evidence declines as time elapses.</u></p> <p><u>D. Except as provided in § 54.1-2970.1 of the Code of Virginia, an approved pediatric treatment facility shall obtain informed consent in writing from the PSAS's legal representative to the maximum extent practicable, provided that if it cannot obtain informed consent in writing, it shall:</u></p> <p><u>1. Obtain oral informed consent from the PSAS's legal representative; and</u></p> <p><u>2. Document in the PSAS's medical records why informed written consent was not obtained.</u></p> <p><u>E. An approved pediatric treatment facility shall maintain documentation of compliance with this section in the PSAS's medical records.</u></p>		
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	<p><u>F. If a PSAS refuses to grant informed assent and the PSAS's legal representative gives informed consent, an approved pediatric treatment facility that is a hospital:</u></p> <ol style="list-style-type: none"> <u>1. May not proceed with PSAS treatment services and shall only screen, treat, and stabilize the PSAS in accordance with EMTALA; and</u> <u>2. May attempt to obtain a PSAS's informed assent at a later time.</u> <p><u>G. If a PSAS refuses to grant informed assent and the PSAS's legal representative gives informed consent, an approved pediatric treatment facility that is not a hospital:</u></p> <ol style="list-style-type: none"> <u>1. May not proceed with PSAS treatment services and shall only screen or treat serious medical injury, pain, or trauma to stabilize the PSAS; and</u> <u>2. May attempt to obtain a PSAS's informed assent at a later time.</u> <p>Statutory Authority <u>§§ 32.1-12, 32.1-162.15:4, and 32.1-162.15:6 of the Code of Virginia.</u></p> <p><u>12VAC5-416-260.</u> <u>Documentation.</u></p> <p><u>An approved pediatric treatment facility shall ensure that all findings of the forensic medical examination are comprehensively and objectively documented.</u></p> <p>Statutory Authority <u>§§ 32.1-12, 32.1-162.15:4, and 32.1-162.15:6 of the Code of Virginia.</u></p>		
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<p>416-260</p>	<p><u>12VAC5-416-260. Documentation.</u> <u>An approved pediatric treatment facility shall ensure that all findings of the forensic medical examination are comprehensively and objectively documented.</u></p>	<p>None</p>	<p>CHANGE: The Board is proposing to promulgate this section.</p> <p>INTENT: The intent of these new requirements is to ensure the findings are complete.</p> <p>RATIONALE: The rationale for these new requirements is that inadequately documented findings may compromise any future criminal investigation or prosecution.</p> <p>LIKELY IMPACT: The likely impact of these new requirements is improved clarity for applicants and regulants.</p>
<p>416-270</p>	<p><u>12VAC5-416-270. Medical history.</u> <u>A. An approved pediatric treatment facility shall document specific information related to the alleged sexual assault, including:</u></p> <ol style="list-style-type: none"> <u>1. Time, date, and place of the alleged sexual assault;</u> <u>2. The PSAS's ability to give consent to the reported sexual activity;</u> <u>3. Alleged use of force, threats of force, weapons, coercion, drugs, or alcohol to facilitate the sexual assault;</u> <u>4. Types or means of the alleged sexual assault;</u> <u>5. Number of alleged assailants;</u> <u>6. The occurrence of penetration of any body part with a penis, finger, or other object;</u> <u>7. Whether the PSAS voided, removed or inserted a tampon, douched, wiped or</u> 	<p>None</p>	<p>CHANGE: The Board is proposing to promulgate this section.</p> <p>INTENT: The intent of these new requirements is to describe the minimum medical history and alleged sexual assault information to be captured for PSASs in conformity with recommendations from the American College of Emergency Physicians.</p> <p>RATIONALE: The rationale for these new requirements is that inadequately documented findings may compromise any future criminal investigation or prosecution.</p> <p>LIKELY IMPACT: The likely impact of these new requirements is improved chances that criminal investigation or prosecution is successful and improved clarity for applicants and regulants.</p>

	<p><u>cleaned the genital area, bathed, showered, gargled, brushed teeth, smoked, ate, drank, chewed gum, changed clothes, or took medications after the alleged sexual assault;</u></p> <p><u>8. Whether the PSAS bit an alleged assailant or was bitten by the alleged assailant; and</u></p> <p><u>9. Any other relevant information as determined by the health care professional who is providing care.</u></p> <p><u>B. To the maximum extent practicable, an approved pediatric treatment facility shall ensure that:</u></p> <p><u>1. Information documented pursuant to subsection A includes direct quotations from the PSAS describing the alleged sexual assault; and</u></p> <p><u>2. Information solicited pursuant to subsection A is through the use of open-ended, non-leading questions that encourage free narrative from the PSAS.</u></p> <p><u>C. An approved pediatric treatment facility shall document the PSAS's medical history, including:</u></p> <p><u>1. Use of contraceptives and which type the PSAS uses;</u></p> <p><u>2. Last menstrual period, if applicable;</u></p> <p><u>3. Last consensual intercourse;</u></p> <p><u>4. Pregnancy status, if applicable;</u></p> <p><u>5. History of anogenital surgery; and</u></p>		
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	<p>6. Any other relevant information as determined by the health care professional who is providing care.</p>		
<p>416-280</p>	<p><u>12VAC5-416-280. Physical examination, laboratory testing, and evidence collection.</u></p> <p><u>A. An approved pediatric treatment facility shall ensure that health care professionals conducting the forensic medical examination or collecting the PERK:</u></p> <ol style="list-style-type: none"> <u>1. Are specially educated and clinically trained to perform these tasks;</u> <u>2. Clearly document all findings; and</u> <u>3. Prevent cross contamination of evidence by changing gloves whenever cross contamination could occur.</u> <p><u>B. An approved pediatric treatment facility shall ensure that in conducting a forensic medical examination:</u></p> <ol style="list-style-type: none"> <u>1. A clean sheet is placed on the floor to be a barrier for the collection paper before the PSAS undresses;</u> <u>2. A PSAS is permitted to remove and place each piece of clothing being collected in a separate paper bag; and</u> <u>3. A health care professional:</u> <ol style="list-style-type: none"> <u>a. Conducts an appropriate evaluation to determine the PSAS's risk of infection or STIs, including HIV,</u> 	<p>None</p>	<p>CHANGE: The Board is proposing to promulgate this section.</p> <p>INTENT: The intent of these new requirements is to ensure that the collection of evidence for a PERK is complete and done in conformity with recommendations from the American College of Emergency Physicians.</p> <p>RATIONALE: The rationale for these new requirements is that improper evidence collection can jeopardize or destroy the potential for criminal investigation or prosecution.</p> <p>LIKELY IMPACT: The likely impact of these new requirements is improved chances that criminal investigation or prosecution is successful and improved clarity for applicants and regulants.</p>

	<p><u>resulting from the alleged sexual assault;</u></p> <p><u>b. Documents the presence of any physical injury, biological evidence, or foreign debris;</u></p> <p><u>c. Photographs and recovers any trace evidence, including sand, soil, leaves, grass, and biological secretions;</u></p> <p><u>d. Documents the location on the body from which trace evidence is collected;</u></p> <p><u>e. Performs appropriate photodocumentation of collection sites and injuries before evidence collection;</u></p> <p><u>f. Recovers debris, moist secretions, and dry secretions in accordance with best practices; and</u></p> <p><u>g. Documents the location, size, and complete description of any trauma, including bite marks, strangulation injuries, or areas of point tenderness, including those occurring around the mouth, breasts, thighs, wrists, upper arms, legs, back, and anogenital region.</u></p> <p><u>C. If drug-facilitated or alcohol-facilitated sexual assault is suspected, an approved pediatric treatment facility shall ensure that blood or urine or both</u></p>		
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	<p>are collected with the assent of the PSAS.</p> <p>D. An approved pediatric treatment facility shall ensure that health care professionals performing a forensic medical examination conduct all necessary laboratory testing.</p> <p>Statutory Authority §§ 32.1-12, 32.1-162.15:4, and 32.1-162.15:6 of the Code of Virginia.</p>		
<p>416-290</p>	<p><u>12VAC5-416-290. Chain of custody.</u></p> <p>A. An approved pediatric treatment facility shall ensure that the chain of custody is maintained for all samples collected during the forensic medical examination.</p> <p>B. An approved pediatric treatment facility shall ensure that all specimens are properly sealed, initialed, and labeled with:</p> <ol style="list-style-type: none"> 1. <u>The name of the approved pediatric treatment facility;</u> 2. <u>The PSAS's name and patient identification number;</u> 3. <u>Date and time of specimen collection;</u> 4. <u>Description and location of the body part of the origin of the specimen;</u> 5. <u>The name and signature of the person collecting the specimen;</u> and 6. <u>Any other information that may be required by law.</u> <p>C. An approved pediatric treatment facility shall ensure that all transfers in the custody of evidence are documented in a written record of:</p>	<p>None</p>	<p>CHANGE: The Board is proposing to promulgate this section.</p> <p>INTENT: The intent of these new requirements is to ensure that chain of custody is maintained in conformity with recommendations from the American College of Emergency Physicians and local law enforcement.</p> <p>RATIONALE: The rationale for these new requirements is that mishandling evidence or breaking the chain of custody can jeopardize or destroy the potential for criminal investigation or prosecution.</p> <p>LIKELY IMPACT: The likely impact of these new requirements is improved chances that criminal investigation or prosecution is successful and improved clarity for applicants and regulants.</p>

	<p><u>1. The name, title, and signature of the person receiving the evidence; and</u></p> <p><u>2. Date and time of transfer.</u></p> <p><u>D. An approved pediatric treatment facility may designate a secured location to store evidence and maintain chain of custody, provided the approved pediatric treatment facility has consulted with local law enforcement on the location, security, and policies and procedures for storage.</u></p>		
<p>416-300</p>	<p><u>12VAC5-416-300. Prophylaxis and contraception.</u></p> <p><u>A. An approved pediatric treatment facility shall provide appropriate oral and written information regarding:</u></p> <p><u>1. The possibility of infection or STIs, including HIV resulting from the alleged sexual assault;</u></p> <p><u>2. Accepted medical procedures and medications for the prevention or treatment of infection or STIs;</u></p> <p><u>3. The indications, contraindications, and potential risks of medical procedures or medications for the prevention or treatment of infection or STIs;</u></p> <p><u>4. The possibility of pregnancy resulting from the alleged sexual assault;</u></p> <p><u>5. Medically and factually accurate oral and written information about emergency contraception;</u></p> <p><u>6. The indications, contraindications, and</u></p>	<p>None</p>	<p>CHANGE: The Board is proposing to promulgate this section.</p> <p>INTENT: The intent of these new requirements is to describe the information to be provided to a patient and the care to be provided or arranged for with regard to STIs and emergency contraception, subject to certain exclusions.</p> <p>RATIONALE: The rationale for these new requirements is that treatment for STIs and emergency contraception are often clinically indicated for alleged sexual assaults and patients should be provided adequate information to make informed choices. Also, VDH recognizes that some pediatric health care facilities may object to emergency contraceptive on religious grounds and has provided an exception.</p> <p>LIKELY IMPACT: The likely impact of these new requirements is patients feeling empowered to make decisions about their care.</p>

	<p>potential risks associated with the use of emergency contraception; and</p> <p>7. The availability of emergency contraception for PSASs.</p> <p>B. Unless the prophylaxis is medically contraindicated, the PSAS refuses to assent to the administration of prophylaxis, or the PSAS's legal representative refuses to consent to the administration of prophylaxis, the approved pediatric treatment facility shall provide, or arrange for, the administration to a PSAS of prophylaxis for STIs in accordance with the:</p> <ol style="list-style-type: none"> 1. Sexually Transmitted Infections Treatment Guidelines, July 2021 (U.S. Centers for Disease Control and Prevention); and 2. Recommendations for Providing Quality Sexually Transmitted Diseases Clinical Services, January 2020 (U.S. Centers for Disease Control and Prevention). <p>C. Unless emergency contraceptive is medically contraindicated, the PSAS refuses to assent to the administration of emergency contraceptive, or the PSAS's legal representative refuses to consent to the administration of emergency contraceptive, the approved pediatric treatment facility shall provide, or arrange for, the administration to a PSAS of emergency contraceptive.</p> <p>D. The provisions of subsection C of this section may not apply to an approved pediatric treatment facility operated under the auspices of a</p>		
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	<p><u>religious institution objecting to the administration or arrangement of administration for emergency contraceptive on religious grounds.</u></p>		
416-310	<p><u>12VAC5-416-310. Anonymous PERK.</u></p> <p><u>A. If a PSAS who undergoes a forensic medical examination elects not to report the offense to law enforcement, the approved pediatric treatment facility shall ensure the health care professional informs the PSAS or the PSAS's legal representative:</u></p> <ol style="list-style-type: none"> <u>1. The PERK will be forwarded to DCLS for storage as an anonymous PERK;</u> <u>2. The anonymous PERK will be stored by DCLS;</u> <u>3. The PSAS has the right to object to the destruction of the anonymous PERK;</u> <u>4. How the PSAS can have the anonymous PERK released to a law enforcement agency at a later date; and</u> <u>5. The rights of the PSAS and PSAS's parent or guardian under § 19.2-11.11 of the Code of Virginia.</u> <p><u>B. The approved pediatric treatment facility shall ensure the health care professional forwards the anonymous PERK to DCLS in accordance with the policies and procedures established by DCLS.</u></p>	None	<p>CHANGE: The Board is proposing to promulgate this section.</p> <p>INTENT: The intent of these new requirements is to describe what a hospital must do when a patient declines to report the offense to law enforcement.</p> <p>RATIONALE: The rationale for these new requirements is that patients should be adequately informed about what happens next to their PERK and their ability to change their mind in the future.</p> <p>LIKELY IMPACT: The likely impact of these new requirements is improved clarity for patients about what will happen to their PERK and for applicants and regulants about their obligations.</p>
416-320	<p><u>12VAC5-416-320. Medical advocacy services.</u></p> <p><u>A. An approved pediatric treatment facility shall:</u></p>	None	<p>CHANGE: The Board is proposing to promulgate this section.</p> <p>INTENT: The intent for these new requirements is to meet</p>

	<p><u>1. Enter into a memorandum of understanding with at least one rape crisis center; and</u></p> <p><u>2. Adopt procedures to ensure compliance with mandatory reporting requirements pursuant to § 63.2-1509 of the Code of Virginia.</u></p> <p><u>B. An approved pediatric treatment facility shall review its memorandums of understanding with rape crisis centers at least triennially and shall document the outcome of this review in writing.</u></p> <p><u>C. An approved pediatric treatment facility shall provide written and oral information about medical advocacy services provided by a rape crisis center with which the approved pediatric treatment facility has entered into a memorandum of understanding pursuant to this section.</u></p>		<p>the statutory requirements for memoranda of understanding (MOUs) with rape crisis centers and provision of information to patients about medical advocacy, and to ensure the MOUs are regularly reviewed.</p> <p>RATIONALE: The rationale for these new requirements is that Chapter 725 (2020 Acts of Assembly) mandates these MOUs, that regular review ensures the MOU continues to serve the purposes of legislation and the contracting parties, and that patients are adequately informed of non-hospital services that may be of assistance.</p> <p>LIKELY IMPACT: The likely impact of these new requirements is improved clarity for patients about what community resources are available and for applicants and regulants about their obligations.</p>
<p>416-330</p>	<p><u>12VAC5-416-330. Discharge and follow-up health care.</u></p> <p><u>A. An approved pediatric treatment facility shall ensure that a PSAS and the PSAS's legal representative is provided with oral and written medical discharge instructions that include:</u></p> <p><u>1. A summary of the examination, which includes:</u></p> <p><u>a. Evidence collected;</u></p> <p><u>b. Tests conducted;</u></p> <p><u>c. Medication prescribed or provided;</u></p> <p><u>d. Information provided during the examination; and</u></p>	<p>None</p>	<p>CHANGE: The Board is proposing to promulgate this section.</p> <p>INTENT: The intent of these new requirements is to meet the statutory requirements for follow-up health care.</p> <p>RATIONALE: The rationale for these new requirements is that care for patients who have experienced an alleged sexual assault does not end after the initial hospital encounter and adequate instructions and follow-up care should be provided.</p> <p>LIKELY IMPACT: The likely impact of these new requirements is improved clarity for patients about what next steps they need to</p>

	<p><u>e. Treatment received;</u></p> <p><u>2. Medication doses to be taken, if any;</u></p> <p><u>3. Recommended examinations and laboratory tests to determine the presence or absence of STIs;</u></p> <p><u>4. Follow-up care related to HIV prophylaxis;</u></p> <p><u>5. Any other follow-up health care appointments needed or scheduled; and</u></p> <p><u>6. Referrals.</u></p> <p><u>B. An approved pediatric treatment facility shall provide to a PSAS and the PSAS's legal representative contact information and the hours of operation for local advocacy programs.</u></p> <p><u>C. An approved pediatric treatment facility shall inform a PSAS and the PSAS's legal representative in writing that the PSAS is not required to disclose the alleged sexual assault to other health care professionals to receive follow-up health care.</u></p> <p><u>D. The follow-up health care appointments that an approved pediatric treatment facility may schedule or recommend to a PSAS and the PSAS's legal representative include:</u></p> <p><u>1. For patients with evidence of acute trauma, a short-term follow-up appointment to reexamine and document the development of visible findings and photograph areas of injury, and an exam two to four weeks later to document resolution of findings or healing of injuries; and</u></p>		<p>take for their care and for applicants and regulants about their obligations.</p>
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	<p><u>2. For all patients, a repeat examination for STIs in accordance with the policies and procedures of the approved pediatric treatment facility and with best practices.</u></p>		
<p>416-340</p>	<p><u>12VAC5-416-340. Approved pediatric treatment facilities with limited capacity.</u></p> <p><u>A. In cases in which an approved pediatric treatment facility is not able to provide the full range of treatment services required by Part III (12VAC5-416-230 et seq.) of this chapter, the PSAS treatment plan shall include:</u></p> <ol style="list-style-type: none"> <u>1. The specific PSAS treatment services that the approved pediatric treatment facility will provide for a PSAS;</u> <u>2. Provisions for PSAS transfer services for a PSAS; and</u> <u>3. The written agreement of an approved pediatric treatment facility to accept transfer of a PSAS who cannot be treated by the originating approved pediatric treatment facility.</u> <p><u>B. If the approved pediatric treatment facility does not provide services 24 hours per day, seven days per week, it shall:</u></p> <ol style="list-style-type: none"> <u>1. Inform the public regarding the need to seek an alternative source of treatment, including emergency medical services; and</u> <u>2. Post conspicuous signage on its premises, including in an area</u> 	<p>None</p>	<p>CHANGE: The Board is proposing to promulgate this section.</p> <p>INTENT: The intent of these new requirements is to meet the statutory requirements for pediatric health care facilities with limited capacity.</p> <p>RATIONALE: The rationale for these new requirements is that Chapter 725 (2020 Acts of Assembly) mandates these pediatric health care facilities include certain elements in their plans and that patients and their legal representatives know a non-24/7 pediatric health care facility will not be available to provide care after hours.</p> <p>LIKELY IMPACT: The likely impact of these new requirements is improved clarity for patients and their legal representatives about where to seek care after hours and for applicants and regulants about their obligations if they are a pediatric health care facility with limited capacity or pediatric health care facilities that does not operate 24/7.</p>

	<p><u>readily visible and accessible to the public from the exterior of the approved pediatric treatment facility.</u></p> <p><u>C. An approved pediatric treatment facility's provision of PSAS transfer services pursuant to subdivision A 2 of this section shall comply with Part V (12VAC5-416-390 et seq.) of this chapter.</u></p> <p>Statutory Authority <u>§§ 32.1-12, 32.1-162.15:4, and 32.1-162.15:6 of the Code of Virginia.</u></p>		
416-350	<p><u>Part IV</u> <u>SAS Transfer Plan</u> <u>12VAC5-416-350. Minimum requirements for SAS transfer plan.</u></p> <p><u>A transfer hospital shall ensure that its SAS transfer plan meets the minimum standards established in Part IV (12VAC5-416-350 et seq.) of this chapter.</u></p>	None	<p>CHANGE: The Board is proposing to promulgate this section.</p> <p>INTENT: The intent of these new requirements is to broadly describe what must be included in the plan.</p> <p>RATIONALE: The rationale for these new requirements is to ensure that applicants and regulants are incorporating all regulatory minimums when developing their plans.</p> <p>LIKELY IMPACT: The likely impact of these new requirements is improved clarity for applicants and regulants.</p>
416-360	<p><u>12VAC5-416-360. Screening.</u></p> <p><u>A. A transfer hospital shall screen patients for sexual assault, as deemed appropriate by a qualified health care professional in accordance with EMTALA.</u></p> <p><u>B. A transfer hospital shall adopt procedures to ensure compliance with mandatory reporting requirements pursuant to §§ 63.2-1509 and 63.2-1606 of the Code of Virginia.</u></p>	EMTALA	<p>CHANGE: The Board is proposing to promulgate this section.</p> <p>INTENT: The intent of these new requirements is to ensure that the hospitals appropriately screen for sexual assault.</p> <p>RATIONALE: The rationale for these new requirements is that not all patients will disclose they are survivors of an alleged sexual assault</p>

			<p>and health care professionals need to be cognizant of these patients.</p> <p>LIKELY IMPACT: The likely impact of these new requirements is improved clarity for applicants and regulants about when to screen patients for sexual assault.</p>
416-370	<p><u>12VAC5-416-370. Acute injuries.</u></p> <p><u>A transfer hospital shall ensure that a SAS is screened, treated, and stabilized in accordance with EMTALA prior to initiating any transfer.</u></p>	EMTALA	<p>CHANGE: The Board is proposing to promulgate this section.</p> <p>INTENT: The intent of these new requirements is to ensure that a hospital's actions under this regulatory chapter comply with EMTALA.</p> <p>RATIONALE: The rationale for these new requirements is to avoid hospitals misunderstanding their obligations under this regulatory chapter when it intersects with their obligations under EMTALA.</p> <p>LIKELY IMPACT: The likely impact of these new requirements is improved clarity for applicants and regulants.</p>
416-380	<p><u>12VAC5-416-380. Transfer coordination.</u></p> <p><u>A. A transfer hospital shall comply with EMTALA in coordinating transfer with a receiving treatment hospital.</u></p> <p><u>B. A transfer hospital shall communicate with the receiving treatment hospital to confirm the availability of a SAFE to provide SAS treatment services to ensure minimal or no delay in the provision of a forensic medical examination.</u></p> <p><u>C. A transfer hospital shall provide a SAS with:</u></p>	EMTALA	<p>CHANGE: The Board is proposing to promulgate this section.</p> <p>INTENT: The intent of these new requirements is to ensure adequate coordination for patient transfers and to ensure patients receive information about emergency contraception.</p> <p>RATIONALE: The rationale for these new requirements is that adequate transfer coordination is needed to ensure patients receive timely care from the receiving hospital and that</p>

	<p><u>1. Written and oral information about:</u></p> <p>a. <u>Emergency contraception;</u></p> <p>b. <u>The indications, contraindications, and potential risks associate with the use of emergency contraception; and</u></p> <p>c. <u>The availability of emergency contraception; and</u></p> <p><u>2. A copy of the SAS's medical record from the encounter, _____ as appropriate.</u></p>		<p>patients are adequately informed about emergency contraception.</p> <p>LIKELY IMPACT: The likely impact of these new requirements is patients will be informed about emergency contraception and improved clarity for applicants and regulants.</p>
<p>416-390</p>	<p><u>Part V</u> <u>PSAS Transfer Plan</u> <u>12VAC5-416-390. Minimum requirements for PSAS transfer plan.</u> <u>An approved pediatric transfer facility shall ensure that its PSAS transfer plan meets the minimum standards established in Part V (12VAC5-416-390 et seq.) of this chapter.</u></p>	<p>None</p>	<p>CHANGE: The Board is proposing to promulgate this section.</p> <p>INTENT: The intent of these new requirements is to broadly describe what must be included in the plan.</p> <p>RATIONALE: The rationale for these new requirements is to ensure that applicants and regulants are incorporating all regulatory minimums when developing their plans.</p> <p>LIKELY IMPACT: The likely impact of these new requirements is improved clarity for applicants and regulants.</p>
<p>416-400</p>	<p><u>12VAC5-416-400. Screening.</u> <u>A. An approved pediatric transfer facility that is a hospital shall screen pediatric patients for sexual assault, as determined to be appropriate by a qualified health care professional in accordance with EMTALA.</u> <u>B. An approved pediatric transfer facility that is not a hospital shall:</u></p>	<p>EMTALA</p>	<p>CHANGE: The Board is proposing to promulgate this section.</p> <p>INTENT: The intent of these new requirements is to ensure that the pediatric health care facilities appropriately screen for sexual assault and have policies in place for mandatory reporting.</p>

	<p>1. <u>Screen pediatric patients for sexual, as determined to be appropriate by a qualified health care professional; and</u></p> <p>2. <u>Have a written policy and procedure specifying the qualifications of the health care professionals at the approved pediatric transfer facility who may make the determination specified in subdivision B 1 of this section.</u></p> <p>C. <u>An approved pediatric transfer facility shall adopt procedures to ensure compliance with mandatory reporting requirements pursuant to § 63.2-1509 of the Code of Virginia.</u></p> <p>D. <u>If an approved pediatric treatment facility does not provide services 24 hours per day, seven days per week, it may not refuse to screen a PSAS solely on the basis that the PSAS arrived before the impending cessation of its daily operations. For the purposes of this subsection, "daily operations" means the publicly posted hours that the approved pediatric treatment facility provides services to patients.</u></p>		<p>RATIONALE: The rationale for these new requirements is that not all patients will disclose they are survivors of an alleged sexual assault and health care professionals need to be cognizant of these patients, as well as ensuring non-24/7 pediatric health care facilities do not turn away patients on that basis they arrived close to—but not after—close of business.</p> <p>LIKELY IMPACT: The likely impact of these new requirements is improved clarity for applicants and regulants about when to screen patients for sexual assault.</p>
<p>416-410</p>	<p><u>12VAC5-416-410. Acute injuries.</u></p> <p>A. <u>An approved pediatric transfer facility that is a hospital shall ensure that a PSAS is screened, treated, and stabilized in accordance with EMTALA prior to initiating any transfer.</u></p> <p>B. <u>An approved pediatric transfer facility that is not a hospital shall ensure that a PSAS is screened, treated, and</u></p>	<p>EMTALA</p>	<p>CHANGE: The Board is proposing to promulgate this section.</p> <p>INTENT: The intent of these new requirements is to ensure that pediatric health care facilities stabilize and treat acute injuries, communicate as appropriate with child protective services or local law enforcement, and comply with EMTALA, as applicable.</p>

	<p><u>stabilized prior to initiating any transfer.</u></p> <p><u>C. If an approved pediatric transfer facility reasonably believes that the PSAS's legal representative has abused or neglected the PSAS, the approved pediatric transfer facility shall consult with child protective services or local law enforcement immediately.</u></p> <p><u>D. If the PSAS's legal representative refuses to grant consent to treatment of an acute injury, the approved pediatric transfer facility shall consult with child protective services or local law enforcement immediately.</u></p>		<p>RATIONALE: The rationale for these new requirements is to ensure patients get adequate care prior to any transfers, to alert child protective services or local law enforcement in cases where a patient may be in danger, and to avoid pediatric health care facilities that are hospitals misunderstanding their obligations under this regulatory chapter when it intersects with their obligations under EMTALA.</p> <p>LIKELY IMPACT: The likely impact of these new requirements is improved clarity for applicants and regulants.</p>
<p>416-420</p>	<p><u>12VAC5-416-420. Transfer coordination.</u></p> <p><u>A. An approved pediatric transfer facility that is a hospital shall comply with EMTALA in coordinating transfer with a receiving approved pediatric treatment facility.</u></p> <p><u>B. An approved pediatric transfer facility shall communicate with the receiving approved pediatric treatment facility to confirm the availability of a SAFE to provide PSAS treatment services to ensure minimal or no delay in the provision of a forensic medical examination.</u></p> <p><u>C. When making a transfer, the approved pediatric transfer facility shall:</u></p> <ol style="list-style-type: none"> <u>1. Ensure the transfer does not unduly burden the PSAS;</u> <u>2. Take precautions to minimize the loss of forensic evidence; and</u> <u>3. Provide a copy of the PSAS's records, including reports of any</u> 	<p>EMTALA</p>	<p>CHANGE: The Board is proposing to promulgate this section.</p> <p>INTENT: The intent of these new requirements is to ensure adequate coordination for patient transfers.</p> <p>RATIONALE: The rationale for these new requirements is that adequate transfer coordination is needed to ensure patients receive timely care from the receiving hospital and that pediatric health care facilities that are hospitals should continue to comply with EMTALA.</p> <p>LIKELY IMPACT: The likely impact of these new requirements is improved clarity for applicants and regulants.</p>

	<p><u>treatment administered or testing performed, to the approved pediatric treatment facility.</u></p>		
<p>416-430</p>	<p><u>12VAC5-416-430. Required transfer disclosures.</u></p> <p><u>A. Prior to initiating a transfer, an approved pediatric transfer facility shall discuss with the PSAS and the PSAS’s legal representative the reasons for the transfer.</u></p> <p><u>B. An approved pediatric transfer facility shall ensure that a PSAS and the PSAS’s legal representative are advised of the impact of accepting or declining a transfer to assist the PSAS in making an informed decision on transfer to include the effect on quality of care, the usefulness of evidence collection, and any criminal investigation or prosecution.</u></p> <p><u>C. An approved pediatric transfer facility shall provide a PSAS and the PSAS’s legal representative with:</u></p> <ol style="list-style-type: none"> <u>1. Written and oral information about:</u> <ol style="list-style-type: none"> <u>a. Emergency contraception;</u> <u>b. The indications, contraindications, and potential risks associated with the use of emergency contraception; and</u> <u>c. The availability of emergency contraception; and</u> <u>2. A copy of the PSAS’s medical record from the encounter, as appropriate.</u> <p>Statutory Authority <u>§§ 32.1-12, 32.1-162.15:5, and 32.1-162.15:6 of the Code of Virginia.</u></p>	<p>None</p>	<p>CHANGE: The Board is proposing to promulgate this section.</p> <p>INTENT: The intent of these new requirements is to ensure to ensure patients and their legal representatives receive information about the transfer and emergency contraception.</p> <p>RATIONALE: The rationale for these new requirements is that patients and legal representatives need adequate information to make decisions about receiving timely care from the receiving facility and about emergency contraception.</p> <p>LIKELY IMPACT: The likely impact of these new requirements is patients and their legal representatives will be informed about transfer and emergency contraception, and improved clarity for applicants and regulants.</p>

<p>DIBR</p>	<p><u>Documents Incorporated by Reference (12VAC5-416)</u></p> <p><u>Recommendations for Providing Quality Sexually Transmitted Diseases Clinical Services, January 2020 (U.S. Centers for Disease Control and Prevention).</u></p> <p><u>Sexually Transmitted Infections Treatment Guidelines, July 2021 (U.S. Centers for Disease Control and Prevention).</u></p>	<p>None</p>	<p>CHANGE: The Board is proposing to promulgate this section.</p> <p>INTENT: The intent of these new requirements is to list the documents incorporated by reference.</p> <p>RATIONALE: The rationale for these new requirements is that the concepts and information found in the documents incorporated by reference are too length and detailed to be replicated in regulation.</p> <p>LIKELY IMPACT: The likely impact of these new requirements is improved clarity for applicants and regulants.</p>
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Office of Regulatory Management
Economic Review Form

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-416
VAC Chapter title(s)	Sexual Assault Survivor Treatment and Transfer Regulation
Action title	Promulgation of New Regulation to Implement Chapter 725 of the 2020 Acts of Assembly
Date this document prepared	State Board of Health

Cost Benefit Analysis

Table 1a: Costs and Benefits of the Proposed Changes (Primary Option)

(1) Direct Costs & Benefits	<ul style="list-style-type: none"> Hospitals that intend to treat adult survivors of sexual assault must have a sexual assault treatment plan approved by the Virginia Department of Health (VDH). Direct Costs: \$1,250 per hospital, which VDH estimates to be 17 based on the number of hospitals that already have forensic nursing programs. Direct Benefits: VDH is not aware of any quantifiable direct benefits at time. Hospitals that intend to transfer adult survivors of sexual assault must have a sexual assault transfer plan approved by VDH. Direct Costs: \$1,250 per inpatient hospital, which VDH estimates to be 88, based on the number of hospitals that do not have forensic nursing programs; \$5,000 per outpatient surgical hospital, which VDH estimates to be 65. Direct Benefits: VDH is not aware of any quantifiable direct benefits at time. Pediatric health care facilities that intend to treat pediatric survivors of sexual assault must have a sexual assault treatment plan approved by VDH. Direct Costs: \$1,250 per hospital, which VDH estimates to be 17 based on the number of hospitals that already have forensic nursing programs; \$1,250 per non-hospital pediatric health care facility that already provide treatment to pediatric survivors, which VDH
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	<p>estimates to be 120; \$5,000 per non-hospital pediatric health care facility that does not currently provide treatment to pediatric survivors but intends to on or after July 1, 2023, which VDH estimates to be 181.</p> <p>Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.</p> <ul style="list-style-type: none"> • Pediatric health care facilities that intend to transfer pediatric survivors of sexual assault must have a sexual assault transfer plan approved by VDH. <p>Direct Costs: \$1,250 per inpatient hospital, which VDH estimates to be 88, based on the number of hospitals that do not have forensic nursing programs; \$5,000 per outpatient surgical hospital, which VDH estimates to be 65; \$5,000 per non-hospital pediatric health care facility, which VDH estimates to be 5,716.</p> <p>Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.</p>
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(2) Quantitative Factors	Estimated Dollar Amount	Present Value	
Direct Costs	(a) \$30,546,000	(c) \$30,546,000	
Direct Benefits	(b) \$0	(d) \$0	
(3) Benefits-Costs Ratio	0.00	(4) Net Benefit	-\$30,546,000

(5) Indirect Costs & Benefits	<p>VDH is not aware of any quantifiable indirect cost to regulants, due to each regulant being able to choose whether to provide transfer or treatment services to adult and pediatric survivors of sexual assault. Indirect costs related to employment of staff trained to conduct forensic medical examinations, if any, would have already been incurred by the hospitals that have forensic nursing programs predating these new requirements.</p> <p>VDH will incur an indirect cost of \$283,696 in Year 0, \$692,391 in Year 1, and \$582,391 annually thereafter for FTE inspectors to review and approve plans and to conduct complaint investigations for non-compliance, and for development and updates to a training program mandated by § 32.1-162.15:4(F) of the Code of Virginia to be made available to “appropriate health care providers who provide services in the hospital's emergency department.”</p>
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	<p>VDH notes that there are numerous indirect costs to survivors of sexual assault and to the public. Nationally, the immediate medical costs for victims who seek care is \$2,084 on average. While VDH does not have data about the economic cost of all types of sexual assault, individual rape victims in the U.S. encounter an estimated lifetime economic cost of \$122,461. The lifetime economic cost of rape across all U.S. victims is nearly \$3.1 trillion, which represents costs already incurred (e.g., among older adults who were victimized in their youth) and costs yet to come (e.g., among younger adults with recent victimization) across the U.S. adult population. It includes \$1.2 trillion in medical costs, \$1.6 trillion in lost productivity at work for victims and perpetrators, and \$234 billion in criminal justice costs. Governments pay about \$1 trillion of the lifetime economic burden of rape, which includes spending for criminal justice, adoption, and medical costs.</p> <p>VDH is not aware of any quantifiable indirect benefits.</p>
(6) Information Sources	Centers for Disease Control and Prevention; Bureau of Justice Statistics; The RAND Corporation; The White House Council on Women and Girls; National Alliance to End Sexual Violence; American Journal of Preventative Medicine; Joint Commission on Health Care
(7) Optional	<p>VDH has numerous challenges and constraints that limit a cost benefit analysis, including limited data availability, limited statutory discretion, and insufficient analytical models.</p> <p>The qualitative benefits the proposed regulatory change is designed to produce is increased knowledge of and awareness of what hospitals and pediatric health care facilities can provide treatment services or transfer services for adult and pediatric survivors. It also creates minimum standards for those services so that care for this patient population is more consistent throughout the Commonwealth.</p>

Table 1b: Costs and Benefits under the Status Quo (No change to the regulation)

(1) Direct Costs & Benefits	<ul style="list-style-type: none"> There are currently no regulation addressing the minimum standards for the treatment and transfer of survivors of sexual assault. <p>Direct Costs: VDH is not aware of any quantifiable direct costs at time.</p> <p>Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.</p>	
(2) Quantitative Factors	Estimated Dollar Amount	Present Value
Direct Costs	(a) \$0	(c) \$0

Direct Benefits	(b) \$0	(d) \$0
(3) Benefits-Costs Ratio	0.00	(4) Net Benefit \$0
(5) Indirect Costs & Benefits	<p>VDH notes that there are numerous indirect costs to survivors of sexual assault and to the public. Nationally, the immediate medical costs for victims who seek care is \$2,084 on average. While VDH does not have data about the economic cost of all types of sexual assault, individual rape victims in the U.S. encounter an estimated lifetime economic cost of \$122,461. The lifetime economic cost of rape across all U.S. victims is nearly \$3.1 trillion, which represents costs already incurred (e.g., among older adults who were victimized in their youth) and costs yet to come (e.g., among younger adults with recent victimization) across the U.S. adult population. It includes \$1.2 trillion in medical costs, \$1.6 trillion in lost productivity at work for victims and perpetrators, and \$234 billion in criminal justice costs. Governments pay about \$1 trillion of the lifetime economic burden of rape, which includes spending for criminal justice, adoption, and medical costs.</p> <p>VDH is not aware of any quantifiable indirect benefit at this time to maintaining the status quo for either regulants or VDH.</p>	
(6) Information Sources	Centers for Disease Control and Prevention; Bureau of Justice Statistics; The RAND Corporation; The White House Council on Women and Girls; National Alliance to End Sexual Violence; American Journal of Preventative Medicine; Joint Commission on Health Care	
(7) Optional	<p>VDH has numerous challenges and constraints that limit a cost benefit analysis, including limited data availability, limited statutory discretion, and insufficient analytical models.</p> <p>The qualitative benefits the proposed regulatory change is designed to produce is increased knowledge of and awareness of what hospitals and pediatric health care facilities can provide treatment services or transfer services for adult and pediatric survivors. It also creates minimum standards for those services so that care for this patient population is more consistent throughout the Commonwealth.</p>	

Table 1c: Costs and Benefits under an Alternative Approach

(1) Direct Costs & Benefits	<ul style="list-style-type: none"> The only alternative that VDH could potentially offer would be to remove specificity from the regulation about the minimum standards for a sexual assault treatment plan approved by VDH for hospitals that intend to treat adult survivors of sexual assault. <p>Direct Costs: \$1,250 per hospital, which VDH estimates to be 17 based on the number of hospitals that already have forensic nursing programs.</p>
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	<p>Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.</p> <ul style="list-style-type: none">• The only alternative that VDH could potentially offer would be to remove specificity from the regulation about the minimum standards for a sexual assault transfer plan approved by VDH for hospitals that intend to transfer adult survivors of sexual assault. <p>Direct Costs: \$1,250 per inpatient hospital, which VDH estimates to be 88, based on the number of hospitals that do not have forensic nursing programs; \$5,000 per outpatient surgical hospital, which VDH estimates to be 65.</p> <p>Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.</p> <ul style="list-style-type: none">• The only alternative that VDH could potentially offer would be to remove specificity from the regulation about the minimum standards for a sexual assault treatment plan approved by VDH for pediatric health care facilities that intend to treat pediatric survivors of sexual assault. <p>Direct Costs: \$1,250 per hospital, which VDH estimates to be 17 based on the number of hospitals that already have forensic nursing programs; \$1,250 per non-hospital pediatric health care facility that already provide treatment to pediatric survivors, which VDH estimates to be 120; \$5,000 per non-hospital pediatric health care facility that does not currently provide treatment to pediatric survivors but intends to on or after July 1, 2023, which VDH estimates to be 181.</p> <p>Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.</p> <ul style="list-style-type: none">• The only alternative that VDH could potentially offer would be to remove specificity from the regulation about the minimum standards for a sexual assault transfer plan approved by VDH for pediatric health care facilities that intend to transfer pediatric survivors of sexual assault. <p>Direct Costs: \$1,250 per inpatient hospital, which VDH estimates to be 88, based on the number of hospitals that do not have forensic nursing programs; \$5,000 per outpatient surgical hospital, which VDH estimates to be 65; \$5,000 per non-hospital pediatric health care facility, which VDH estimates to be 5,716.</p>
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	Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.		
(2) Quantitative Factors	Estimated Dollar Amount	Present Value	
Direct Costs	(a) \$30,546,000	(c) \$30,546,000	
Direct Benefits	(b) \$0	(d) \$0	
(3) Benefits-Costs Ratio	0.00	(4) Net Benefit	-\$30,546,000
(5) Indirect Costs & Benefits	<p>VDH is not aware of any quantifiable indirect cost to regulants, due to each regulant being able to choose whether to provide transfer or treatment services to adult and pediatric survivors of sexual assault. Indirect costs related to employment of staff trained to conduct forensic medical examinations, if any, would have already been incurred by the hospitals that have forensic nursing programs predating these new requirements.</p> <p>VDH will incur an indirect cost of \$283,696 in Year 0, \$692,391 in Year 1, and \$582,391 annually thereafter for FTE inspectors to review and approve plans and to conduct complaint investigations for non-compliance, and for development and updates to a training program mandated by § 32.1-162.15:4(F) of the Code of Virginia to be made available to “appropriate health care providers who provide services in the hospital's emergency department.”</p> <p>VDH notes that there are numerous indirect costs to survivors of sexual assault and to the public. Nationally, the immediate medical costs for victims who seek care is \$2,084 on average. While VDH does not have data about the economic cost of all types of sexual assault, individual rape victims in the U.S. encounter an estimated lifetime economic cost of \$122,461. The lifetime economic cost of rape across all U.S. victims is nearly \$3.1 trillion, which represents costs already incurred (e.g., among older adults who were victimized in their youth) and costs yet to come (e.g., among younger adults with recent victimization) across the U.S. adult population. It includes \$1.2 trillion in medical costs, \$1.6 trillion in lost productivity at work for victims and perpetrators, and \$234 billion in criminal justice costs. Governments pay about \$1 trillion of the lifetime economic burden of rape, which includes spending for criminal justice, adoption, and medical costs.</p> <p>VDH is not aware of any quantifiable indirect benefits.</p>		

(6) Information Sources	Centers for Disease Control and Prevention; Bureau of Justice Statistics; The RAND Corporation; The White House Council on Women and Girls; National Alliance to End Sexual Violence; American Journal of Preventative Medicine; Joint Commission on Health Care
(7) Optional	<p>VDH has numerous challenges and constraints that limit a cost benefit analysis, including limited data availability, limited statutory discretion, and insufficient analytical models.</p> <p>The qualitative benefits the proposed regulatory change is designed to produce is increased knowledge of and awareness of what hospitals and pediatric health care facilities can provide treatment services or transfer services for adult and pediatric survivors. It also creates minimum standards for those services so that care for this patient population is more consistent throughout the Commonwealth.</p>

Impact on Local Partners

Table 2: Impact on Local Partners

(1) Direct Costs & Benefits	<ul style="list-style-type: none"> • Hospitals that intend to treat adult survivors of sexual assault must have a sexual assault treatment plan approved by VDH. Direct Costs: \$1,250 per hospital; however, VDH is not aware of any local partner operating a hospital intending to treat adult survivors of sexual assault or that currently has a forensic nursing program. Direct Benefits: VDH is not aware of any quantifiable direct benefits at time. • Hospitals that intend to transfer adult survivors of sexual assault must have a sexual assault transfer plan approved by VDH. Direct Costs: \$1,250 per inpatient hospital; \$5,000 per outpatient surgical hospital. VDH is aware of one local partner that operates an inpatient hospital that it anticipates will likely transfer adult survivors. Direct Benefits: VDH is not aware of any quantifiable direct benefits at time. • Pediatric health care facilities that intend to treat pediatric survivors of sexual assault must have a sexual assault treatment plan approved by VDH. Direct Costs: \$1,250 per hospital; \$1,250 per non-hospital pediatric health care facility that already provide treatment to pediatric survivors; \$5,000 per non-hospital pediatric health care facility that does not currently provide treatment to pediatric survivors but intends
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	<p>to on or after July 1, 2023. VDH is not aware of any local partner operating a hospital intending to treat pediatric survivors of sexual assault or that currently has a forensic nursing program. VDH does not have an available estimate of how many non-hospital pediatric health care facilities local partners are operating that intend to treat pediatric survivors or that currently has a forensic nursing program.</p> <p>Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.</p> <ul style="list-style-type: none"> • Pediatric health care facilities that intend to transfer pediatric survivors of sexual assault must have a sexual assault transfer plan approved by VDH. <p>Direct Costs: \$1,250 per inpatient hospital; \$5,000 per outpatient surgical hospital; \$5,000 per non-hospital pediatric health care. VDH is aware of one local partner that operates an inpatient hospital that it anticipates will likely transfer pediatric survivors. VDH does not have an available estimate of how many non-hospital pediatric health care facilities local partners are operating that intend to transfer pediatric survivors.</p> <p>Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.</p>
(2) Quantitative Factors	Estimated Dollar Amount
Direct Costs	(a) \$1,250 at minimum (see above discussion about limited data availability re: non-hospital pediatric health care facilities operated by local partners)
Direct Benefits	(b) \$0
(3) Indirect Costs & Benefits	<p>VDH is not aware of any quantifiable indirect cost to local partners, due to each local partner being able to choose whether to provide transfer or treatment services to adult and pediatric survivors of sexual assault. VDH is not aware of any local partner that is providing treatment services to adult and/or pediatric survivors.</p> <p>VDH will incur an indirect cost of \$283,696 in Year 0, \$692,391 in Year 1, and \$582,391 annually thereafter for FTE inspectors to review and approve plans and to conduct complaint investigations for non-compliance, and for development and updates to a training program mandated by § 32.1-162.15:4(F) of the Code of Virginia to be made available to “appropriate health care providers who provide services in the hospital's emergency department.”</p>

	<p>VDH notes that there are numerous indirect costs to survivors of sexual assault and to the public. Nationally, the immediate medical costs for victims who seek care is \$2,084 on average. While VDH does not have data about the economic cost of all types of sexual assault, individual rape victims in the U.S. encounter an estimated lifetime economic cost of \$122,461. The lifetime economic cost of rape across all U.S. victims is nearly \$3.1 trillion, which represents costs already incurred (e.g., among older adults who were victimized in their youth) and costs yet to come (e.g., among younger adults with recent victimization) across the U.S. adult population. It includes \$1.2 trillion in medical costs, \$1.6 trillion in lost productivity at work for victims and perpetrators, and \$234 billion in criminal justice costs. Governments pay about \$1 trillion of the lifetime economic burden of rape, which includes spending for criminal justice, adoption, and medical costs.</p> <p>VDH is not aware of any quantifiable indirect benefits.</p>
(4) Information Sources	Centers for Disease Control and Prevention; Bureau of Justice Statistics; The RAND Corporation; The White House Council on Women and Girls; National Alliance to End Sexual Violence; American Journal of Preventative Medicine; Joint Commission on Health Care
(5) Assistance	None.
(6) Optional	<p>VDH has numerous challenges and constraints that limit a cost benefit analysis, including limited data availability, limited statutory discretion, and insufficient analytical models.</p> <p>The qualitative benefits the proposed regulatory change is designed to produce is increased knowledge of and awareness of what hospitals and pediatric health care facilities can provide treatment services or transfer services for adult and pediatric survivors. It also creates minimum standards for those services so that care for this patient population is more consistent throughout the Commonwealth.</p>

Economic Impacts on Families

Table 3: Impact on Families

(1) Direct Costs & Benefits	Families will not incur any direct costs or benefits of the regulatory change as they are not subject to the mandates contained in 12VAC5-416.
(2) Quantitative Factors	Estimated Dollar Amount

Direct Costs	(a) \$0
Direct Benefits	(b) \$0
(3) Indirect Costs & Benefits	<p>VDH is not aware of any quantifiable indirect cost to families.</p> <p>VDH will incur an indirect cost of \$283,696 in Year 0, \$692,391 in Year 1, and \$582,391 annually thereafter for FTE inspectors to review and approve plans and to conduct complaint investigations for non-compliance, and for development and updates to a training program mandated by § 32.1-162.15:4(F) of the Code of Virginia to be made available to “appropriate health care providers who provide services in the hospital's emergency department.”</p> <p>VDH notes that there are numerous indirect costs to survivors of sexual assault—which includes their families—and to the public. Nationally, the immediate medical costs for victims who seek care is \$2,084 on average. While VDH does not have data about the economic cost of all types of sexual assault, individual rape victims in the U.S. encounter an estimated lifetime economic cost of \$122,461. The lifetime economic cost of rape across all U.S. victims is nearly \$3.1 trillion, which represents costs already incurred (e.g., among older adults who were victimized in their youth) and costs yet to come (e.g., among younger adults with recent victimization) across the U.S. adult population. It includes \$1.2 trillion in medical costs, \$1.6 trillion in lost productivity at work for victims and perpetrators, and \$234 billion in criminal justice costs. Governments pay about \$1 trillion of the lifetime economic burden of rape, which includes spending for criminal justice, adoption, and medical costs.</p> <p>VDH is not aware of any quantifiable indirect benefits.</p>
(4) Information Sources	Centers for Disease Control and Prevention; Bureau of Justice Statistics; The RAND Corporation; The White House Council on Women and Girls; National Alliance to End Sexual Violence; American Journal of Preventative Medicine; Joint Commission on Health Care
(5) Optional	<p>VDH has numerous challenges and constraints that limit a cost benefit analysis, including limited data availability, limited statutory discretion, and insufficient analytical models.</p> <p>The qualitative benefits the proposed regulatory change is designed to produce is increased knowledge of and awareness of what hospitals and pediatric health care facilities can provide treatment services or transfer services for adult and pediatric survivors. It also creates minimum standards</p>

	for those services so that care for this patient population is more consistent throughout the Commonwealth.
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Impacts on Small Businesses

Table 4: Impact on Small Businesses

<p>(1) Direct Costs & Benefits</p>	<ul style="list-style-type: none"> <p>• Hospitals that intend to treat adult survivors of sexual assault must have a sexual assault treatment plan approved by VDH.</p> <p>Direct Costs: \$1,250 per hospital; however, VDH is not aware of any hospital intending to treat adult survivors of sexual assault or that currently has a forensic nursing program that qualifies as a small business.</p> <p>Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.</p> <p>• Hospitals that intend to transfer adult survivors of sexual assault must have a sexual assault transfer plan approved by VDH.</p> <p>Direct Costs: \$1,250 per inpatient hospital; \$5,000 per outpatient surgical hospital. VDH is not aware of any inpatient hospital intending to transfer adult survivors of sexual assault that qualifies as a small business. VDH is not aware of how many outpatient surgical hospitals intending to transfer adult survivors of sexual assault that qualifies as a small business.</p> <p>Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.</p> <p>• Pediatric health care facilities that intend to treat pediatric survivors of sexual assault must have a sexual assault treatment plan approved by VDH.</p> <p>Direct Costs: \$1,250 per hospital; \$1,250 per non-hospital pediatric health care facility that already provide treatment to pediatric survivors; \$5,000 per non-hospital pediatric health care facility that does not currently provide treatment to pediatric survivors but intends to on or after July 1, 2023. VDH is not aware of any hospital intending to treat pediatric survivors of sexual assault that qualifies as a small business. VDH does not have an available estimate of how many non-hospital pediatric health care facilities intending to treat pediatric survivors or that currently has a forensic nursing program qualify as</p>
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	<p>a small business, but for the purposes of this analysis, it will assume 75% are small businesses.</p> <p>Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.</p> <ul style="list-style-type: none"> • Pediatric health care facilities that intend to transfer pediatric survivors of sexual assault must have a sexual assault transfer plan approved by VDH. <p>Direct Costs: \$1,250 per inpatient hospital; \$5,000 per outpatient surgical hospital; \$5,000 per non-hospital pediatric health care. VDH is not aware of any hospital intending to transfer pediatric survivors of sexual assault that qualifies as a small business. VDH does not have an available estimate of how many non-hospital pediatric health care facilities intending to transfer pediatric survivors qualify as a small business, but for the purposes of this analysis, it will assume 75% are small businesses.</p> <p>Direct Benefits: VDH is not aware of any quantifiable direct benefits at time.</p>
(2) Quantitative Factors	Estimated Dollar Amount
Direct Costs	(a) \$22,225,125
Direct Benefits	(b) \$0
(3) Indirect Costs & Benefits	<p>VDH is not aware of any quantifiable indirect cost to small businesses, due to each small business being able to choose whether to provide transfer or treatment services to adult and pediatric survivors of sexual assault.</p> <p>VDH will incur an indirect cost of \$283,696 in Year 0, \$692,391 in Year 1, and \$582,391 annually thereafter for FTE inspectors to review and approve plans and to conduct complaint investigations for non-compliance, and for development and updates to a training program mandated by § 32.1-162.15:4(F) of the Code of Virginia to be made available to “appropriate health care providers who provide services in the hospital's emergency department.”</p> <p>VDH notes that there are numerous indirect costs to survivors of sexual assault and to the public. Nationally, the immediate medical costs for victims who seek care is \$2,084 on average. While VDH does not have data about the economic cost of all types of sexual assault, individual rape victims in the</p>

	<p>U.S. encounter an estimated lifetime economic cost of \$122,461. The lifetime economic cost of rape across all U.S. victims is nearly \$3.1 trillion, which represents costs already incurred (e.g., among older adults who were victimized in their youth) and costs yet to come (e.g., among younger adults with recent victimization) across the U.S. adult population. It includes \$1.2 trillion in medical costs, \$1.6 trillion in lost productivity at work for victims and perpetrators, and \$234 billion in criminal justice costs. Governments pay about \$1 trillion of the lifetime economic burden of rape, which includes spending for criminal justice, adoption, and medical costs.</p> <p>VDH is not aware of any quantifiable indirect benefits.</p>
(4) Alternatives	<p>In developing the proposed regulations, the Board of Health (Board) considered that pediatric health care facilities likely consist primarily of small businesses. Providing a small business exemption would result in the overwhelming number of pediatric health care facilities being exempt from the requirements, just as establishing performance standards or less stringent requirements specific to small business would have the effect of lowered standards and requirements for a large majority of those to whom this regulatory chapter applies. Chapter 725 (2020 Acts of Assembly) does not give the Board the discretion to exempt small businesses from the requirements.</p> <p>Additionally, as these standards and requirements are aimed at ensuring both adequate care to adult and pediatric survivors as well as evidence for potential criminal prosecution, the Board cannot lower these standards without potentially endangering patients or jeopardizing the administration of justice. Further, Chapter 725 (2020 Acts of Assembly) also prescribes the content of transfer and treatment plans, the requirement that hospitals and pediatric health care facilities submit them for approval, VDH's timeline for reviewing and approving submitted plans, and the reporting requirements for hospitals. Consequently, there are no other alternative regulatory methods to minimizing the adverse impact on small businesses that the Board could utilize without being inconsistent with the principles of justice and the public health, safety, and welfare in accomplishing the objectives of the legislative mandates.</p> <p>However, there is some flexibility built into the regulation for all regulants (not just small businesses) in that individual regulants may ask for a variance that would allow for an individualized alternative to enable compliance with the purpose of a specific regulatory standard, if compliance would otherwise be economically burdensome and be an impractical hardship unique to the regulant.</p>

(5) Information Sources	Centers for Disease Control and Prevention; Bureau of Justice Statistics; The RAND Corporation; The White House Council on Women and Girls; National Alliance to End Sexual Violence; American Journal of Preventative Medicine; Joint Commission on Health Care
(6) Optional	<p>VDH has numerous challenges and constraints that limit a cost benefit analysis, including limited data availability, limited statutory discretion, and insufficient analytical models.</p> <p>The qualitative benefits the proposed regulatory change is designed to produce is increased knowledge of and awareness of what hospitals and pediatric health care facilities can provide treatment services or transfer services for adult and pediatric survivors. It also creates minimum standards for those services so that care for this patient population is more consistent throughout the Commonwealth.</p>

Changes to Number of Regulatory Requirements

Table 5: Total Number of Requirements

	Number of Requirements			
Chapter number	Initial Count	Additions	Subtractions	Net Change
416	0	120	0	120

1 **Project 6686 - NOIRA**

2 **Department of Health**

3 **Promulgation of New Regulation to Implement Chapter 725 of the 2020 Acts of Assembly**

4 Chapter 416

5 Sexual Assault Survivor Treatment and Transfer Regulation

6 Part I

7 General Information

8 **12VAC5-416-10. Definitions.**

9 The following words and terms when used in this regulation shall have the following meanings
10 unless the context clearly indicates otherwise:

11 "Administrator" means the person appointed by the governing body as having responsibility
12 for the overall management of a hospital or pediatric health care facility. Job titles may include
13 chief executive officer, director, executive director, office manager, or business manager.

14 "Anonymous physical evidence recovery kit" or "anonymous PERK" has the same meaning
15 as in § 19.2-11.5 of the Code of Virginia.

16 "Applicant" means a hospital or pediatric health care facility that does not have an approved
17 plan.

18 "Approved pediatric transfer facility" means a pediatric health care facility for which a PSAS
19 transfer plan has been approved pursuant to this chapter

20 "Approved pediatric treatment facility" means a pediatric health care facility for which a PSAS
21 treatment plan has been approved pursuant to this chapter.

22 "Approved plan" means a SAS treatment plan, PSAS treatment plan, SAS transfer plan, or
23 PSAS transfer plan that has been approved pursuant to this chapter.

24 "Assent" means the expressed willingness of an individual to participate in an activity.

25 "Board" means the State Board of Health.

26 "Clinic" means an outpatient establishment, facility, or department of a hospital where patients
27 are given medical diagnosis, treatment, or advice, including of a specialist nature. This includes
28 a clinic operated by a local health department, but does not include a clinic directly maintained or
29 operated by the federal government.

30 "Commissioner" means the State Health Commissioner.

31 "DCLS" means the Division of Consolidated Laboratory Services of the Virginia Department
32 of General Services.

33 "Department" means the Department of Health.

34 "Directed plan of correction" means a plan prescribed by the department that details specific
35 corrective actions for cited violations in inspection findings that shall be taken by the regulant to
36 achieve specific outcomes within specific timeframes.

37 "Emergency contraception" means medication approved by the U.S. Food and Drug
38 Administration that can significantly reduce the risk of pregnancy if taken within 72 hours after
39 sexual assault.

40 "EMTALA" means the Emergency Medical Treatment and Labor Act (42 USC § 1395dd et
41 seq.)

42 "Follow-up health care" means any physical examination, laboratory tests to determine the
43 presence of STIs, or appropriate medications, including HIV prophylaxis, provided to a SAS or
44 PSAS by a health care professional within 90 days after the date on which treatment or transfer
45 services pursuant to this chapter are first provided.

46 "Forensic medical examination" means health care services provided to a SAS or PSAS that
47 include medical history, physical examination, laboratory testing, assessment for drug-facilitated
48 or alcohol-facilitated sexual assault, collection of evidence in accordance with the requirements
49 of Chapter 1.2 (§ 19.2-11.5 et seq.) of Title 19.2 of the Code of Virginia, discharge and follow-up
50 health care planning necessary to ensure the health, safety, and welfare of the SAS or PSAS,
51 and the collection and preservation of evidence that may be used in a criminal proceeding.

52 "Health care professional" means any person (i) licensed, certified, or registered by a health
53 regulatory board of the Department of Health Professions or (ii) holding a multistate licensure
54 privilege to practice nursing or an applicant for licensure, certification or registration.

55 "Hospital" means any hospital licensed by the department pursuant to Article 1 (§ 32.1-123 et
56 seq.) of Chapter 5 of Title 32.1 of the Code of Virginia.

57 "Inspector" means an individual employed by the department and designated by the
58 commissioner to conduct inspections, investigations, or evaluations.

59 "Legal representative" means a PSAS's parent, guardian, or any person who by order of a
60 court of component jurisdiction has legal custody of the PSAS.

61 "OLC" means the Office of Licensure and Certification of the department.

62 "Pediatric health care facility" means a hospital, clinic, or physician's office that provides health
63 care services to pediatric patients.

64 "Physician's office" means the office of one or more physicians, surgeons, or nurse
65 practitioners with autonomous practice privileges. A physician's office does not mean a hospital
66 as defined in § 32.1-123 of the Code of Virginia or a facility directly maintained or operated by the
67 federal government.

68 "Physical evidence recovery kit" or "PERK" has the same meaning as in § 19.2-11.5 of the
69 Code of Virginia.

70 "Plan of correction" means a plan developed by a regulant and approved by the department
71 that is the regulant's written response to inspection findings and details corrective actions to cited
72 violations, who is responsible for implementing corrective actions, how the regulant will prevent
73 reoccurrence, and specifies the date by which the regulant will correct those deficiencies.

74 "Proposed plan" means a SAS treatment plan, PSAS treatment plan, SAS transfer plan, or
75 PSAS transfer plan that has been submitted pursuant to this chapter to the Department.

76 "PSAS" means a pediatric survivor of sexual assault who is less than 18 years of age.

77 "PSAS transfer plan" means a plan for the transfer of a PSAS to an approved pediatric
78 treatment facility that includes PSAS transfer services and the written agreement of an approved
79 pediatric treatment facility to accept transfer.

80 "PSAS transfer services" means an appropriate medical examination and such stabilizing
81 treatment as may be necessary prior to the transfer of a PSAS from an approved pediatric transfer
82 facility to an approved pediatric treatment facility in accordance with the provisions of a PSAS
83 transfer plan approved by the department.

84 "PSAS treatment plan" means a plan for the treatment of a PSAS at an approved pediatric
85 treatment facility that includes PSAS treatment services and the storage, retention, and
86 dissemination of photographic evidence.

87 "PSAS treatment services" means a forensic medical examination and other health care
88 services provided to a PSAS by an approved pediatric treatment facility in accordance with this
89 chapter.

90 "Rape crisis center" has the same meaning as ascribed in 34 USC § 12291(a)(25).

91 "Regulant" means a treatment hospital, transfer hospital, approved pediatric treatment facility,
92 or approved pediatric transfer facility that has a PSAS treatment plan, PSAS transfer plan, SAS
93 treatment plan, or SAS transfer plan approved by the department.

94 "SAS" means a survivor of sexual assault who is 18 years of age or older.

95 "Sexual assault forensic examiner" or "SAFE" means a sexual assault nurse examiner,
96 physician, physician assistant, nurse practitioner, or registered nurse who has completed training
97 that meets or is substantially similar to the Sexual Assault Nurse Examiner Education Guidelines
98 established by the International Association of Forensic Nurses or its successor.

99 "SAS transfer plan" means a plan for the transfer of a SAS to a treatment hospital that includes
100 SAS transfer services and the written agreement of a treatment hospital to accept transfer.

101 "SAS transfer services" means an appropriate medical examination and such stabilizing
102 treatment as may be necessary prior to the transfer of a SAS from a transfer hospital to a
103 treatment hospital in accordance with the provisions of a SAS transfer plan approved by the
104 department.

105 "SAS treatment plan" means a plan for the treatment of a SAS at a treatment hospital that
106 includes SAS treatment services and the storage, retention, and dissemination of photographic
107 evidence.

108 "SAS treatment services" means a forensic medical examination and other health care
109 services provided to a SAS by a treatment hospital in accordance with this chapter.

110 "STI" means sexually transmitted infection.

111 "Transfer hospital" means a hospital with a SAS transfer plan approved by the department.

112 "Transportation service" means transportation provided to a SAS or PSAS who is transferred
113 from a transfer hospital, treatment hospital, approved pediatric treatment facility, or approved
114 pediatric transfer facility to a treatment hospital or approved pediatric treatment facility pursuant
115 to a SAS transfer plan or PSAS transfer plan approved in accordance with this chapter.

116 "Treatment hospital" means a hospital with a SAS treatment plan approved by the department
117 to provide SAS treatment services to a SAS who presents with a complaint of sexual assault
118 within the previous seven days or who have disclosed past sexual assault by a specific individual
119 and were in the care of that individual within the previous seven days.

120 **Statutory Authority**

121 §§ 32.1-12, 32.1-162.15:4, 32.1-162.15:5, and 32.1-162.15:6 of the Code of Virginia.

122 **12VAC5-416-20. Plans required.**

123 A. A hospital shall:

124 1. Develop either a:

125 a. SAS treatment plan that meets the requirements of Part II (12VAC5-416-110 et
126 seq.) of this chapter; or

127 b. SAS transfer plan that meets the requirements of Part IV (12VAC5-416-350 et seq.)
128 of this chapter; and

129 2. Submit any such plan to the department as specified by 12VAC5-416-30.

130 B. A hospital may not provide SAS treatment services or SAS transfer services unless the
131 department has granted approval of the proposed plan, except that a hospital may provide SAS

132 treatment services or SAS transfer services prior to approval of its initial proposed plan if the
133 hospital was providing one or more of these services on or before July 1, 2023.

134 C. A pediatric health care facility shall:

135 1. Develop either a:

136 a. PSAS treatment plan that meets the requirements of Part III (12VAC5-416-230 et
137 seq.) of this chapter; or

138 b. PSAS transfer plan that meets the requirements of Part V (12VAC5-416-390 et seq.)
139 of this chapter; and

140 2. Submit any such plan to the department as specified by 12VAC5-416-30.

141 D. A pediatric health care facility may not provide PSAS treatment services or PSAS transfer
142 services unless the department has granted approval of the proposed plan, except that a pediatric
143 health care facility may provide PSAS treatment services or PSAS transfer services prior to
144 approval of its initial proposed plan if the pediatric health care facility was providing one or more
145 of these services on or before July 1, 2023.

146 **Statutory Authority**

147 §§ 32.1-12, 32.1-162.15:4, 32.1-162.15:5, and 32.1-162.15:6 of the Code of Virginia.

148 **12VAC5-416-30. Request for plan approval.**

149 A. An applicant shall transmit to the OLC its proposed plan by electronic mail or postal mail
150 no sooner than 60 calendar days before the applicant's desired effective date for the proposed
151 plan.

152 B. The OLC shall consider a proposed plan submission to be complete when all components
153 of the proposed plan are included in the submission. The OLC may deny approval to an applicant
154 whose proposed plan has been incomplete for more than 180 calendar days.

155 C. An applicant may withdraw a proposed plan at any time prior to the OLC's determination
156 of whether to approve the proposed plan by notifying the OLC in writing of its intent to withdraw.

157 D. The OLC shall notify the applicant of the outcome of its review in writing no more than 30
158 calendar days after receipt of the proposed plan. If the OLC denies approval of the proposed plan,
159 the OLC shall provide a written statement setting forth the reasons for denial.

160 E. The OLC shall grant the administrator or his designee the opportunity to revise and
161 resubmit a proposed plan that the OLC initially determines to be unacceptable. The administrator
162 or his designee shall resubmit the proposed plan to the OLC no more than 15 calendar days after
163 the OLC has notified the administrator or his designee pursuant to subsection D.

164 **Statutory Authority**

165 §§ 32.1-12, 32.1-162.15:4, 32.1-162.15:5, and 32.1-162.15:6 of the Code of Virginia.

166 **12VAC5-416-40. Review and renewal of plan approval.**

167 A. A regulant shall:

168 1. Review its approved plan or plans at least triennially with the administrator or his
169 designee and appropriate clinical staff; and

170 2. Document in writing the triennial review process and any recommendations for updates.

171 B. If a regulant determines that pursuant to subsection A that an update is needed to an
172 approved plan, it shall submit the proposed plan to the OLC in writing no less than 60 days in
173 advance of the proposed plan's implementation date.

174 C. The OLC shall notify the regulant of the outcome of its review in writing no more than 30
175 calendar days after receipt of the proposed plan. If the OLC denies approval of the proposed plan,
176 the OLC shall provide a written statement setting forth the reasons for denial.

177 D. The OLC shall grant the administrator or his designee the opportunity to revise and
178 resubmit a proposed plan that the OLC initially determines to be unacceptable. The administrator
179 or his designee shall resubmit the proposed plan to the OLC no more than 15 calendar days after
180 the OLC has notified the administrator or his designee pursuant to subsection C of this section.

181 **Statutory Authority**

182 §§ 32.1-12, 32.1-162.15:4, 32.1-162.15:5, and 32.1-162.15:6 of the Code of Virginia.

183 **12VAC5-416-50. Change notification.**

184 A. A treatment hospital proposing to transition to a transfer hospital shall:

185 1. Notify the OLC in writing no less than 60 calendar days in advance of transitioning to a
186 transfer hospital; and

187 2. Submit a SAS transfer plan with its notification.

188 B. A transfer hospital proposing to transition to a treatment hospital shall:

189 1. Notify the OLC in writing no less than 60 calendar days in advance of transitioning to a
190 treatment hospital; and

191 2. Submit a SAS treatment plan with its notification.

192 C. An approved pediatric treatment facility proposing to transition to an approved pediatric
193 transfer facility shall:

194 1. Notify the OLC in writing no less than 60 calendar days in advance of transitioning to
195 an approved pediatric transfer facility; and

196 2. Submit a PSAS transfer plan with its notification.

197 D. An approved pediatric transfer facility proposing to transition to an approved pediatric
198 treatment facility shall:

199 1. Notify the OLC in writing no less than 60 calendar days in advance of transitioning to
200 an approved pediatric treatment facility; and

201 2. Submit a PSAS treatment plan with its notification.

202 **Statutory Authority**

203 §§ 32.1-12, 32.1-162.15:4, 32.1-162.15:5, and 32.1-162.15:6 of the Code of Virginia.

204 **12VAC5-416-60. Complaints.**

205 A. The OLC shall investigate complaints regarding alleged violations of this chapter or Article
206 8 (§ 32.1-162.15:2 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia. The OLC shall
207 determine if an investigation requires an on-site inspection. In making this determination, the OLC
208 shall consider several factors, to include:

209 1. If the complainant has first-hand knowledge of the alleged incident;

210 2. The regulatory history of the regulant or applicant, including the number of substantiated
211 prior complaints;

212 3. If the OLC has recently inspected the regulant or applicant, and if the incident would
213 have been observed during the prior inspection; and

214 4. The nature of the complaint, including degree of potential serious harm to SASs,
215 PSASs, or other patients.

216 B. The OLC may request records from a regulant or applicant to assist in making a
217 determination pursuant to subsection A. The regulant or applicant shall provide the requested
218 records no more than 5 business days after the OLC makes the request.

219 C. When the investigation is complete, the OLC shall notify the complainant, if known, and the
220 regulant or applicant in writing of the findings of the investigation.

221 D. For any violation cited during a complaint investigation, the administrator or his designee
222 shall submit a plan of correction in accordance with 12VAC5-416-80.

223 **Statutory Authority**

224 §§ 32.1-12, 32.1-162.15:4, 32.1-162.15:5, 32.1-162.15:6, and 32.1-162.15:10 of the Code of
225 Virginia.

226 **12VAC5-416-70. Inspections.**

227 A. The OLC may combine an inspection of a treatment hospital or transfer hospital with an
228 inspection conducted pursuant to § 32.1-126 of the Code of Virginia.

229 B. A regulant or applicant shall make available to the inspector any requested records and
230 shall allow access to interview the agents, employees, contractors, and any person under the
231 regulant's or applicant's control, direction, or supervision.

232 1. Upon request of the inspector after the inspector's arrival:

233 a. The treatment hospital or transfer hospital shall provide to the inspector a list of all
234 SASs it treated or transferred in the previous 12 months; and

235 b. The approved pediatric treatment facility or approved pediatric transfer facility shall
236 provide to the inspector a list of all PSASs it treated or transferred in the previous 12
237 months.

238 2. If copies of records are removed from the premises, the regulant or applicant may redact
239 names and addresses of patients contained in such records prior to removal.

240 3. The inspector shall inform the regulant or applicant that it may redact names and
241 addresses of patients prior to the inspector removing copies of records from the premises.

242 C. The OLC shall provide a written inspection report to the administrator. If the OLC cites one
243 or more violations in the written inspection report, the administrator or his designee shall submit
244 a plan of correction in accordance with 12VAC5-416-80.

245 **Statutory Authority**

246 §§ 32.1-12, 32.1-25, 32.1-162.15:4, 32.1-162.15:5, and 32.1-162.15:6 of the Code of Virginia.

247 **12VAC5-416-80. Plan of correction; directed plan of correction.**

248 A. Upon receipt of a written inspection report, the administrator or his designee shall prepare
249 a written plan of correction addressing each violation cited at the time of inspection.

250 B. The administrator shall submit to the OLC a written plan of correction no more than 15
251 working days after receipt of the inspection report. The plan of correction shall contain for each
252 violation cited:

253 1. A description of the corrective action or actions to be taken and the position title of the
254 employees to implement the corrective action;

255 2. The expected correction date, not to exceed 45 working days from the exit date of the
256 inspection; and

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

258 C. A regulant or applicant shall ensure that the person responsible for the validity of the plan
259 of correction signs, dates, and indicates their title on the plan of correction.

260 D. The OLC shall:

261 1. Notify the administrator or his designee if the OLC determines any item in the plan of
262 correction is unacceptable; and

263 2. Grant the administrator or his designee an opportunity to revise and resubmit a plan of
264 correction that the OLC initially determines to be unacceptable. If the administrator or his
265 designee revises and resubmits the plan of correction, the revision is due to the OLC no

266 more than 15 working days after the OLC has notified the administrator or his designee
267 pursuant to subdivision 1 of this subsection.

- 268 E. The department may impose a directed plan of correction when a regulant or applicant:
269 1. Has one or more violations that warrant directing the regulant or applicant to take
270 specific actions; or
271 2. Has been cited for the same violation in the most recent prior inspection.

272 F. Upon request of the OLC, a regulant or applicant shall produce evidence that all or part of
273 a plan of correction or directed plan of correction has been implemented. The OLC may conduct
274 an inspection to verify any portion of a plan of correction or directed plan of correction.

275 G. The administrator or his designee shall ensure the plan of correction or directed plan of
276 correction is implemented and monitored so that compliance is maintained.

277 **Statutory Authority**

278 §§ 32.1-12, 32.1-25, 32.1-162.15:4, 32.1-162.15:5, and 32.1-162.15:6 of the Code of Virginia.

279 **12VAC5-416-90. Allowable variances.**

280 A. The commissioner may authorize a variance only to a specific standard or requirement of
281 this chapter, not to regulations of another agency or to any standards or requirements in federal,
282 state, or local laws. A variance shall:

- 283 1. Require advance written approval from the commissioner;
284 2. Not be extended to general applicability; and
285 3. Not endanger the health, safety, or well-being of SASs, PSASs, other patients, or the
286 public.

287 B. A regulant may request a variance at any time. The request for a variance shall describe
288 in writing:

- 289 1. How compliance with the current standard or requirement is economically burdensome
290 and constitutes impractical hardship unique to the regulant; and
291 2. Proposed alternatives to meet the purpose of the standard or requirement that will
292 ensure the health, safety, and well-being of SASs, PSASs, other patients, and the public.

293 C. The regulant may withdraw a request for a variance at any time by notifying the OLC in
294 writing.

295 D. The commissioner shall notify the regulant in writing of the commissioner's decision on the
296 variance request. If granted, the commissioner may attach conditions to a variance that, in the
297 sole judgment of the commissioner, protects the health, safety, and well-being of SASs, PSASs,
298 other patients, and the public.

299 E. The commissioner may rescind or modify a variance if:

- 300 1. The impractical hardship unique to the regulant changes or no longer exists;
301 2. Additional information becomes known that alters the basis for the original decision,
302 including if the regulant failed to comply with the standard or requirement prior to receiving
303 a variance;
304 3. The regulant fails to meet any conditions attached to the variance; or
305 4. Results of the variance jeopardize the health, safety, or well-being of SASs, PSASs,
306 other patients, and the public.

307 F. If a variance is denied, expires, or is rescinded, the commissioner or his designee shall
308 enforce the standard or requirement to which the variance was granted.

309 G. The administrator shall develop and document procedures for monitoring the
310 implementation of any variance.

311 **Statutory Authority**

312 §§ 32.1-12, 32.1-162.15:4, 32.1-162.15:5, and 32.1-162.15:6 of the Code of Virginia.

313 **12VAC5-416-100. Violations of this chapter.**

314 A. A hospital or pediatric health care facility may not violate the provisions of this chapter or
315 Article 8 (§ 32.1-162.15:2 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia.

316 B. The commissioner may:

317 1. For each violation of subsection A of this section by a hospital:

318 a. Deny, revoke, or suspend the license to operate the hospital in accordance with the
319 Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia);

320 b. Refer the hospital for criminal prosecution pursuant to subsection A of § 32.1-27 of
321 the Code of Virginia; or

322 c. Petition an appropriate court for an injunction, mandamus, or other appropriate
323 remedy or imposition of a civil penalty against the hospital pursuant to subsection B or
324 C of § 32.1-27 of the Code of Virginia; and

325 2. For each violation of subsection A of this section by a pediatric health care facility:

326 a. Report the health care professionals involved in the violation to the appropriate
327 health regulatory board in the Department of Health Professions;

328 b. Refer the pediatric health care facility for criminal prosecution pursuant to
329 subsection A of § 32.1-27 of the Code of Virginia; or

330 c. Petition an appropriate court for an injunction, mandamus, or other appropriate
331 remedy or imposition of a civil penalty against the pediatric health care facility pursuant
332 to subsection B or C of § 32.1-27 of the Code of Virginia.

333 C. If the commissioner determines that a violation of subsection A of this section by a hospital
334 jeopardizes the health or safety of patients, the commissioner may immediately revoke, suspend,
335 or deny a license. Suspension of a license shall in all cases be for an indefinite time.

336 D. Upon receipt of a completed application and a nonrefundable service charge prescribed by
337 § 32.1-130, the commissioner may issue a new license to the hospital that has had its license
338 revoked if the commissioner determines that:

339 1. The conditions upon which revocation was based have been corrected; and

340 2. The hospital is in compliance with this chapter, Article 8 (§ 32.1-162.15:2 et seq.) of
341 Chapter 5 of Title 32.1 of the Code of Virginia, and all other applicable state and federal
342 law and regulations.

343 E. Upon receipt of a completed application, the commissioner may partially or completely
344 restore a suspended license to the hospital if the commissioner determines that:

345 1. The conditions upon which suspension was based have been completely or partially
346 corrected; and

347 2. The interests of the public will not be jeopardized by resumption of operation.

348 F. The hospital shall submit evidence relevant to subdivisions D 1, D 2, E 1, and E 2 of this
349 section that is satisfactory to the commissioner or his designee. The commissioner or his
350 designee may conduct an inspection prior to making a determination.

351 G. The commissioner may not require an additional fee for restoring a license pursuant to
352 subsection E of this section.

353 **Statutory Authority**

354 §§ 32.1-12, 32.1-27, 32.1-135, 32.1-162.15:4, 32.1-162.15:5, and 32.1-162.15:6 of the Code of
355 Virginia.

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Part II

SAS Treatment Plan

12VAC5-416-110. Minimum requirements for SAS treatment plan.

A treatment hospital shall ensure that its SAS treatment plan meets the minimum standards established in Part II (12VAC5-416-110 et seq.) of this chapter and includes the provision of a forensic medical examination to a SAS when ordered by a health care professional and with the consent of the SAS.

Statutory Authority

§§ 32.1-12 and 32.1-162.15:4 of the Code of Virginia.

12VAC5-416-120. Staffing and education.

A. A treatment hospital shall ensure that at least one SAFE is available during all hours of operation in person.

B. A treatment hospital shall ensure that health care professionals providing services in its emergency department annually complete training developed and made available by the department on the topics of:

1. Sexual assault;
2. Detection of sexual assault;
3. Provision of services for SASs and PSASs; and
4. Collection of evidence in cases involving alleged sexual assault.

C. If the training specified in subsection B is not available, a treatment hospital shall substitute the training for continuing education provided by the treatment hospital or by third parties on the same topics identified in this subsection.

Statutory Authority

§§ 32.1-12 and 32.1-162.15:4 of the Code of Virginia.

12VAC5-416-130. Informed consent.

A. Except as provided in § 54.1-2970.1 of the Code of Virginia, a treatment hospital shall obtain informed consent from the SAS for:

1. Medical evaluation and treatment, including the administration of prophylaxis and emergency contraception, the need for follow-up care, and medical advocacy services and counseling;
2. Reporting the alleged crime;
3. Performing a forensic medical examination;
4. Photodocumentation;
5. Evidence collection; and
6. Transferal of evidence to law enforcement.

B. In obtaining informed consent for evidence collection, a treatment hospital shall inform the SAS that the ability to collect viable evidence declines as time elapses.

C. Except as provided in § 54.1-2970.1 of the Code of Virginia, a treatment hospital shall obtain informed consent in writing from the SAS to the maximum extent practicable, provide that if it cannot obtain informed consent in writing, it shall:

1. Obtain oral informed consent from the SAS; and
2. Document in the SAS's medical records why informed written consent was not obtained.

398 D. A treatment hospital shall maintain documentation of compliance with this section in the
399 SAS's medical records.

400 **Statutory Authority**

401 §§ 32.1-12 and 32.1-162.15:4 of the Code of Virginia.

402 **12VAC5-416-140. Documentation.**

403 A treatment hospital shall ensure that all findings of the forensic medical examination are
404 comprehensively and objectively documented.

405 **Statutory Authority**

406 §§ 32.1-12 and 32.1-162.15:4 of the Code of Virginia.

407 **12VAC5-416-150. Medical history.**

408 A. A treatment hospital shall document specific information related to the alleged sexual
409 assault, including:

- 410 1. Time, date, and place of the alleged sexual assault;
- 411 2. The SAS's ability to give consent to the reported sexual activity;
- 412 3. Alleged use of force, threats of force, weapons, coercion, drugs, or alcohol to facilitate
413 the sexual assault;
- 414 4. Types or means of the alleged sexual assault;
- 415 5. Number of alleged assailants;
- 416 6. The occurrence of penetration of any body part with a penis, finger, or other object;
- 417 7. Whether the SAS voided, removed or inserted a tampon, douched, wiped or cleaned
418 the genital area, bathed, showered, gargled, brushed teeth, smoked, ate, drank, chewed
419 gum, changed clothes, or took medications after the alleged sexual assault;
- 420 8. Whether the SAS bit an alleged assailant or was bitten by the alleged assailant; and
- 421 9. Any other relevant information as determined by the health care professional who is
422 providing care.

423 B. To the maximum extent practicable, a treatment hospital shall ensure that:

- 424 1. Information documented pursuant to subsection A includes direct quotations from the
425 SAS describing the alleged sexual assault; and
- 426 2. Information solicited pursuant to subsection A is through the use of open-ended, non-
427 leading questions that encourage free narrative from the SAS.

428 C. A treatment hospital shall document the SAS's medical history, including:

- 429 1. Use of contraceptives and which type the SAS uses;
- 430 2. Last menstrual period, if applicable;
- 431 3. Last consensual intercourse;
- 432 4. Pregnancy status, if applicable;
- 433 5. History of anogenital surgery; and
- 434 6. Any other relevant information as determined by the health care professional who is
435 providing care.

436 **Statutory Authority**

437 §§ 32.1-12 and 32.1-162.15:4 of the Code of Virginia.

438 **12VAC5-416-160. Physical examination, laboratory testing, and evidence collection.**

439 A. A treatment hospital shall ensure that health care professionals conducting the forensic
440 medical examination or collecting the PERK:

- 441 1. Are specially educated and clinically trained to perform these tasks;
442 2. Clearly document all findings; and
443 3. Prevent cross contamination of evidence by changing gloves whenever cross
444 contamination could occur.

445 B. A treatment hospital shall ensure that in conducting a forensic medical examination:

- 446 1. A clean sheet is placed on the floor to be a barrier for the collection paper before the
447 SAS undresses;
448 2. A SAS is permitted to remove and place each piece of clothing being collected in a
449 separate paper bag; and
450 3. A health care professional:
451 a. Conducts an appropriate evaluation to determine the SAS's risk of infection or STIs,
452 including HIV, resulting from the alleged sexual assault;
453 b. Documents the presence of any physical injury, biological evidence, or foreign
454 debris;
455 c. Photographs and recovers any trace evidence, including sand, soil, leaves, grass,
456 and biological secretions;
457 d. Documents the location on the body from which trace evidence is collected;
458 e. Performs appropriate photodocumentation of collection sites and injuries before
459 evidence collection;
460 f. Recovers debris, moist secretions, and dry secretions in accordance with best
461 practices; and
462 g. Documents the location, size, and complete description of any trauma, including
463 bite marks, strangulation injuries, or areas of point tenderness, including those
464 occurring around the mouth, breasts, thighs, wrists, upper arms, legs, back, and
465 anogenital region.

466 C. If drug-facilitated or alcohol-facilitated sexual assault is suspected, a treatment hospital
467 shall ensure that blood or urine or both are collected with the consent of the SAS.

468 D. A treatment hospital shall ensure that health care professionals performing a forensic
469 medical examination conduct all necessary laboratory testing.

470 **Statutory Authority**

471 §§ 32.1-12 and 32.1-162.15:4 of the Code of Virginia.

472 **12VAC5-416-170. Chain of custody.**

473 A. A treatment hospital shall ensure that the chain of custody is maintained for all samples
474 collected during the forensic medical examination.

475 B. A treatment hospital shall ensure that all specimens are properly sealed, initialed, and
476 labeled with:

- 477 1. The name of the treatment hospital;
478 2. The SAS's name and patient identification number;
479 3. Date and time of specimen collection;
480 4. Description and location of the body part of the origin of the specimen;
481 5. The name and signature of the person collecting the specimen; and
482 6. Any other information that may be required by law.

483 C. A treatment hospital shall ensure that all transfers in the custody of evidence are
484 documented in a written record of:

- 485 1. The name, title, and signature of the person receiving the evidence; and
486 2. Date and time of transfer.

487 D. A treatment hospital may designate a secured location to store evidence and maintain
488 chain of custody, provided the treatment hospital has consulted with local law enforcement on the
489 location, security, and policies and procedures for storage.

490 **Statutory Authority**

491 §§ 32.1-12 and 32.1-162.15:4 of the Code of Virginia.

492 **12VAC5-416-180. Prophylaxis and contraception.**

493 A. A treatment hospital shall provide appropriate oral and written information regarding:

- 494 1. The possibility of infection or STIs, including HIV resulting from the alleged sexual
495 assault;
496 2. Accepted medical procedures and medications for the prevention or treatment of
497 infection or STIs;
498 3. The indications, contraindications, and potential risks of medical procedures or
499 medications for the prevention or treatment of infection or STIs;
500 4. The possibility of pregnancy resulting from the alleged sexual assault;
501 5. Medically and factually accurate oral and written information about emergency
502 contraception;
503 6. The indications, contraindications, and potential risks associated with the use of
504 emergency contraception; and
505 7. The availability of emergency contraception for SASs.

506 B. Unless the prophylaxis is medically contraindicated or the SAS refuses to consent to the
507 administration of prophylaxis, the treatment hospital shall provide, or arrange for, the
508 administration to a SAS of prophylaxis for STIs in accordance with the:

- 509 1. [Sexually Transmitted Infections Treatment Guidelines, July 2021 \(U.S. Centers for](#)
510 [Disease Control and Prevention\)](#); and
511 2. [Recommendations for Providing Quality Sexually Transmitted Diseases Clinical](#)
512 [Services, January 2020 \(U.S. Centers for Disease Control and Prevention\).](#)

513 C. Unless emergency contraceptive is medically contraindicated or the SAS refuses to
514 consent to the administration of emergency contraceptive, the treatment hospital shall provide, or
515 arrange for, the administration to a SAS of emergency contraceptive.

516 D. The provisions of subsection C of this section may not apply to a treatment hospital
517 operated under the auspices of a religious institution objecting to the administration or
518 arrangement of administration for emergency contraceptive on religious grounds.

519 **Statutory Authority**

520 §§ 32.1-12 and 32.1-162.15:4 of the Code of Virginia.

521 **12VAC5-416-190. Anonymous PERK.**

522 A. If a SAS who undergoes a forensic medical examination elects not to report the offense to
523 law enforcement, the treatment hospital shall ensure that the health care professional informs the
524 SAS:

- 525 1. The PERK will be forwarded to DCLS for storage as an anonymous PERK;
526 2. The anonymous PERK will be stored by DCLS;
527 3. The SAS has the right to object to the destruction of the anonymous PERK;
528 4. How the SAS can have the anonymous PERK released to a law enforcement agency
529 at a later date; and

530 5. The rights of the SAS pursuant to § 19.2-11.11 of the Code of Virginia.

531 B. The treatment hospital shall ensure that the health care professional forwards the
532 anonymous PERK to DCLS in accordance with the policies and procedures established by DCLS.

533 **Statutory Authority**

534 §§ 32.1-12 and 32.1-162.15:4 of the Code of Virginia.

535 **12VAC5-416-200. Medical advocacy services.**

536 A. A treatment hospital shall:

537 1. Enter into a memorandum of understanding with at least one rape crisis center; and

538 2. Adopt procedures to ensure compliance with mandatory reporting requirements
539 pursuant to §§ 63.2-1509 and 63.2-1606 of the Code of Virginia.

540 B. A treatment hospital shall review its memorandums of understanding with rape crisis
541 centers at least triennially and shall document the outcome of this review in writing.

542 C. A treatment hospital shall provide written and oral information to the SAS about medical
543 advocacy services provided by a rape crisis center with which the hospital has entered into a
544 memorandum of understanding pursuant to this section.

545 **Statutory Authority**

546 §§ 32.1-12 and 32.1-162.15:4 of the Code of Virginia.

547 **12VAC5-416-210. Discharge and follow-up health care.**

548 A. A treatment hospital shall ensure that a SAS is provided with oral and written medical
549 discharge instructions that include:

550 1. A summary of the examination, which includes:

551 a. Evidence collected;

552 b. Tests conducted;

553 c. Medication prescribed or provided;

554 d. Information provided during the examination; and

555 e. Treatment received;

556 2. Medication doses to be taken, if any;

557 3. Recommended examinations and laboratory tests to determine the presence or
558 absence of STIs;

559 4. Follow-up care related to HIV prophylaxis;

560 5. Any other follow-up health care appointments needed or scheduled; and

561 6. Referrals.

562 B. A treatment hospital shall provide to a SAS contact information and the hours of operation
563 for local advocacy programs.

564 C. A treatment hospital shall inform a SAS in writing that the SAS is not required to disclose
565 the alleged sexual assault to other health care professionals to receive follow-up health care.

566 D. The follow-up health care appointments that a treatment hospital may schedule or
567 recommend to a SAS include:

568 1. For patients with evidence of acute trauma, a short-term follow-up appointment to
569 reexamine and document the development of visible findings and photograph areas of
570 injury, and an exam two to four weeks later to document resolution of findings or healing
571 of injuries; and

572 2. For all patients, a repeat examination for STIs in accordance with the policies and
573 procedures of the treatment hospital and with best practices.

574 **Statutory Authority**

575 §§ 32.1-12 and 32.1-162.15:4 of the Code of Virginia.

576 **12VAC5-416-220. Reporting requirements.**

577 A treatment hospital shall report to the department by December 1 of each year:

- 578 1. The total number of SASs to whom a forensic medical examination was provided; and
579 2. The total number of PERKs offered and completed.

580 **Statutory Authority**

581 §§ 32.1-12 and 32.1-162.15:4 of the Code of Virginia.

582 Part III

583 PSAS Treatment Plan

584 **12VAC5-416-230. Minimum requirements for PSAS treatment plan.**

585 An approved pediatric treatment facility shall ensure that its PSAS treatment plan meets the
586 minimum standards established in Part III (12VAC5-416-230 et seq.) of this chapter and includes
587 the provision of a forensic medical examination to a PSAS when ordered by a health care
588 professional and with the assent of the PSAS and consent of the PSAS's legal representative.

589 **Statutory Authority**

590 §§ 32.1-12, 32.1-162.15:4, and 32.1-162.15:6 of the Code of Virginia.

591 **12VAC5-416-240. Pediatric staffing.**

592 An approved pediatric treatment facility shall ensure that at least one SAFE is available during
593 all hours of operation in person.

594 **Statutory Authority**

595 §§ 32.1-12, 32.1-162.15:4, and 32.1-162.15:6 of the Code of Virginia.

596 **12VAC5-416-250. Informed assent and consent for treatment.**

597 A. An approved pediatric treatment facility:

- 598 1. Shall ensure that all necessary and reasonable efforts are made to obtain informed
599 assent of PSASs who are six years of age or older prior to and during treatment, unless
600 the attending health care professional reasonably believes that the PSAS lacks the
601 developmental and linguistic capacity to give informed assent;
602 2. May obtain informed assent of PSASs who are less than six years of age prior to and
603 during treatment, if the attending health care professional reasonably believes that the
604 PSAS has the developmental and linguistic capacity to give informed assent; and
605 3. Shall ensure that the attending health care professional documents in the PSAS's
606 medical record the informed assent or the attending health care professional's judgment
607 that the PSAS lacks the developmental and linguistic capacity to give informed assent.

608 B. Except as provided in § 54.1-2970.1 of the Code of Virginia, an approved pediatric health
609 care facility shall obtain informed consent from the PSAS's legal representative for:

- 610 1. Medical evaluation and treatment, including the administration of prophylaxis and
611 emergency contraception, the need for follow-up care, and medical advocacy services
612 and counseling;
613 2. Reporting the alleged crime;
614 3. Performing a forensic medical examination;
615 4. Photodocumentation;
616 5. Evidence collection; and

617 6. Transferal of evidence to law enforcement.

618 C. In obtaining informed consent for evidence collection, an approved pediatric treatment
619 facility shall inform the PSAS and the PSAS's legal representative that the ability to collect viable
620 evidence declines as time elapses.

621 D. Except as provided in § 54.1-2970.1 of the Code of Virginia, an approved pediatric
622 treatment facility shall obtain informed consent in writing from the PSAS's legal representative to
623 the maximum extent practicable, provided that if it cannot obtain informed consent in writing, it
624 shall:

- 625 1. Obtain oral informed consent from the PSAS's legal representative; and
626 2. Document in the PSAS's medical records why informed written consent was not
627 obtained.

628 E. An approved pediatric treatment facility shall maintain documentation of compliance with
629 this section in the PSAS's medical records.

630 F. If a PSAS refuses to grant informed assent and the PSAS's legal representative gives
631 informed consent, an approved pediatric treatment facility that is a hospital:

- 632 1. May not proceed with PSAS treatment services and shall only screen, treat, and
633 stabilize the PSAS in accordance with EMTALA; and
634 2. May attempt to obtain a PSAS's informed assent at a later time.

635 G. If a PSAS refuses to grant informed assent and the PSAS's legal representative gives
636 informed consent, an approved pediatric treatment facility that is not a hospital:

- 637 1. May not proceed with PSAS treatment services and shall only screen or treat serious
638 medical injury, pain, or trauma to stabilize the PSAS; and
639 2. May attempt to obtain a PSAS's informed assent at a later time.

640 **Statutory Authority**

641 §§ 32.1-12, 32.1-162.15:4, and 32.1-162.15:6 of the Code of Virginia.

642 **12VAC5-416-260. Documentation.**

643 An approved pediatric treatment facility shall ensure that all findings of the forensic medical
644 examination are comprehensively and objectively documented.

645 **Statutory Authority**

646 §§ 32.1-12, 32.1-162.15:4, and 32.1-162.15:6 of the Code of Virginia.

647 **12VAC5-416-270. Medical history.**

648 A. An approved pediatric treatment facility shall document specific information related to the
649 alleged sexual assault, including:

- 650 1. Time, date, and place of the alleged sexual assault;
651 2. The PSAS's ability to give consent to the reported sexual activity;
652 3. Alleged use of force, threats of force, weapons, coercion, drugs, or alcohol to facilitate
653 the sexual assault;
654 4. Types or means of the alleged sexual assault;
655 5. Number of alleged assailants;
656 6. The occurrence of penetration of any body part with a penis, finger, or other object;
657 7. Whether the PSAS voided, removed or inserted a tampon, douched, wiped or cleaned
658 the genital area, bathed, showered, gargled, brushed teeth, smoked, ate, drank, chewed
659 gum, changed clothes, or took medications after the alleged sexual assault;
660 8. Whether the PSAS bit an alleged assailant or was bitten by the alleged assailant; and

661 9. Any other relevant information as determined by the health care professional who is
662 providing care.

663 B. To the maximum extent practicable, an approved pediatric treatment facility shall ensure
664 that:

665 1. Information documented pursuant to subsection A includes direct quotations from the
666 PSAS describing the alleged sexual assault; and

667 2. Information solicited pursuant to subsection A is through the use of open-ended, non-
668 leading questions that encourage free narrative from the PSAS.

669 C. An approved pediatric treatment facility shall document the PSAS's medical history,
670 including:

671 1. Use of contraceptives and which type the PSAS uses;

672 2. Last menstrual period, if applicable;

673 3. Last consensual intercourse;

674 4. Pregnancy status, if applicable;

675 5. History of anogenital surgery; and

676 6. Any other relevant information as determined by the health care professional who is
677 providing care.

678 **Statutory Authority**

679 §§ 32.1-12, 32.1-162.15:4, and 32.1-162.15:6 of the Code of Virginia.

680 **12VAC5-416-280. Physical examination, laboratory testing, and evidence collection.**

681 A. An approved pediatric treatment facility shall ensure that health care professionals
682 conducting the forensic medical examination or collecting the PERK:

683 1. Are specially educated and clinically trained to perform these tasks;

684 2. Clearly document all findings; and

685 3. Prevent cross contamination of evidence by changing gloves whenever cross
686 contamination could occur.

687 B. An approved pediatric treatment facility shall ensure that in conducting a forensic medical
688 examination:

689 1. A clean sheet is placed on the floor to be a barrier for the collection paper before the
690 PSAS undresses;

691 2. A PSAS is permitted to remove and place each piece of clothing being collected in a
692 separate paper bag; and

693 3. A health care professional:

694 a. Conducts an appropriate evaluation to determine the PSAS's risk of infection or
695 STIs, including HIV, resulting from the alleged sexual assault;

696 b. Documents the presence of any physical injury, biological evidence, or foreign
697 debris;

698 c. Photographs and recovers any trace evidence, including sand, soil, leaves, grass,
699 and biological secretions;

700 d. Documents the location on the body from which trace evidence is collected;

701 e. Performs appropriate photodocumentation of collection sites and injuries before
702 evidence collection;

703 f. Recovers debris, moist secretions, and dry secretions in accordance with best
704 practices; and

705 g. Documents the location, size, and complete description of any trauma, including
706 bite marks, strangulation injuries, or areas of point tenderness, including those
707 occurring around the mouth, breasts, thighs, wrists, upper arms, legs, back, and
708 anogenital region.

709 C. If drug-facilitated or alcohol-facilitated sexual assault is suspected, an approved pediatric
710 treatment facility shall ensure that blood or urine or both are collected with the assent of the PSAS.

711 D. An approved pediatric treatment facility shall ensure that health care professionals
712 performing a forensic medical examination conduct all necessary laboratory testing.

713 **Statutory Authority**

714 §§ 32.1-12, 32.1-162.15:4, and 32.1-162.15:6 of the Code of Virginia.

715 **12VAC5-416-290. Chain of custody.**

716 A. An approved pediatric treatment facility shall ensure that the chain of custody is maintained
717 for all samples collected during the forensic medical examination.

718 B. An approved pediatric treatment facility shall ensure that all specimens are properly sealed,
719 initialed, and labeled with:

- 720 1. The name of the approved pediatric treatment facility;
- 721 2. The PSAS's name and patient identification number;
- 722 3. Date and time of specimen collection;
- 723 4. Description and location of the body part of the origin of the specimen;
- 724 5. The name and signature of the person collecting the specimen; and
- 725 6. Any other information that may be required by law.

726 C. An approved pediatric treatment facility shall ensure that all transfer in the custody of
727 evidence are documented in a written record of:

- 728 1. The name, title, and signature of the person receiving the evidence; and
- 729 2. Date and time of transfer.

730 D. An approved pediatric treatment facility may designate a secured location to store evidence
731 and maintain chain of custody, provided the approved pediatric treatment facility has consulted
732 with local law enforcement on the location, security, and policies and procedures for storage.

733 **Statutory Authority**

734 §§ 32.1-12, 32.1-162.15:4, and 32.1-162.15:6 of the Code of Virginia.

735 **12VAC5-416-300. Prophylaxis and contraception.**

736 A. An approved pediatric treatment facility shall provide appropriate oral and written
737 information regarding:

- 738 1. The possibility of infection or STIs, including HIV resulting from the alleged sexual
739 assault;
- 740 2. Accepted medical procedures and medications for the prevention or treatment of
741 infection or STIs;
- 742 3. The indications, contraindications, and potential risks of medical procedures or
743 medications for the prevention or treatment of infection or STIs;
- 744 4. The possibility of pregnancy resulting from the alleged sexual assault;
- 745 5. Medically and factually accurate oral and written information about emergency
746 contraception;
- 747 6. The indications, contraindications, and potential risks associated with the use of
748 emergency contraception; and

749 7. The availability of emergency contraception for PSASs.

750 B. Unless the prophylaxis is medically contraindicated, the PSAS refuses to assent to the
751 administration of prophylaxis, or the PSAS's legal representative refuses to consent to the
752 administration of prophylaxis, the approved pediatric treatment facility shall provide, or arrange
753 for, the administration to a PSAS of prophylaxis for STIs in accordance with the:

754 1. [Sexually Transmitted Infections Treatment Guidelines, July 2021 \(U.S. Centers for](#)
755 [Disease Control and Prevention\)](#); and

756 2. [Recommendations for Providing Quality Sexually Transmitted Diseases Clinical](#)
757 [Services, January 2020 \(U.S. Centers for Disease Control and Prevention\)](#).

758 C. Unless emergency contraceptive is medically contraindicated, the PSAS refuses to assent
759 to the administration of emergency contraceptive, or the PSAS's legal representative refuses to
760 consent to the administration of emergency contraceptive, the approved pediatric treatment
761 facility shall provide, or arrange for, the administration to a PSAS of emergency contraceptive.

762 D. The provisions of subsection C of this section may not apply to an approved pediatric
763 treatment facility operated under the auspices of a religious institution objecting to the
764 administration or arrangement of administration for emergency contraceptive on religious
765 grounds.

766 **Statutory Authority**

767 §§ 32.1-12, 32.1-162.15:4, and 32.1-162.15:6 of the Code of Virginia.

768 **12VAC5-416-310. Anonymous PERK.**

769 A. If a PSAS who undergoes a forensic medical examination elects not to report the offense
770 to law enforcement, the approved pediatric treatment facility shall ensure the health care
771 professional informs the PSAS or the PSAS's legal representative:

772 1. The PERK will be forwarded to DCLS for storage as an anonymous PERK;

773 2. The anonymous PERK will be stored by DCLS;

774 3. The PSAS has the right to object to the destruction of the anonymous PERK;

775 4. How the PSAS can have the anonymous PERK released to a law enforcement agency
776 at a later date; and

777 5. The rights of the PSAS and PSAS's parent or guardian under § 19.2-11.11 of the Code
778 of Virginia.

779 B. The approved pediatric treatment facility shall ensure the health care professional forwards
780 the anonymous PERK to DCLS in accordance with the policies and procedures established by
781 DCLS.

782 **Statutory Authority**

783 §§ 32.1-12, 32.1-162.15:4, and 32.1-162.15:6 of the Code of Virginia.

784 **12VAC5-416-320. Medical advocacy services.**

785 A. An approved pediatric treatment facility shall:

786 1. Enter into a memorandum of understanding with at least one rape crisis center; and

787 2. Adopt procedures to ensure compliance with mandatory reporting requirements
788 pursuant to § 63.2-1509 of the Code of Virginia.

789 B. An approved pediatric treatment facility shall review its memorandums of understanding
790 with rape crisis centers at least triennially and shall document the outcome of this review in writing.

791 C. An approved pediatric treatment facility shall provide written and oral information about
792 medical advocacy services provided by a rape crisis center with which the approved pediatric
793 treatment facility has entered into a memorandum of understanding pursuant to this section.

794 **Statutory Authority**

795 §§ 32.1-12, 32.1-162.15:4, and 32.1-162.15:6 of the Code of Virginia.

796 **12VAC5-416-330. Discharge and follow-up health care.**

797 A. An approved pediatric treatment facility shall ensure that a PSAS and the PSAS's legal
798 representative is provided with oral and written medical discharge instructions that include:

799 1. A summary of the examination, which includes:

800 a. Evidence collected;

801 b. Tests conducted;

802 c. Medication prescribed or provided;

803 d. Information provided during the examination; and

804 e. Treatment received;

805 2. Medication doses to be taken, if any;

806 3. Recommended examinations and laboratory tests to determine the presence or
807 absence of STIs;

808 4. Follow-up care related to HIV prophylaxis;

809 5. Any other follow-up health care appointments needed or scheduled; and

810 6. Referrals.

811 B. An approved pediatric treatment facility shall provide to a PSAS and the PSAS's legal
812 representative contact information and the hours of operation for local advocacy programs.

813 C. An approved pediatric treatment facility shall inform a PSAS and the PSAS's legal
814 representative in writing that the PSAS is not required to disclose the alleged sexual assault to
815 other health care professionals to receive follow-up health care.

816 D. The follow-up health care appointments that an approved pediatric treatment facility may
817 schedule or recommend to a PSAS and the PSAS's legal representative include:

818 1. For patients with evidence of acute trauma, a short-term follow-up appointment to
819 reexamine and document the development of visible findings and photograph areas of
820 injury, and an exam two to four weeks later to document resolution of findings or healing
821 of injuries; and

822 2. For all patients, a repeat examination for STIs in accordance with the policies and
823 procedures of the approved pediatric treatment facility and with best practices.

824 **Statutory Authority**

825 §§ 32.1-12, 32.1-162.15:4, and 32.1-162.15:6 of the Code of Virginia.

826 **12VAC5-416-340. Approved pediatric treatment facilities with limited capacity.**

827 A. In cases in which an approved pediatric treatment facility is not able to provide the full range
828 of treatment services required by Part III (12VAC5-416-230 et seq.) of this chapter, the PSAS
829 treatment plan shall include:

830 1. The specific PSAS treatment services that the approved pediatric treatment facility will
831 provide for a PSAS;

832 2. Provisions for PSAS transfer services for a PSAS; and

833 3. The written agreement of an approved pediatric treatment facility to accept transfer of
834 a PSAS who cannot be treated by the originating approved pediatric treatment facility.

835 B. If the approved pediatric treatment facility does not provide services 24 hours per day,
836 seven days per week, it shall:

837 1. Inform the public regarding the need to seek an alternative source of treatment,
838 including emergency medical services; and

839 2. Post conspicuous signage on its premises, including in an area readily visible and
840 accessible to the public from the exterior of the approved pediatric treatment facility.

841 C. An approved pediatric treatment facility's provision of PSAS transfer services pursuant to
842 subdivision A 2 of this section shall comply with Part V (12VAC5-416-390 et seq.) of this chapter.

843 **Statutory Authority**

844 §§ 32.1-12, 32.1-162.15:4, and 32.1-162.15:6 of the Code of Virginia.

845 Part IV

846 SAS Transfer Plan

847 **12VAC5-416-350. Minimum requirements for SAS transfer plan.**

848 A transfer hospital shall ensure that its SAS transfer plan meets the minimum standards
849 established in Part IV (12VAC5-416-350 et seq.) of this chapter.

850 **Statutory Authority**

851 §§ 32.1-12 and 32.1-162.15:5 of the Code of Virginia.

852 **12VAC5-416-360. Screening.**

853 A. A transfer hospital shall screen patients for sexual assault, as deemed appropriate by a
854 qualified health care professional in accordance with EMTALA.

855 B. A transfer hospital shall adopt procedures to ensure compliance with mandatory reporting
856 requirements pursuant to §§ 63.2-1509 and 63.2-1606 of the Code of Virginia.

857 **Statutory Authority**

858 §§ 32.1-12 and 32.1-162.15:5 of the Code of Virginia.

859 **12VAC5-416-370. Acute injuries.**

860 A transfer hospital shall ensure that a SAS is screened, treated, and stabilized in accordance
861 with EMTALA prior to initiating any transfer.

862 **Statutory Authority**

863 §§ 32.1-12 and 32.1-162.15:5 of the Code of Virginia.

864 **12VAC5-416-380. Transfer coordination.**

865 A. A transfer hospital shall comply with EMTALA in coordinating transfer with a receiving
866 treatment hospital.

867 B. A transfer hospital shall communicate with the receiving treatment hospital to confirm the
868 availability of a SAFE to provide SAS treatment services to ensure minimal or no delay in the
869 provision of a forensic medical examination.

870 C. A transfer hospital shall provide a SAS with:

871 1. Written and oral information about:

872 a. Emergency contraception;

873 b. The indications, contraindications, and potential risks associate with the use of
874 emergency contraception; and

875 c. The availability of emergency contraception; and

876 2. A copy of the SAS's medical record from the encounter, as appropriate.

877 **Statutory Authority**

878 §§ 32.1-12 and 32.1-162.15:5 of the Code of Virginia.

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Part V

PSAS Transfer Plan

12VAC5-416-390. Minimum requirements for PSAS transfer plan.

An approved pediatric transfer facility shall ensure that its PSAS transfer plan meets the minimum standards established in Part V (12VAC5-416-390 et seq.) of this chapter.

Statutory Authority

§§ 32.1-12, 32.1-162.15:5, and 32.1-162.15:6 of the Code of Virginia.

12VAC5-416-400. Screening.

A. An approved pediatric transfer facility that is a hospital shall screen pediatric patients for sexual assault, as determined to be appropriate by a qualified health care professional in accordance with EMTALA.

B. An approved pediatric transfer facility that is not a hospital shall:

1. Screen pediatric patients for sexual, as determined to be appropriate by a qualified health care professional; and

2. Have a written policy and procedure specifying the qualifications of the health care professionals at the approved pediatric transfer facility who may make the determination specified in subdivision B 1 of this section.

C. An approved pediatric transfer facility shall adopt procedures to ensure compliance with mandatory reporting requirements pursuant to § 63.2-1509 of the Code of Virginia.

D. If an approved pediatric treatment facility does not provide services 24 hours per day, seven days per week, it may not refuse to screen a PSAS solely on the basis that the PSAS arrived before the impending cessation of its daily operations. For the purposes of this subsection, "daily operations" means the publicly posted hours that the approved pediatric treatment facility provides services to patients.

Statutory Authority

§§ 32.1-12, 32.1-162.15:5, and 32.1-162.15:6 of the Code of Virginia.

12VAC5-416-410. Acute injuries.

A. An approved pediatric transfer facility that is a hospital shall ensure that a PSAS is screened, treated, and stabilized in accordance with EMTALA prior to initiating any transfer.

B. An approved pediatric transfer facility that is not a hospital shall ensure that a PSAS is screened, treated, and stabilized prior to initiating any transfer.

C. If an approved pediatric transfer facility reasonably believes that the PSAS's legal representative has abused or neglected the PSAS, the approved pediatric transfer facility shall consult with child protective services or local law enforcement immediately.

D. If the PSAS's legal representative refuses to grant consent to treatment of an acute injury, the approved pediatric transfer facility shall consult with child protective services or local law enforcement immediately.

Statutory Authority

§§ 32.1-12, 32.1-162.15:5, and 32.1-162.15:6 of the Code of Virginia.

12VAC5-416-420. Transfer coordination.

A. An approved pediatric transfer facility that is a hospital shall comply with EMTALA in coordinating transfer with a receiving approved pediatric treatment facility.

921 B. An approved pediatric transfer facility shall communicate with the receiving approved
922 pediatric treatment facility to confirm the availability of a SAFE to provide PSAS treatment services
923 to ensure minimal or no delay in the provision of a forensic medical examination.

924 C. When making a transfer, the approved pediatric transfer facility shall:

- 925 1. Ensure the transfer does not unduly burden the PSAS;
- 926 2. Take precautions to minimize the loss of forensic evidence; and
- 927 3. Provide a copy of the PSAS's records, including reports of any treatment administered
928 or testing performed, to the approved pediatric treatment facility.

929 **Statutory Authority**

930 §§ 32.1-12, 32.1-162.15:5, and 32.1-162.15:6 of the Code of Virginia.

931 **12VAC5-416-430. Required transfer disclosures.**

932 A. Prior to initiating a transfer, an approved pediatric transfer facility shall discuss with the
933 PSAS and the PSAS's legal representative the reasons for the transfer.

934 B. An approved pediatric transfer facility shall ensure that a PSAS and the PSAS's legal
935 representative are advised of the impact of accepting or declining a transfer to assist the PSAS
936 in making an informed decision on transfer to include the effect on quality of care, the usefulness
937 of evidence collection, and any criminal investigation or prosecution.

938 C. An approved pediatric transfer facility shall provide a PSAS and the PSAS's legal
939 representative with:

- 940 1. Written and oral information about:
 - 941 a. Emergency contraception;
 - 942 b. The indications, contraindications, and potential risks associated with the use of
943 emergency contraception; and
 - 944 c. The availability of emergency contraception; and
- 945 2. A copy of the PSAS's medical record from the encounter, as appropriate.

946 **Statutory Authority**

947 §§ 32.1-12, 32.1-162.15:5, and 32.1-162.15:6 of the Code of Virginia.

948 Documents Incorporated by Reference (12VAC5-416)

949 [Recommendations for Providing Quality Sexually Transmitted Diseases Clinical Services,](#)
950 [January 2020 \(U.S. Centers for Disease Control and Prevention\).](#)

951 [Sexually Transmitted Infections Treatment Guidelines, July 2021 \(U.S. Centers for Disease](#)
952 [Control and Prevention\).](#)



COMMONWEALTH of VIRGINIA

Department of Health
P O BOX 2448
RICHMOND, VA 23218

Colin M. Greene, MD, MPH
State Health Commissioner

TTY 7-1-1 OR
1-800-828-1120

MEMORANDUM

DATE: August 8, 2022

TO: State Board of Health

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

SUBJECT: Proposed – Prescription Drug Pricing Transparency Regulation – Promulgation of Regulatory Chapter

Enclosed for your review are proposed amendments to the Prescription Drug Price Transparency Regulation.

Chapter 304 of the 2021 Acts of Assembly, Special Session I created Code of Virginia §§ 32.1-23.3, 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 required the creation of emergency regulations, which were promulgated on January 17, 2022 and will expire on July 16, 2023. These proposed amendments are for the permanent replacement to the emergency regulations.

The State Board of Health is requested to approve the proposed amendments. Should the Board of Health approve them, they will be submitted to the Office of the Attorney General to begin the Executive Branch review process. Following Executive Branch review and approval, the proposed amendments will be submitted to the Virginia Register of Regulations and the Virginia Regulatory Town Hall website for publication with a 60-day comment period. Following the close of that public comment period, VDH will draft the final amendments.



townhall.virginia.gov

Proposed Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-219-10 et seq.
VAC Chapter title(s)	Prescription Drug Price Transparency Regulation
Action title	Promulgation of New Regulation to Implement Chapter 304 of the 2021 Acts of Assembly, Special Session I
Date this document prepared	

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

Brief Summary

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

Chapter 304 (2021 Acts of Assembly, Special Session I) requires the Virginia Department of Health (VDH) to promulgate regulations to effectuate the act, specifically the specification of prescription drugs for the purpose of data collection and procedures for auditing information provided by health carriers, pharmacy benefits managers, wholesale distributors, and manufacturers, as well as a schedule of civil penalties for failure to report the information required, based on the severity of the violation. As the requirement to report prescription drug price information is new, there is no already existing regulatory chapter that would best fit this mandate, so VDH intends to promulgate a new regulatory chapter for these standards. Following the promulgation of emergency regulation, VDH now intends to promulgate a permanent regulation to replace the emergency regulation.

Acronyms and Definitions

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

“Commissioner” means the State Health Commissioner.

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

“PBM” means a pharmacy benefits manager.

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

“VDH” means the Virginia Department of Health.

“WAC” means wholesale acquisition cost.

Mandate and Impetus

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

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

Legal Basis

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

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

Purpose

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

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

Substance

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

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

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

12VAC5-219-10. Definitions.

Removes the definition of "price"; modifies the definitions for "discount" and "launched"; and adds a definition for "National Drug Code" or "NDC."

12VAC5-219-30. Notice.

Removes subsection B and its subdivisions about the use of alternate drug group systems other than Medi-Span© since NDC has replaced "drug group" in the data elements tables for reporting entities.

12VAC5-219-50. Carrier reporting requirements.

Removes "drug group" from the data elements table and replaces it with "NDC" and clarifies that carriers should include data on each drug product of an outpatient prescription drug in their annual reports.

12VAC5-219-60. Pharmacy benefits manager reporting requirements.

Removes "drug group" from the data elements table and replaces it with "NDC" and clarifies that PBMs should include data on each drug product of a prescription drug in their annual reports.

12VAC5-219-70. Manufacturer reporting requirements.

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

12VAC5-219-80. Wholesale distributor reporting requirements.

Removes “drug group” from the data elements table and replaces it with “NDC” and clarifies that wholesale distributors should include data on each drug product of a prescription drug in their reports if reports are required by VDH.

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

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

12VAC5-219-9999. DOCUMENTS INCORPORATED BY REFERENCE.

Amended to reference the updated submission manual.

Issues

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

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

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

Requirements More Restrictive than Federal

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

There are no applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

Consistent with § 2.2-4007.04 of the Code of Virginia, identify any other state agencies, localities, or other entities particularly affected by the regulatory change. Other entities could include local partners such as tribal governments, school boards, community services boards, and similar regional organizations. "Particularly affected" are those that are likely to bear any identified disproportionate material impact which would not be experienced by other agencies, localities, or entities. "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulation or regulatory change are most likely to occur. If no agency, locality, or entity is particularly affected, include a specific statement to that effect.

Other State Agencies Particularly Affected

There are no other state agencies particularly affected.

Localities Particularly Affected

There are no localities particularly affected by the regulatory change.

Other Entities Particularly Affected

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

Economic Impact

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

Impact on State Agencies

<p><i>For your agency:</i> projected costs, savings, fees, or revenues resulting from the regulatory change, including:</p> <ul style="list-style-type: none"> 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. 	<p>Fund source is general funds and is a fixed, on-going cost to the agency. The FIS published by DPB for Chapter 304 (2021 Acts of Assembly, Special Session I) is accurate as written compared to the agency's internal estimates.</p> <p><u>Fiscal Year & Cost</u> 2022 - \$393,801 2023 - \$318,801 2024 - \$318,801 2025 - \$318,801 2026 - \$318,801 2027 - \$318,801</p> <p>The costs of the statutory mandate that this regulatory chapter is responsive to cannot be absorbed within existing resources, which prompted the General Assembly to amend the Appropriations Act to provide the above identified amounts.</p>
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<i>For other state agencies:</i> projected costs, savings, fees, or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.	N/A
<i>For all agencies:</i> Benefits the regulatory change is designed to produce.	The benefits the regulatory change is designed to produce is increased knowledge of and transparency for prescription drug pricing and the factors that influence consumer healthcare costs.

Impact on Localities

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

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

Impact on Other Entities

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

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

<p>Benefits the regulatory change is designed to produce.</p>	<p>The benefits the regulatory change is designed to produce is increased knowledge of and transparency for prescription drug pricing and the factors that influence consumer healthcare costs. It also enables the state to collect statutorily required information in a consistent form and manner, specifies the means of data validation, notice, and response related to review and approval of data submitted to the state, and sets forth the means of disciplinary action, civil penalties, and available appellate procedures for entities that fail to meet the requirements of the statute.</p>
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Alternatives to Regulation

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

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

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

Regulatory Flexibility Analysis

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

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

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

Periodic Review and Small Business Impact Review Report of Findings

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

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

Public Comment

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

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

	<p>Commenters request that CMOs be excluded from the reporting requirements of 12VAC5-219-70 and only require manufacturers that set or change the WAC to report. Commenters request that the definition of “manufacturer” be modified to match DSCSA language.</p>	
<p>Pharmaceutical Research and Manufacturers of America (PhRMA)</p>	<p>Commenter requested changes to:</p> <ul style="list-style-type: none"> • 12VAC5-219-10 (Definitions) to remove “coupons, out-of-pocket cost assistance, premium assistance, or copay assistance” from the definition of “Discount”; clarify “launched” to reflect the date a product is first made available for sale in Virginia; remove the term “acquired” from the definition of “launch”; and strike the term “price” from the list of definitions • 12VAC5-219-40 (Allowable Variances) to include “...Nothing in this section will be interpreted to impose greater requirements on reporting entities than those set forth in statute.” • 12VAC5-219-70 (Manufacturer Reporting Requirements; Data Element Chart) to remove from final regulations due to not being items that manufacturers are required to report per Code, thereby exceeding VDH authority to include: <ul style="list-style-type: none"> ○ WAC Unit ○ Drug group: Medi-Span® Generic Product Identifier (GPI): Medi-Span® GPI is a proprietary data element of Medi-Span’s drug pricing compendium, and manufacturers may not have access to this information. ○ Date of initial generic competition ○ WAC at market introduction ○ WAC on January 1 of prior calendar year 	<p>VDH notes these comments and suggestions and responds that:</p> <ul style="list-style-type: none"> • VDH has modified 12VAC5-219-10 in response to the comments. • VDH has not modified 12VAC5-219-40 because the variance process requires the reporting entity to identify proposed alternatives to meet the purpose of the standard or requirement, which is why the regulatory texts states that the Commissioner “[m]ay attach conditions to a variance that, in the sole judgment of the commissioner, satisfies, supports, or furthers the purpose of the standard or requirement”; the language proposed by the commenter may conflict with the essential function of a variance, i.e., to provide individualized flexibility while meeting the purpose of the requirement. • VDH disagrees with the commenter’s contention that the data elements specified in 12VAC5-219-70 exceeds VDH’s authority to include. Subsection D of Code of Virginia § 32.1-23.4 requires that VDH be able to audit the data submitted; the data elements listed for each reporting entity are intended to enable VDH (through the NDSO) to conduct such audits. VDH has removed “drug group” from the data elements listed and replaced it with “NDC” as the NDC is not proprietary data. • VDH believes that the language proposed subsection F (previously subsection D in the emergency 12VAC5-219-70) already achieves the same purpose that the commenter’s language would.

	<ul style="list-style-type: none"> ○ WAC on December 31 of the prior calendar year ● 12VAC5-219-70 (Manufacturer Reporting Requirements; Subsection D) to read: “A manufacturer’s obligations pursuant to the section shall be fully satisfied by the submission to the nonprofit data services organization with which the Department of Health has entered into a contract pursuant to Section 32.1-23.3 of information and data that a manufacturer includes in the manufacturer’s annual consolidation report on Securities and Exchange Commission Form 10-K or any other public disclosure.” 	
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Public Participation

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

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

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

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

Detail of Changes

List all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Use all tables that apply, but delete inapplicable tables.

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

New chapter-section number	New requirements to be added to VAC	Other regulations and laws that apply	Change, intent, rationale, and likely impact of new requirements
219-20	<p>12VAC5-219-20. Registration.</p> <p>A. Each reporting entity shall furnish to and maintain with the NDSO:</p> <ol style="list-style-type: none"> 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. <p>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.</p> <p>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.</p> <ol style="list-style-type: none"> 1. A reporting entity shall file any report otherwise due on April 1 for the preceding calendar year pursuant to Part II (12VAC5-219-50 et seq.) of this chapter prior to its closure, discontinuation, or acquisition if the reporting entity plans or anticipates that between January 1 and April 1: <ol style="list-style-type: none"> 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 		<p>CHANGE: VDH is proposing to promulgate these new requirements and make them permanent.</p> <p>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.</p> <p>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.</p> <p>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.</p>

	<p>discontinuation of its business as a carrier, PBM, manufacturer, or wholesale distributor.</p> <p>2. The legal entity acquiring a reporting entity shall ensure that it complies with the provisions of this chapter.</p> <p>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.</p>		
<p>219-40</p>	<p>12VAC5-219-40. Allowable variances.</p> <p>A. The commissioner may authorize a variance to Part II (12VAC5-219-50 et seq.) of this chapter.</p> <p>B. A variance shall require advance written approval from the commissioner.</p> <p>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:</p> <ol style="list-style-type: none"> 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; 		<p>CHANGE: VDH is proposing to promulgate these new requirements.</p> <p>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.</p> <p>RATIONALE: The rationale for these new requirements is to permit the commissioner to address unforeseen circumstances that complicate a regulant's compliance with a requirement in this chapter.</p> <p>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.</p>

	<p>5. Proposed alternatives to meet the purpose of the standard or requirement; and</p> <p>6. Other information, if any, believed by the requester to be pertinent to the request.</p> <p>D. The requester shall provide additional information as may be requested or required by the commissioner to evaluate the variance request.</p> <p>E. The requester may withdraw a request for a variance at any time.</p> <p>F. The commissioner shall notify the requester in writing of the commissioner's decision on the variance request. If granted, the commissioner:</p> <ol style="list-style-type: none"> 1. Shall identify: <ol style="list-style-type: none"> 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. <p>G. The requester shall comply with the standard or requirement to which a variance has been requested unless a variance has been granted.</p> <p>H. The commissioner may rescind or modify a variance if:</p> <ol style="list-style-type: none"> 1. The impractical hardship unique to the requester changes or no longer exists; 2. Additional information becomes known that 		
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	<p>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;</p> <p>3. The requester fails to meet any conditions attached to the variance; or</p> <p>4. Results of the variance fail to satisfy, support, or further the purpose of the standard or requirement.</p> <p>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.</p>		
<p>219-100</p>	<p>Part III Enforcement Article 1 Data Validation and Audits 12VAC5-219-100. Data validation; notification; response.</p> <p>A. The NDSO shall:</p> <p>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;</p> <p>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;</p> <p>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;</p>		<p>CHANGE: VDH is proposing to promulgate these new requirements.</p> <p>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.</p> <p>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.</p> <p>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.</p>

	<p>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</p> <p>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.</p> <p>B. Each reporting entity notified under subsection A shall make changes necessary to correct the report within 30 calendar days of the notification.</p> <p>C. If a reporting entity fails to correct the report within 30 calendar days, the NDSO shall:</p> <ol style="list-style-type: none"> 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. <p>D. If a reporting entity fails to correct the report within 15 calendar days of the second notice:</p> <ol style="list-style-type: none"> 1. The NDSO shall provide to the commissioner within 1 		
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	<p>business day of the second failure to correct:</p> <ol style="list-style-type: none"> 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 <p>2. The commissioner shall deem the second failure to correct as a failure to report pursuant to Part II (12VAC5-219-50 et seq.) of this chapter.</p>		
<p>219-110</p>	<p>12VAC5-219-110. Audit; corrective action plan.</p> <p>A. When submitting any notification or report to the NDSO, a reporting entity shall include:</p> <ol style="list-style-type: none"> 1. A signed, written certification of the accuracy of any notification or report filed in a physical format; and 2. Electronic certification of the accuracy of any notification or report filed by email or through the NDSO's online collection tool. <p>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.</p> <p>C. The NDSO shall send a copy of the audit findings to the reporting entity no more than 5 business days after</p>		<p>CHANGE: VDH is proposing to promulgate these new requirements.</p> <p>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.</p> <p>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.</p> <p>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.</p>

	<p>the conclusion of the audit at its email mailing address of record.</p> <p>D. If any deficiencies are found during the audit:</p> <ol style="list-style-type: none"> 1. The NDSO shall: <ol style="list-style-type: none"> 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. <p>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:</p> <ol style="list-style-type: none"> 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. <p>F. The reporting entity shall ensure that the person</p>		
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	<p>responsible for the implementation of the corrective action plan signs, dates, and indicates their title on the corrective action plan.</p> <p>G. The NDSO shall:</p> <ol style="list-style-type: none"> 1. Notify the reporting entity if the NDSO determines any item in the corrective action plan is unacceptable; 2. Grant the reporting entity two opportunities to revise and resubmit a corrective action plan that the NDSO initially determines to be unacceptable. If the reporting entity revises and resubmits the corrective action plan, the revision is due to the NDSO and the commissioner no more than 15 business days after the NDSO has notified the reporting entity pursuant to subdivision 1 of this subsection. <p>H. If a reporting entity fails to comply with the corrective action plan:</p> <ol style="list-style-type: none"> 1. The NDSO shall provide to the commissioner any correspondence between the NDSO and the reporting entity after the notification sent pursuant to subsection D of this section; and 2. The commissioner shall deem the failure to comply as a failure to report pursuant to Part II (12VAC5-219-50 et seq.) of this chapter. 		
219-120	<p style="text-align: center;">Article 2 Administrative Process</p> <p>12VAC5-219-120. Sanctions.</p>		<p>CHANGE: VDH is proposing to promulgate these new requirements.</p>

	<p>A. A reporting entity may not violate the provisions of this chapter.</p> <p>B. The commissioner may:</p> <ol style="list-style-type: none"> 1. For each violation of this chapter, petition an appropriate court for an injunction, mandamus, or other appropriate remedy or imposition of a civil penalty against the reporting entity pursuant to subsection B or C of § 32.1-27 of the Code of Virginia; and 2. For each violation of Part II (12VAC5-219-50 et seq.) of this chapter, levy a civil penalty upon the reporting entity as specified in subsection B of 12VAC5-219-130 and pursuant to subsection C of § 32.1-23.4 of the Code of Virginia, in accordance with the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia). <p>C. Each day that a reporting entity fails to report in violation of this chapter is a sufficient cause for imposition of one or more sanctions. If a reporting entity knowingly submits false, inaccurate, or misleading data pursuant to the reporting requirements of this chapter, the commissioner shall deem that submission as a failure to report.</p>		<p>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.</p> <p>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.</p> <p>LIKELY IMPACT: The likely impact of these new requirements is improved clarity for reporting entities.</p>
<p>219-130</p>	<p>12VAC5-219-130. Civil penalty.</p> <p>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.</p> <p>B. Except as provided in subsection A of this section,</p>		<p>CHANGE: VDH is proposing to promulgate these new requirements.</p> <p>INTENT: The intent of these new requirements is to create a schedule of civil penalties based on the severity of the violation.</p>

	<p>the commissioner shall levy a civil penalty upon the reporting entity in an amount of:</p> <ol style="list-style-type: none"> 1. For the first offense: <ol style="list-style-type: none"> a. \$500 for the first day in which the reporting entity fails to report; b. \$1,000 for the second day in which the reporting entity fails to report; c. \$1,500 for the third day in which the reporting entity fails to report; d. \$2,000 for the fourth day in which the reporting entity fails to report; and e. \$2,500 for the fifth day and each subsequent day in which the reporting entity fails to report; and 2. For the second offense: <ol style="list-style-type: none"> a. \$1,000 for the first day in which the reporting entity fails to report; b. \$1,750 for the second day in which the reporting entity fails to report; and c. \$2,500 for the third and each subsequent day in which the reporting entity fails to report; and 3. For the third and all subsequent offenses, \$2,500 for each day in which the reporting entity fails to report. <p>The commissioner shall assess civil penalties in the aggregate on a per day basis.</p> <p>C. The commissioner shall deem the first day in which the reporting entity fails to report as:</p> <ol style="list-style-type: none"> 1. April 2 for a reporting entity that fails to submit any information or 		<p>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.</p> <p>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.</p>
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	<p>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;</p> <p>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;</p> <p>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</p> <p>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.</p> <p>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.</p> <p>E. A reporting entity shall remit a check or money order for a civil penalty payable to the Treasurer of Virginia.</p> <p>1. If a check, money draft, or similar instrument for</p>		
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	<p>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.</p> <p>2. Unless otherwise provided, the commissioner may not refund civil penalties or fees.</p> <p>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.</p> <p>1. On all past due civil penalties, the commissioner shall assess and charge:</p> <ul style="list-style-type: none"> 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. <p>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.</p>		
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<p>219-140</p>	<p>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 pursuant to § 2.2-4019 of the Code of Virginia: 1. In writing to the commissioner; and 2. No more than 14 calendar days after the date of receipt of the notice of civil penalty imposition. B. In requesting an informal fact finding proceeding pursuant to subsection A of this section, a reporting entity: 1. Shall identify with specificity the reason or alleged good cause for its failure to report; and 2. May present factual data, argument, information, or proof in support of its reason or alleged good cause for its failure to report. C. The request for an informal fact finding proceeding: 1. May not toll the imposition of a civil penalty on a per day basis, as specified in subsection B of 12VAC5-219-130; 2. Shall toll all assessments and charges under subdivision F 1 of 12VAC5-219-130 until a case decision after an informal fact finding proceeding has been served. D. If a reporting entity does not request an informal fact finding proceeding pursuant to subsection A of this section, the civil penalty</p>		<p>CHANGE: VDH is proposing to promulgate these new requirements.</p> <p>INTENT: The intent of these new requirements is outline the procedural steps that a reporting entity must take to request an informal fact-finding proceeding and the effect of an informal fact-finding conference on the accumulation of civil penalties.</p> <p>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.</p> <p>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.</p>
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	<p>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.</p> <p>E. If a reporting entity remains aggrieved by a case decision after an informal fact finding proceeding, it may seek review of the case decision in accordance with Article 5 (§ 2.2-4025 et seq.) of Chapter 40 of Title 2.2. of the Code of Virginia.</p>		
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Table 3: Changes to the Emergency Regulation

Emergency chapter-section number	New chapter-section number, if applicable	Current <u>emergency</u> requirement	Change, intent, rationale, and likely impact of new or changed requirements since emergency stage
219-10	Same as emergency chapter-section number	<p>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.</p>	<p>CHANGE: VDH is proposing to eliminate the definition of "price" and promulgate these changed requirements since emergency stage requirements:</p> <p>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.</p>

		<p>“Department” means the State Department of Health.</p> <p>“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.</p> <p>“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.</p> <p>“Enrollee” has the same meaning as ascribed to the term in § 38.2-3407.10 of the Code of Virginia.</p> <p>“FDA” means the U.S. Food and Drug Administration.</p> <p>“Generic drug” has the same meaning as ascribed to the term in § 54.1-3436.1 of the Code of Virginia.</p> <p>“Health benefits plan” has the same meaning as ascribed to the term in § 38.2-3438 of the Code of Virginia.</p> <p>“IRS” means the U.S. Internal Revenue Service.</p> <p>“Launched” means the month and year on which a manufacturer acquired or first marketed a prescription drug for sale in the United States.</p> <p>“Manufacturer” has the same meaning as ascribed to the term in § 54.1-3401 of the Code of Virginia.</p> <p>“New prescription drug” has the same meaning as ascribed to the term in § 54.1-3442.02 of the Code of Virginia.</p> <p>“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.</p> <p>“Outpatient prescription drug” means a prescription drug that</p>	<p>"Commissioner" means the State Health Commissioner.</p> <p>"Department" means the Virginia Department of Health.</p> <p>"Discount" means any price concessions, however characterized, offered or provided by a reporting entity for a prescription drug, including rebates and reductions in price, that has the effect of reducing the cost of a prescription drug for a consumer.</p> <p>"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.</p> <p>"Enrollee" has the same meaning as ascribed to the term in § 38.2-3407.10 of the Code of Virginia.</p> <p>"FDA" means the U.S. Food and Drug Administration.</p> <p>"Generic drug" has the same meaning as ascribed to the term in § 54.1-3436.1 of the Code of Virginia.</p> <p>"Health benefit plan" has the same meaning as ascribed to the term in § 38.2-3438 of the Code of Virginia.</p> <p>"IRS" means the U.S. Internal Revenue Service.</p> <p>"Launched" means the month and year on which a manufacturer first marketed a prescription drug for sale in the Commonwealth.</p> <p>"Manufacturer" has the same meaning as ascribed to the term in § 54.1-3401 of the Code of Virginia.</p> <p>"National Drug Code" or "NDC" means a unique numeric code assigned by the FDA for each finished drug product or unfinished drug subject to the listing requirements of 21 CFR Part 207.</p> <p>"New prescription drug" has the same meaning as ascribed to the term in § 54.1-3442.02 of the Code of Virginia.</p> <p>"Nonprofit data services organization" or "NDSO" has the same meaning as ascribed to the</p>
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		<p>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.</p> <p>“Pharmacy benefits management” had the same meaning as ascribed to the term in § 38.2-3407.15:4 of the Code of Virginia.</p> <p>“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.</p> <p>“Premium” means the amount members pay to a carrier or health benefit plan for their medical and prescription drug insurance.</p> <p>“Price” means the amount of money an individual consumer pays at retail for a prescription drug in the absence of a discount.</p> <p>“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.</p> <p>“Rebate” has the same meaning as ascribed to the term in § 38.2-3407.22 of the Code of Virginia.</p> <p>“Reporting entity” means carriers, PBMs, wholesale distributors, and manufacturers.</p> <p>“Specialty drug” means a prescription drug that:</p> <ol style="list-style-type: none"> 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: 	<p>term in § 32.1-23.4 of the Code of Virginia.</p> <p>“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.</p> <p>“Pharmacy benefits management” has the same meaning as ascribed to the term in § 38.2-3407.15:4 of the Code of Virginia.</p> <p>“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.</p> <p>“Premium” means the amount members pay to a carrier or health benefit plan for their medical and prescription drug insurance.</p> <p>“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.</p> <p>“Rebate” has the same meaning as ascribed to the term in § 38.2-3407.22 of the Code of Virginia.</p> <p>“Reporting entity” means carriers, PBMs, wholesale distributors, and manufacturers.</p> <p>“Specialty drug” means a prescription drug that:</p> <ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> a. Prescribed for a person with a chronic, complex,
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		<p>a. Prescribed for a person with a chronic, complex, rare, or life-threatening medical condition;</p> <p>b. Requires specialized supply chain features, product handling, or administration by the dispensing pharmacy; or</p> <p>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.</p> <p>It is presumed that a prescription drug, appearing on Medicare Part D's specialty tier is a specialty drug.</p> <p>"Spending" means the amount of money, expressed in U.S. dollars, expended after discounts.</p> <p>"Therapeutically equivalent" means a generic drug that is:</p> <ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> a. A pharmaceutical equivalent to a brand-name drug in that it: <ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> i. It does not present a known or potential bioequivalence problem, and they meet an 	<p>rare, or life-threatening medical condition;</p> <p>b. Requires specialized supply chain features, product handling, or administration by the dispensing pharmacy; or</p> <p>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.</p> <p>A prescription drug appearing on Medicare Part D's specialty tier is presumed to be a specialty drug.</p> <p>"Spending" means the amount of money, expressed in United States dollars, expended after discounts.</p> <p>"Therapeutically equivalent" means a generic drug that is:</p> <ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> a. A pharmaceutical equivalent to a brand-name drug in that it: <ol style="list-style-type: none"> (1) Contains identical amounts of the identical active drug ingredient in the identical dosage form and route of administration; and (2) Meets compendial or other applicable standards of strength, quality, purity, and identity; or b. A bioequivalent to a brand-name drug in that: <ol style="list-style-type: none"> (1) It does not present a known or potential bioequivalence problem, and they meet an acceptable in vitro standard; or
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		<p>acceptable in vitro standard; or</p> <p>ii. If it does present such a known or potential problem, it is shown to meet an appropriate bioequivalence standard.</p> <p>"USAN Council" means the United States Adopted Names Council.</p> <p>"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.</p> <p>"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.</p> <p>"Wholesale distributor" has the same meaning as ascribed to the term in § 54.1-3401 of the Code of Virginia.</p> <p>"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.</p>	<p>(2) If it does present such a known or potential problem, it is shown to meet an appropriate bioequivalence standard.</p> <p>"USAN Council" means the United States Adopted Names Council.</p> <p>"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.</p> <p>"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.</p> <p>"Wholesale distributor" has the same meaning as ascribed to the term in § 54.1-3401 of the Code of Virginia.</p> <p>"30-day equivalent supply" means the total daily dosage units of a prescription drug recommended by its prescribing label as approved by the FDA for 30 days or fewer. If there is more than one such recommended daily dosage, the largest recommended daily dosage will be considered for purposes of determining a 30-day equivalent supply. "30-day equivalent supply" includes a 30-day supply and a single course of treatment under subsection B of § 54.1-3442.02 of the Code of Virginia.</p> <p>INTENT: The intent of these changed requirements since emergency stage requirements is to provide definitions for terms used in the regulation.</p> <p>RATIONALE: The rationale for these changed requirements since emergency stage requirements is that these terms could have multiple meanings unless defined and that the lack of definitions</p>
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			<p>could lead to confusions among regulants.</p> <p>LIKELY IMPACT: The likely impact of these changed requirements since emergency stage requirements is improved clarity for regulants.</p>
<p>219-30</p>	<p>Same as emergency chapter-section number</p>	<p>12VAC5-219-30. Notice.</p> <p>A. The NDSO shall send to the reporting entity at the last known electronic mailing address of record:</p> <ol style="list-style-type: none"> 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. <p>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:</p> <ol style="list-style-type: none"> 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. <p>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.</p> <p>D. The NDSO shall provide any record requested by the commissioner or department</p>	<p>CHANGE: VDH is proposing to remove subsection B from the emergency stage:</p> <p>12VAC5-219-30. Notice.</p> <p>A. The NDSO shall send to the reporting entity at the last known electronic mailing address of record:</p> <ol style="list-style-type: none"> 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. <p>B. The department shall send notices pursuant to Part III (12VAC5-219-100 et seq.) of this chapter and case decisions to the last known electronic mailing address of record and mailing address of record.</p> <p>C. The NDSO shall provide any record requested by the commissioner or department related to the enforcement or administration of § 32.1-23.4 of the Code of Virginia or this chapter no more than 10 business days after the request, except as otherwise agreed to between the NDSO and the commissioner or the department.</p> <p>INTENT: The intent of these new requirements is to specify how reporting entities will be contact by the NDSO and VDH, and to ensure</p>

		<p>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.</p>	<p>that VDH has timely access to records involving the reporting entity.</p> <p>RATIONALE: The rationale for these new requirements is to set clear expectations on how the NDSO and VDH will contact a reporting entity and on the timeliness of information sharing so that VDH can adjudicate enforcement in an efficient manner.</p> <p>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.</p>
<p>219-50</p>	<p>Same as emergency chapter-section number</p>	<p>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:</p> <ol style="list-style-type: none"> 1. For covered outpatient prescription drugs that were prescribed to enrollees during the immediately preceding calendar year: <ol style="list-style-type: none"> 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 	<p>CHANGE: VDH is proposing to promulgate these changed requirements since emergency stage requirements:</p> <p>Documents Incorporated By Reference (12VAC5-219) Prescription Drug Price Transparency Regulation Submission Manual, Version 1.1, 2022, Virginia Health Information (rev. 9/2022).</p> <p>INTENT: The intent of these changed requirements since emergency stage is to incorporate by reference the most up-to-date format and file standards for data reports.</p> <p>RATIONALE: The rationale for these changed requirements since emergency stage is that there should be a standardized format and file for all reports as that increase the likelihood that the data received is uniform and reduces the amount of time the NDSO spends to validate the data.</p> <p>LIKELY IMPACT: The likely impact of these changed requirements</p>

		<p>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;</p> <p>2. The percent increase in annual net spending for prescription drugs after accounting for aggregated discounts;</p> <p>3. The percent increase in premiums that were attributable to each health care service, including prescription drugs;</p> <p>4. The percentage of specialty drugs with utilization management requirements; and</p> <p>5. The premium reductions that were attributable to specialty drug utilization management.</p> <p>B. In determining which outpatient prescription drugs are reportable under subdivision A 1 of this section, the carrier shall:</p> <p>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;</p> <p>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</p> <p>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.</p> <p>C. A carrier may not disclose the identity of a specific health benefit plan or the price charged for a</p>	<p>since emergency stage is improved clarity for reporting entities on the format and file standards when filing data reports.</p>
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	<p>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.</p> <p>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.</p> <p>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:</p>									
	<table border="1" style="border-style: dashed;"> <thead> <tr> <th>Data Element Name</th> <th>Data Element Definition</th> </tr> </thead> <tbody> <tr> <td>Carrier tax identification number</td> <td>The 9-digit tax taxpayer identification number used by the IRS.</td> </tr> <tr> <td>Carrier name</td> <td>The legal name of the reporting entity.</td> </tr> <tr> <td>Health benefit plan category</td> <td>The 2-digit health plan category identifier. The first digit corresponds to the insurance line and valid values are D (Medicaid); R (Medicare); C (commercial); and O (other). The second digit corresponds to the insurance policy type and</td> </tr> </tbody> </table>	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	
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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									

		<p>valid values include I (individual); F (fully insured group); S (self insured group); and C (Commonwealth of Virginia employees).</p>
	Health benefit plan unique identifier	<p>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.</p>
	Proprietary drug name	<p>The brand or trademark name of the prescription drug reported to the FDA.</p>
	Non-proprietary drug name	<p>The generic name of the prescription drug assigned by the USAN Council.</p>
	WAC unit	<p>The lowest identifiable quantity of the prescription drug that is dispensed, exclusive of any diluent without reference to volume measures pertaining to liquids.</p>
	Drug group	<p>The first two digits of the</p>

		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.	

		<p>Comments : A text field for : any additional : information the : carrier wishes to : provide.</p>													
<p>219-60</p>	<p>Same as emergency chapter-section number</p>	<p>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:</p> <table border="1" data-bbox="558 1304 967 1877"> <thead> <tr> <th>Data Element Name</th> <th>Data Element Definition</th> </tr> </thead> <tbody> <tr> <td>PBM tax identification number</td> <td>The 9-digit tax 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> </tbody> </table>	Data Element Name	Data Element Definition	PBM tax identification number	The 9-digit tax 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.	<p>CHANGE: VDH is proposing to remove "drug group" as a data element and promulgate these changed requirements since emergency stage requirements:</p> <p>12VAC5-219-60. Pharmacy benefits manager reporting requirements. A. Every PBM providing pharmacy benefits management under contract to a carrier shall report annually by April 1 to the NDSO the following information for each prescription drug upon which the carrier is reporting pursuant to 12VAC5-219-50: 1. The aggregate amount of rebates received by the PBM; 2. The aggregate amount of rebates distributed to the relevant health benefit plan; and 3. The aggregate amount of rebates passed on to enrollees of each health benefit plan at the point of sale that reduced the enrollees' applicable deductible, copayment, coinsurance, or other cost-sharing amount. B. A PBM shall report on all drug products of a prescription drug determined to be reportable pursuant to subsection A of this section. C. Every PBM shall provide the information specified in subsection A of this section on a form prescribed by the department that includes the following data elements:</p> <table border="1" data-bbox="993 1619 1403 1877"> <thead> <tr> <th>Data Element Name</th> <th>Data Element Definition</th> </tr> </thead> <tbody> <tr> <td>PBM tax identification number</td> <td>The 9-digit tax identification number used by the IRS.</td> </tr> </tbody> </table>	Data Element Name	Data Element Definition	PBM tax identification number	The 9-digit tax identification number used by the IRS.
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Data Element Name	Data Element Definition														
PBM tax identification number	The 9-digit tax identification number used by the IRS.														

		Non-proprietary drug name	The generic name of the prescription drug assigned by the USAN Council.	PBM name	The legal name of the reporting entity.
		Drug group	The first two digits of the Medi-Span® Generic Product Identifier assigned to the proprietary prescription drug	Proprietary drug name	The brand or trademark name of the prescription drug reported to the FDA.
		Brand-name or generic	Whether the prescription drug is brand-name or generic.	Non-proprietary drug name	The generic name of the prescription drug assigned by the USAN Council.
		Carrier name	The legal name of the carrier to whom rebates were distributed or passed on.	NDC	The NDC assigned to each drug product of a prescription drug.
		Total rebates	Total aggregate rebates received or negotiated directly with the manufacturer in the last calendar year, for business in the Commonwealth.	Brand-name or generic	Whether the prescription drug is brand-name or generic.
		Total rebates distributed	Total aggregate rebates distributed to the relevant health benefit plan in the last calendar year, for business in the Commonwealth.	Carrier name	The legal name of the carrier to whom rebates were distributed or passed on.
		Total rebates passed on	Total aggregate rebates passed on to all enrollees of a health benefit	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

		<p>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.</p> <p>Comments: A text field for any additional information the PBM wishes to provide.</p>	<p>the Commonwealth.</p> <p>Total rebates passed on</p> <p>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.</p> <p>Comments: A text field for any additional information the PBM wishes to provide.</p> <p>INTENT: The intent of these changed requirements since emergency stage requirements is to incorporate the minimum data required to be reported by PBMs pursuant to Va. Code § 38.2-3407.15:6 and to specify and define the data fields to be completed by the PBM so that compliance may be determined and so that the NDSO can validate and audit the data.</p> <p>RATIONALE: The rationale for these changed requirements since emergency stage requirements is that the regulations should parallel the statutory requirements, that the minimum data to be reported must facilitate the validation and auditing of data, and that providing required data field names and definitions should result in uniform reporting by PBMs.</p>
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			<p>LIKELY IMPACT: The likely impact of these changed requirements since emergency stage requirements is improved clarity for PBMs on what data is to be reported and how it should be formatted.</p>
<p>219-70</p>	<p>Same as emergency chapter-section number</p>	<p>12VAC5-219-70. Manufacturer reporting requirements. A. Every manufacturer shall report annually by April 1 to the NDSO on each of its:</p> <ol style="list-style-type: none"> 1. Brand-name prescription drug and biologic, other than a biosimilar, with: <ol style="list-style-type: none"> 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. <ol style="list-style-type: none"> 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. <p>B. For each prescription drug identified in subsection A of this section, a manufacturer shall report:</p>	<p>CHANGE: VDH is proposing to remove “drug group” as a data element and promulgate these changed requirements since emergency stage requirements:</p> <p>12VAC5-219-70. Manufacturer reporting requirements. A. Except as provided in subsection D of this section, every manufacturer shall report annually by April 1 to the NDSO on each of its:</p> <ol style="list-style-type: none"> 1. Brand-name prescription drug and biologic, other than a biosimilar, with: <ol style="list-style-type: none"> 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. <ol style="list-style-type: none"> 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

		<p>1. The name of the prescription drug;</p> <p>2. Whether the prescription drug is a brand name or generic;</p> <p>3. The effective date of the change in WAC;</p> <p>4. Aggregate, company-level research and development costs for the most recent year for which final audit data is available;</p> <p>5. The name of each of the manufacturer's new prescription drugs approved by the FDA within the previous three calendar years;</p> <p>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</p> <p>7. A concise statement regarding the factor or factors that caused the increase in WAC.</p> <p>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:</p> <table border="1" data-bbox="558 1255 954 1885"> <thead> <tr> <th>Data Element Name</th> <th>Data Element Definition</th> </tr> </thead> <tbody> <tr> <td>Manufacturer tax identification number</td> <td>The 9-digit tax identification number used by the Taxpayer.</td> </tr> <tr> <td>Manufacturer 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> </tbody> </table>	Data Element Name	Data Element Definition	Manufacturer tax identification number	The 9-digit tax identification number used by the Taxpayer.	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.	<p>WAC of such generic drug during the previous 12 months.</p> <p>B. For each prescription drug identified in subsection A of this section, a manufacturer shall report:</p> <ol style="list-style-type: none"> The name of the prescription drug; Whether the prescription drug is a brand name or generic; The effective date of the change in WAC; Aggregate, company-level research and development costs for the most recent year for which final audit data is available; The name of each of the manufacturer's new prescription drugs approved by the FDA within the previous three calendar years; 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 A concise statement regarding the factor or factors that caused the increase in WAC. <p>C. A manufacturer shall report on all drug products of a prescription drug determined to be reportable pursuant to subsection A of this section.</p> <p>D. A manufacturer that does not own the NDC of a prescription drug or does not control the WAC of a prescription drug shall report annually by April 1 to the NDSO that it has no data responsive to the requirements of this section.</p> <p>E. Except as provided in subsection D of this section, every manufacturer shall provide the information specified in subsections A and B of this section on a form prescribed by the department that includes the following data elements:</p> <table border="1" data-bbox="993 1772 1393 1885"> <thead> <tr> <th>Data Element Name</th> <th>Data Element Definition</th> </tr> </thead> <tbody> <tr> <td></td> <td></td> </tr> </tbody> </table>	Data Element Name	Data Element Definition		
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Manufacturer tax identification number	The 9-digit tax identification number used by the Taxpayer.														
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.														
Data Element Name	Data Element Definition														

		Non-proprietary drug name	The generic name of the prescription drug assigned by the USAN Council.	Manufacturer tax identification number	The 9-digit tax payer Identification Number (TIN) used by the IRS.
		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.	Manufacturer name	The legal name of the reporting entity.
		Drug group	The first two digits of the Medi-Span® Generic Product Identifier assigned to the prescription drug.	Proprietary drug name	The brand or trademark name of the prescription drug reported to the FDA.
		Brand-name drug or generic drug	Whether the report is about a brand-name drug or generic drug.	Non-proprietary drug name	The generic name of the prescription drug assigned by the USAN Council.
		Subject to generic competition	The month and year of initial generic competition.	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.
		Date of initial generic competition	The year of market introduction of the prescription drug.	NDC	The NDC assigned to each drug product of a prescription drug.
		WAC at market introduction	The manufacturer's list price to wholesalers or direct purchasers in	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.

		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.	Date of initial generic competition	The year of market introduction of the prescription drug.
	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 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 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,	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.

		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.	Effective date of change in WAC	The month and year that the WAC changed.
	Year of research and development costs	The year in which final audit data is available.	Justification for current-year WAC increase	The reason or reasons that the manufacturer increased the WAC of the prescription drug compared with last year.
	Comments	A text field for any additional information the manufacturer wishes to provide.	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.
	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		Year of research and development costs	The year in which final audit data is available.

		<p>Commission Form 10-K or any other public disclosure.</p>	<p>Comments : A text field for : : any additional : : information the : : manufacturer : : wishes to : : provide. : -----</p> <p>F. To satisfy the reporting requirements of this section, a manufacturer may submit information and data that a manufacturer includes in its annual consolidation report on the U.S. Securities and Exchange Commission Form 10-K or any other public disclosure.</p> <p>INTENT: The intent of these changed requirements since emergency stage requirements is to incorporate the minimum data required to be reported by manufacturers pursuant to Va. Code § 54.1-3442.02; to specify and define the data fields to be completed by the manufacturer so that compliance may be determined and so that the NDSO can validate and audit the data, if the manufacturer chooses to not utilize the flexibility provided for in the proposed subsection F; and to address concerns from commenters about manufacturers who do not have data to report because they do not control the WAC.</p> <p>RATIONALE: The rationale for these changed requirements since emergency stage requirements is that the regulations should parallel the statutory requirements; that providing required data field names and definitions should result in uniform reporting by manufacturers, if the manufacturer chooses to not utilize the flexibility provided for in the proposed subsection F; that the minimum data to be reported must facilitate the validation and auditing of data; and that regulatory flexibility should be afforded to the extent permitted under law.</p>
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			<p>LIKELY IMPACT: The likely impact of these changed requirements since emergency stage requirements is improved clarity for manufacturers on what data is to be reported and how it should be formatted.</p>
<p>219-80</p>	<p>Same as emergency chapter-section number</p>	<p>12VAC5-219-80. Wholesale distributor reporting requirements. A. For the purposes of this section, "cost" means the expense incurred and the monetary value of the resources used or consumed in the provision of a prescription drug by a wholesale drug distributor. B. If the department determines that data received from carriers, PBMs, and manufacturers is insufficient, the department may request wholesale distributors to report the information specific in subsection B of this section. 1. The department shall publish a general notice in the Virginia Register that contains its determination, the request for wholesale distributors reporting, and the deadline for wholesale distributors to report pursuant to subsection B of this section. 2. The NDSO shall notify every wholesale distributor of the department's determination and request by electronic mail at its electronic mailing address of record. C. If requested by the department pursuant to subsection B of this section and no more than 45 calendar days after the publication of the general notice pursuant to subdivision B 1 of this section, a wholesale distributor shall report for the 25 costliest prescription drugs dispensed in the Commonwealth, including each drug product of a reportable prescription drug: 1. The WAC directly negotiated with a manufacturer in the last calendar year;</p>	<p>CHANGE: VDH is proposing to remove "drug group" as a data element and promulgate these changed requirements since emergency stage requirements:</p> <p>12VAC5-219-80. Wholesale distributor reporting requirements. A. For the purposes of this section, "cost" means the expense incurred and the monetary value of the resources used or consumed in the provision of a prescription drug by a wholesale drug distributor. B. If the department determines that data received from carriers, PBMs, and manufacturers is insufficient, the department may request wholesale distributors to report the information specific in subsection B of this section. 1. The department shall publish a general notice in the Virginia Register that contains its determination, the request for wholesale distributors reporting, and the deadline for wholesale distributors to report pursuant to subsection B of this section. 2. The NDSO shall notify every wholesale distributor of the department's determination and request by electronic mail at its electronic mailing address of record. C. If requested by the department pursuant to subsection B of this section and no more than 45 calendar days after the publication of the general notice pursuant to subdivision B 1 of this section, a wholesale distributor shall report for the 25 costliest prescription drugs dispensed in the Commonwealth, including each drug product of a reportable prescription drug:</p>

		<p>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.</p> <p>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.</p> <p>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:</p> <table border="1" data-bbox="553 982 969 1885"> <thead> <tr> <th>Data Element Name</th> <th>Data Element Description</th> </tr> </thead> <tbody> <tr> <td>Wholesale distributor tax identification number</td> <td>The 9-digit tax taxpayer identification number used by the IRS.</td> </tr> <tr> <td>Wholesale distributor name</td> <td>The legal name of the reporting entity.</td> </tr> <tr> <td>Proprietary drug name</td> <td>The brand or trademark name of the prescription drug reported to the FDA.</td> </tr> <tr> <td>Non-proprietary drug name</td> <td>The generic name of the prescription drug assigned by the USAN Council.</td> </tr> <tr> <td>WAC unit</td> <td>The lowest identifiable quantity of the prescription</td> </tr> </tbody> </table>	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	<p>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.</p> <p>D. In determining which prescription drugs are reportable under subsection C of this section, the wholesale distributor shall average the cost for all drug products of a dispensed prescription drug.</p> <p>E. A wholesale manufacturer shall report on all drug products of a prescription drug determined to be reportable pursuant to subsections C and D of this section.</p> <p>F. Every wholesale distributor shall provide the information specified in subsection C of this section on a form prescribed by the department that includes the following data elements:</p> <table border="1" data-bbox="992 1226 1408 1885"> <thead> <tr> <th>Data Element Name</th> <th>Data Element Description</th> </tr> </thead> <tbody> <tr> <td>Wholesale distributor tax identification number</td> <td>The 9-digit tax taxpayer identification number used by the IRS.</td> </tr> <tr> <td>Wholesale distributor name</td> <td>The legal name of the reporting entity.</td> </tr> <tr> <td>Proprietary drug name</td> <td>The brand or trademark name of the prescription drug reported to the FDA.</td> </tr> <tr> <td>Non-proprietary drug name</td> <td>The generic name of the prescription</td> </tr> </tbody> </table>	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
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		drug that is dispensed, exclusive of any diluent without reference to volume measures pertaining to liquids.		drug assigned by the USAN Council.
	Drug group	The first two digits of the Medi-Span® Generic Product Identifier assigned to the prescription drug.	WAC unit	The lowest identifiable quantity of the prescription drug that is dispensed, exclusive of any diluent without reference to volume measures pertaining to liquids.
	Current year 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.	NDC	The NDC assigned to each drug product of a prescription drug.
	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.	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.
	Total manufacturer discounts	Total aggregate discounts for each	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

		<p>prescription drug directly negotiated with a manufacturer in the last calendar year, for business in the Commonwealth.</p> <p>Total pharmacy discounts, dispensing fees, and other fees</p> <p>Comments</p> <p>F. The commissioner, the department, and the NDSO may not disclose:</p> <ol style="list-style-type: none"> 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. 	<p>issued in the Commonwealth.</p> <p>Total manufacturer discounts</p> <p>Total pharmacy discounts, dispensing fees, and other fees</p> <p>Comments</p> <p>G. The commissioner, the department, and the NDSO may not disclose:</p> <ol style="list-style-type: none"> 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. <p>INTENT: The intent of these new requirements is to incorporate the minimum data required to be reported by wholesale distributors pursuant to Va. Code § 54.1-3436.1 if required and to specify and define the data fields to be</p>
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			<p>completed by the wholesale distributors so that compliance may be determined and so that the NDSO can validate and audit the data by the wholesale distributor.</p> <p>RATIONALE: The rationale for these new requirements is that the regulations should parallel the statutory requirements, that the minimum data to be reported must facilitate the validation and auditing of data, and that providing required data field names and definitions should result in uniform reporting by wholesale distributors.</p> <p>LIKELY IMPACT: The likely impact of these new requirements is improved clarity for wholesale distributors on what data is to be reported, how it should be formatted, and how VDH will notify wholesale distributors that data reporting is required.</p>
<p>219-90</p>	<p>Same as emergency chapter-section number</p>	<p>12VAC5-219-90. Method of report submission. A. A reporting entity shall submit any report required by Part II (12VAC5-219-50 et seq.) of this chapter to the NDSO through the NDSO's online collection tool. B. A reporting entity shall submit any required report by uploading electronic spreadsheet files, or other methods as determined by the NDSO, that include all required information for each report and that comply with the NDSO's Prescription Drug Price Transparency Regulation (12VAC5-219-10) Submission Manual, Version 1.0. C. The NDSO shall notify each reporting entity in writing at least 30 calendar days before any change in the report collection method.</p>	<p>CHANGE: VDH is proposing to promulgate these changed requirements since emergency stage:</p> <p>12VAC5-219-90. Method of report submission. A. A reporting entity shall submit any report required by Part II (12VAC5-219-50 et seq.) of this chapter to the NDSO through the NDSO's online collection tool. B. A reporting entity shall submit any required report by uploading electronic spreadsheet files, or other methods as determined by the NDSO, that include all required information for each report and that comply with the NDSO's Prescription Drug Price Transparency Regulation (12VAC5-219-10) Submission Manual, Version 1.1. C. The NDSO shall notify each reporting entity in writing at least 30 calendar days before any change in the report collection method.</p> <p>INTENT: The intent of these changed requirements since</p>

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

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Office of Regulatory Management
Economic Review Form

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 24, 2022

Cost Benefit Analysis

Table 1a: Costs and Benefits of the Proposed Changes (Primary Option)

<p>(1) Direct Costs & Benefits</p>	<p>Chapter 304 (2021 Act of Assembly, Special Session I) mandates that health carriers, manufacturers, and pharmacy benefit managers (PBMs) report annually the cost of prescription drugs that meet the statutory reporting thresholds to the non-profit data services organization with whom the Virginia Department of Health (VDH) has a contract. Wholesale distributors may be required to report, but only if the data provided by health carriers, manufacturers, and PBMs is insufficient.</p> <ul style="list-style-type: none"> In the proposed stage, VDH is proposing to make permanent the majority of the previously promulgated emergency regulations, except for some minor changes to the definitions of 12VAC5-416, replacing a proprietary data element with a nonproprietary one, adding a data element so a reporter would indicate what reporting threshold a prescription drug was tied to, providing clarification to mandated reporters that all drug products (strengths, formulations, etc.) were reportable, and updating the version number of the submission manual. <p>Direct Costs: Regulators with an annual reporting obligation are estimated to have an annual cost not to exceed \$2,500 for reporting, recordkeeping and other administrative costs required for compliance. VDH will incur an annual cost of \$275,000 under its contract with the non-profit data services organization for collection, compilation, and publication of data collected.</p> <p>Direct Benefits: VDH is not aware of any quantifiable direct benefits at this time.</p>	
<p>(2) Quantitative Factors</p>	<p>Estimated Dollar Amount</p>	<p>Present Value</p>

Direct Costs	(a) \$11,925,000	(c) \$10,477,435	
Direct Benefits	(b) \$0	(d) \$0	
(3) Benefits-Costs Ratio	0.00	(4) Net Benefit	-\$10,477,435
(5) Indirect Costs & Benefits	<p>VDH is not aware of any quantifiable indirect cost to regulants, due to the low cost of compliance per regulant, especially as many of these are already subject to prescription drug price transparency requirements in other states. Indirect costs related to price modifications, if any, would have already been incurred as part of compliance with prescription drug price transparency requirements in other states that predate Virginia’s program. VDH will incur an indirect cost of \$43,801 annually for a wage position to determine compliance, assess and collect penalties for non-compliance, and provide administrative support for any resulting proceedings under the Administrative Process Act.</p> <p>VDH is not aware of any quantifiable indirect benefits.</p>		
(6) Information Sources	<p>National Academy for State Health Policy; Oregon Department of Consumer and Business Services; Maine Health Data Organization; Washington State Health Care Authority; Virginia Health Information; Ten2Eleven Business Solutions, LLC</p>		
(7) Optional	<p>VDH has numerous challenges and constraints that limit a cost benefit analysis, including limited data availability, limited statutory discretion, and insufficient analytical models.</p> <p>The qualitative benefits of the regulatory change are increased knowledge of and transparency for prescription drug pricing and the factors that influence consumer healthcare costs, which in turn can be used by policymakers to help make better informed decisions that affect healthcare costs in the Commonwealth, such as, potentially, the creation of a prescription drug affordability board or allowing the purchase of prescription drugs from Canada. Additionally, states that already have prescription drug price transparency requirements have noted a trend in which fewer prescription drugs have experienced price increases that would trigger reporting, which may indicate that the pharmaceutical industry is moderating its year-over-year price increases in response to the reporting requirements; however, launch prices and overall spending on prescription drugs have continued to increase.</p>		

Table 1b: Costs and Benefits under the Status Quo (No change to the regulation)

<p>(1) Direct Costs & Benefits</p>	<p>Chapter 304 (2021 Act of Assembly, Special Session I) mandates that health carriers, manufacturers, and pharmacy benefit managers (PBMs) report annually the cost of prescription drugs that meet the statutory reporting thresholds to the non-profit data services organization with whom the Virginia Department of Health (VDH) has a contract. Wholesale distributors may be required to report, but only if the data provided by health carriers, manufacturers, and PBMs is insufficient.</p> <ul style="list-style-type: none"> The current emergency regulations incorporate those statutory requirements and address the mandate that the data collected by audited. <p>Direct Costs: Regulators with an annual reporting obligation are estimated to have an annual cost not to exceed \$2,500 for reporting, recordkeeping and other administrative costs required for compliance. VDH will incur an annual cost of \$275,000 under its contract with the non-profit data services organization for collection, compilation, and publication of data collected.</p> <p>Direct Benefits: VDH is not aware of any quantifiable direct benefits at this time.</p>		
<p>(2) Quantitative Factors</p>	<p>Estimated Dollar Amount</p>	<p>Present Value</p>	
<p>Direct Costs</p>	<p>(a) \$11,925,000</p>	<p>(c) \$10,477,435</p>	
<p>Direct Benefits</p>	<p>(b) \$0</p>	<p>(d) \$0</p>	
<p>(3) Benefits-Costs Ratio</p>	<p>0.00</p>	<p>(4) Net Benefit</p>	<p>-\$10,477,435</p>
<p>(5) Indirect Costs & Benefits</p>	<p>VDH is not aware of any quantifiable indirect cost to regulators, due to the low cost of compliance per regulator, especially as many of these are already subject to prescription drug price transparency requirements in other states. Indirect costs related to price modifications, if any, would have already been incurred as part of compliance with prescription drug price transparency requirements in other states that predate Virginia's program. VDH will incur an indirect cost of \$43,801 annually for a wage position to determine compliance, assess and collect penalties for non-compliance, and provide administrative support for any resulting proceedings under the Administrative Process Act.</p>		

	VDH is not aware of any quantifiable indirect benefits.
(6) Information Sources	National Academy for State Health Policy; Oregon Department of Consumer and Business Services; Maine Health Data Organization; Washington State Health Care Authority; Virginia Health Information; Ten2Eleven Business Solutions, LLC
(7) Optional	<p>VDH has numerous challenges and constraints that limit a cost benefit analysis, including limited data availability, limited statutory discretion, and insufficient analytical models.</p> <p>The qualitative benefits of the regulatory change are increased knowledge of and transparency for prescription drug pricing and the factors that influence consumer healthcare costs, which in turn can be used by policymakers to help make better informed decisions that affect healthcare costs in the Commonwealth, such as, potentially, the creation of a prescription drug affordability board or allowing the purchase of prescription drugs from Canada. Additionally, states that already have prescription drug price transparency requirements have noted a trend in which fewer prescription drugs have experiencing price increases that would trigger reporting, which may indicate that the pharmaceutical industry is moderating its year-over-year price increases in response to the reporting requirements; however, launch prices and overall spending on prescription drugs have continued to increase.</p>

Table 1c: Costs and Benefits under an Alternative Approach

(1) Direct Costs & Benefits	<p>Chapter 304 (2021 Acts of Assembly, Special Session I) requires annual reporting by health carriers, manufacturers, and PBMs and requires the promulgation of regulations. Therefore, VDH does not have the authority to offer an alternative in lieu of regulation, nor does it have the authority to approve information disclosure requirements or performance standards in lieu of the mandatory reporting requirements.</p> <ul style="list-style-type: none"> The only alternative that VDH could potentially offer would be to remove specificity from the regulation about the minimum data elements to be provided. <p>Direct Costs: Regulators with an annual reporting obligation are estimated to have an annual cost not to exceed \$2,500 for reporting, recordkeeping and other administrative costs required for compliance. If there were less specificity about the minimum data elements to be provided, a portion of regulators would likely incur additional costs from having to supplement or correct incomplete</p>
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	<p>reports, which VDH conservatively estimates to cost \$250 and involve 15% of regulants. VDH will incur an annual cost of \$275,000 under its contract with the non-profit data services organization for collection, compilation, and publication of data collected.</p> <p>Direct Benefits: VDH is not aware of any quantifiable direct benefits at this time.</p>		
(2) Quantitative Factors	Estimated Dollar Amount	Present Value	
Direct Costs	(a) \$12,065,000	(c) \$10,600,440	
Direct Benefits	(b) \$0	(d) \$0	
(3) Benefits-Costs Ratio	0.00	(4) Net Benefit	-\$10,600,440
(5) Indirect Costs & Benefits	<p>VDH is not aware of any quantifiable indirect cost to regulants, due to the low cost of compliance per regulant, especially as many of these are already subject to prescription drug price transparency requirements in other states. Indirect costs related to price modifications, if any, would have already been incurred as part of compliance with prescription drug price transparency requirements in other states that predate Virginia’s program. VDH will incur an indirect cost of \$43,801 annually for a wage position to determine compliance, assess and collect penalties for non-compliance, and provide administrative support for any resulting proceedings under the Administrative Process Act.</p> <p>VDH is not aware of any quantifiable indirect benefits.</p>		
(6) Information Sources	<p>National Academy for State Health Policy; Oregon Department of Consumer and Business Services; Maine Health Data Organization; Washington State Health Care Authority; Virginia Health Information; Ten2Eleven Business Solutions, LLC</p>		
(7) Optional	<p>VDH has numerous challenges and constraints that limit a cost benefit analysis, including limited data availability, limited statutory discretion, and insufficient analytical models.</p> <p>The qualitative benefits of the regulatory change are increased knowledge of and transparency for prescription drug pricing and the factors that influence consumer healthcare costs, which in turn can be used by policymakers to help make better informed decisions that affect healthcare costs in the Commonwealth, such as, potentially, the creation of a prescription drug</p>		

	<p>affordability board or allowing the purchase of prescription drugs from Canada. Additionally, states that already have prescription drug price transparency requirements have noted a trend in which fewer prescription drugs have experiencing price increases that would trigger reporting, which may indicate that the pharmaceutical industry is moderating its year-over-year price increases in response to the reporting requirements; however, launch prices and overall spending on prescription drugs have continued to increase.</p>
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Impact on Local Partners

Table 2: Impact on Local Partners

(1) Direct Costs & Benefits	Local partners will not be affected by direct costs or benefits of the regulatory change as they are not subject to the mandates contained in Chapter 304 (2021 Acts of Assembly, Special Session I) and thus will incur no direct cost or benefit.
(2) Quantitative Factors	Estimated Dollar Amount
Direct Costs	(a) \$0
Direct Benefits	(b) \$0
(3) Indirect Costs & Benefits	VDH is not aware of any quantifiable indirect costs or benefits for local partners. To the extent that prescription drug price increases may be moderated, VDH cannot quantify that indirect benefit at this time.
(4) Information Sources	See response to (1) of this Table.
(5) Assistance	N/A
(6) Optional	<p>VDH has numerous challenges and constraints that limit a cost benefit analysis, including limited data availability, limited statutory discretion, and insufficient analytical models.</p> <p>The qualitative benefits of the regulatory change are increased knowledge of and transparency for prescription drug pricing and the factors that influence consumer healthcare costs, which in turn can be used by local partners to make better informed decisions that affect healthcare costs in the</p>

	Commonwealth. Additionally, states that already have prescription drug price transparency requirements have noted a trend in which fewer prescription drugs have experiencing price increases that would trigger reporting, which may indicate that the pharmaceutical industry is moderating its year-over-year price increases in response to the reporting requirements; however, launch prices and overall spending on prescription drugs have continued to increase.
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Economic Impacts on Families

Table 3: Impact on Families

(1) Direct Costs & Benefits	Families will not be affected by direct costs or benefits of the regulatory change as they are not subject to the mandates contained in Chapter 304 (2021 Acts of Assembly, Special Session I) and thus will incur no direct cost or benefit.
(2) Quantitative Factors	Estimated Dollar Amount
Direct Costs	(a) \$0
Direct Benefits	(b) \$0
(3) Indirect Costs & Benefits	VDH is not aware of any quantifiable indirect costs or benefits for families. To the extent that prescription drug price increases may be moderated, VDH cannot quantify that indirect benefit at this time.
(4) Information Sources	See response to (1) of this Table.
(5) Optional	<p>VDH has numerous challenges and constraints that limit a cost benefit analysis, including limited data availability, limited statutory discretion, and insufficient analytical models.</p> <p>The qualitative benefits of the regulatory change are increased knowledge of and transparency for prescription drug pricing and the factors that influence consumer healthcare costs, which in turn can be used by local partners to make better informed decisions that affect healthcare costs in the Commonwealth. Additionally, states that already have prescription drug price transparency requirements have noted a trend in which fewer prescription drugs have experiencing price increases that would trigger reporting, which may indicate that the pharmaceutical industry is moderating its year-over-year price increases in response to the reporting requirements;</p>

	however, launch prices and overall spending on prescription drugs have continued to increase.
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Impacts on Small Businesses

Table 4: Impact on Small Businesses

(1) Direct Costs & Benefits	<p>Direct Costs: Regulants with an annual reporting obligation are estimated to have an annual cost not to exceed \$2,500 for reporting, recordkeeping and other administrative costs required for compliance. VDH speculate that they may be at most 50 small businesses affected (and possibly none), though health carriers, manufacturers, and PBMs are not required to disclose nor have any volunteered whether they qualify as “small businesses” within the meaning of Code of Virginia § 2.2-4007.1. VDH will incur an annual cost of \$275,000 under its contract with the non-profit data services organization for collection, compilation, and publication of data collected; assuming there are 50 small business impacted, 14% of the \$275,000 is attributable to small businesses or \$37,466.</p> <p>Direct Benefits: VDH is not aware of any quantifiable direct benefits at this time.</p>
(2) Quantitative Factors	Estimated Dollar Amount
Direct Costs	(a) 1,624,660
Direct Benefits	(b) \$0
(3) Indirect Costs & Benefits	<p>VDH is not aware of any quantifiable indirect cost to small businesses, due to the low cost of compliance per regulant, especially as many of these are already subject to prescription drug price transparency requirements in other states. Indirect costs related to price modifications, if any, would have already been incurred as part of compliance with prescription drug price transparency requirements in other states that predate Virginia’s program. VDH will incur an indirect cost of \$43,801 annually for a wage position to determine compliance, assess and collect penalties for non-compliance, and provide administrative support for any resulting proceedings under the Administrative Process Act; assuming there are 50 small business impacted, 14% of the \$43,801 is attributable to small businesses or \$5,967.</p> <p>VDH is not aware of any quantifiable indirect benefits.</p>

(4) Alternatives	Chapter 304 (2021 Acts of Assembly, Special Session I) requires annual reporting by health carriers, manufacturers, and PBMs and does not grant VDH the authority to exempt or excuse small businesses from these statutory mandates. However, VDH did build some flexibility into the regulation for all regulants in that individual regulants may ask for a variance that would allow for an individualized alternative to enable compliance with the purpose of a specific regulatory standard, if compliance would otherwise be economically burdensome and be an impractical hardship unique to the regulant.
(5) Information Sources	National Academy for State Health Policy; Virginia Health Information; Ten2Eleven Business Solutions, LLC
(6) Optional	<p>VDH has numerous challenges and constraints that limit a cost benefit analysis, including limited data availability, limited statutory discretion, and insufficient analytical models.</p> <p>The qualitative benefits of the regulatory change are increased knowledge of and transparency for prescription drug pricing and the factors that influence consumer healthcare costs, which in turn can be used by local partners to make better informed decisions that affect healthcare costs in the Commonwealth. Additionally, states that already have prescription drug price transparency requirements have noted a trend in which fewer prescription drugs have experiencing price increases that would trigger reporting, which may indicate that the pharmaceutical industry is moderating its year-over-year price increases in response to the reporting requirements; however, launch prices and overall spending on prescription drugs have continued to increase.</p>

Changes to Number of Regulatory Requirements

Table 5: Total Number of Requirements

	Number of Requirements			
Chapter number	Initial Count	Additions	Subtractions	Net Change
416	151	10	0	10

1 **Project 6828 - Emergency/NOIRA**

2 **Department of Health**

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

5 Chapter 219

6 Prescription Drug Price Transparency Regulation

7 Part I

8 General Information and Requirements

9 **12VAC5-219-10. Definitions.**

10 The following words and terms when used in this chapter have the following meanings unless
11 the context clearly indicates otherwise:

12 "Biologic" means a therapeutic drug, made from a living organism such as human, animal,
13 yeast or microorganisms, which is licensed under a Biologic License Application by the FDA.

14 "Biosimilar" has the same meaning as ascribed to the term in § 54.1-3442.02 of the Code of
15 Virginia.

16 "Brand-name drug" has the same meaning as ascribed to the term in §§ 54.1-3436.1 and
17 54.1-3442.02 of the Code of Virginia.

18 "Carrier" has the same meaning as ascribed to the term in § 38.2-3407.10 of the Code of
19 Virginia.

20 "Commissioner" means the State Health Commissioner.

21 "Department" means the Virginia Department of Health.

22 "Discount" means any price concessions, however characterized, offered or provided by a
23 reporting entity for a prescription drug, including rebates and reductions in price, that has the
24 effect of reducing the cost of a prescription drug for a consumer.

25 "Drug product" means a finished dosage form, such as a tablet or solution, that contains a
26 prescription generally, but not necessarily, in association with inactive ingredients and that has
27 been issued a National Drug Code by the FDA.

28 "Enrollee" has the same meaning as ascribed to the term in § 38.2-3407.10 of the Code of
29 Virginia.

30 "FDA" means the U.S. Food and Drug Administration.

31 "Generic drug" has the same meaning as ascribed to the term in § 54.1-3436.1 of the Code
32 of Virginia.

33 "Health benefit plan" has the same meaning as ascribed to the term in § 38.2-3438 of the
34 Code of Virginia.

35 "IRS" means the U.S. Internal Revenue Service.

36 "Launched" means the month and year on which a manufacturer first marketed a prescription
37 drug for sale in the Commonwealth.

38 "Manufacturer" has the same meaning as ascribed to the term in § 54.1-3401 of the Code of
39 Virginia.

40 "National Drug Code" or "NDC" means a unique numeric code assigned by the FDA for each
41 finished drug product or unfinished drug subject to the listing requirements of 21 CFR Part 207.

42 "New prescription drug" has the same meaning as ascribed to the term in § 54.1-3442.02 of
43 the Code of Virginia.

44 "Nonprofit data services organization" or "NDSO" has the same meaning as ascribed to the
45 term in § 32.1-23.4 of the Code of Virginia.

46 "Outpatient prescription drug" means a prescription drug that may be obtained only by
47 prescription and dispensed by a pharmacy licensed to dispense prescription drugs in Virginia,
48 including from a retail, outpatient, mail order, or other delivery setting. Outpatient prescription drug
49 excludes prescription drugs provided as part of or incident to and in the same setting as inpatient
50 and outpatient hospital services, hospice services, and dental services.

51 "Pharmacy benefits management" has the same meaning as ascribed to the term in § 38.2-
52 3407.15:4 of the Code of Virginia.

53 "Pharmacy benefits manager" or "PBM" has the same meaning as ascribed to the term in §
54 38.2-3407.15:4 of the Code of Virginia.

55 "Premium" means the amount members pay to a carrier or health benefit plan for their medical
56 and prescription drug insurance.

57 "Prescription drug" has the same meaning as ascribed to the term in § 54.1-3401 of the Code
58 of Virginia. "Prescription drug" includes biologics and biosimilars for which a prescription is
59 needed.

60 "Rebate" has the same meaning as ascribed to the term in § 38.2-3407.22 of the Code of
61 Virginia.

62 "Reporting entity" means carriers, PBMs, wholesale distributors, and manufacturers.

63 "Specialty drug" means a prescription drug that:

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

67 2. Is:

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

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

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

75 A prescription drug appearing on Medicare Part D's specialty tier is presumed to be a specialty
76 drug.

77 "Spending" means the amount of money, expressed in United States dollars, expended after
78 discounts.

79 "Therapeutically equivalent" means a generic drug that is:

80 1. Approved as safe and effective;

81 2. Adequately labeled;

82 3. Manufactured in compliance with 21 CFR Part 210, 21 CFR Part 211, and 21 CFR Part
83 212; and

84 4. Either:

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

86 (1) Contains identical amounts of the identical active drug ingredient in the identical
87 dosage form and route of administration; and

88 (2) Meets compendial or other applicable standards of strength, quality, purity, and
89 identity; or

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

91 (1) It does not present a known or potential bioequivalence problem, and they meet
92 an acceptable in vitro standard; or

93 (2) If it does present such a known (or) potential problem, it is shown to meet an
94 appropriate bioequivalence standard.

95 "USAN Council" means the United States Adopted Names Council.

96 "Utilization management" means strategies, including drug utilization review, prior
97 authorization, step therapy, quantity or dose limits, and comparative effectiveness reviews, to
98 reduce a patient's exposure to inappropriate drugs and lower the cost of treatment.

99 "Wholesale acquisition cost" or "WAC" has the same meaning as ascribed to the term in §§
100 54.1-3436.1 and 54.1-3442.02 of the Code of Virginia.

101 "Wholesale distributor" has the same meaning as ascribed to the term in § 54.1-3401 of the
102 Code of Virginia.

103 "30-day equivalent supply" means the total daily dosage units of a prescription drug
104 recommended by its prescribing label as approved by the FDA for 30 days or fewer. If there is
105 more than one such recommended daily dosage, the largest recommended daily dosage will be
106 considered for purposes of determining a 30-day equivalent supply. "30-day equivalent supply"
107 includes a 30-day supply and a single course of treatment under subsection B of § 54.1-3442.02
108 of the Code of Virginia.

109 **Statutory Authority**

110 § 32.1-23.4 of the Code of Virginia.

111 **12VAC5-219-20. Registration.**

112 A. Each reporting entity shall furnish to and maintain with the NDSO:

- 113 1. Its legal name and any fictitious names under which it operates;
- 114 2. Its current mailing address of record; and
- 115 3. Its current electronic mailing address of record.

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

118 C. Each reporting entity shall notify the NDSO of its business closing, discontinuation of
119 business as a carrier, PBM, manufacturer, or wholesale distributor, or acquisition at least 30 days
120 prior to such closure, discontinuation, or acquisition.

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

- 125 a. Its business will close;
- 126 b. Its business as a carrier, PBM, manufacturer, or wholesale distributor will be
127 discontinued; or
- 128 c. Its acquisition will result in the discontinuation of its business as a carrier, PBM,
129 manufacturer, or wholesale distributor.

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

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

134 **Statutory Authority**

135 § 32.1-23.4 of the Code of Virginia.

136 **12VAC5-219-30. Notice.**

137 A. The NDSO shall send to the reporting entity at the last known electronic mailing address
138 of record:

139 1. An annual notice on or before March 1 regarding its reporting obligations under Part II
140 (12VAC5-219-50 et seq.) of this chapter. Failure to receive this notice does not relieve the
141 reporting entity of the obligation to timely report;

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

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

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

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

151 **Statutory Authority**

152 § 32.1-23.4 of the Code of Virginia.

153 **12VAC5-219-40. Allowable variances.**

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

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

157 C. The department, the NDSO, or a reporting entity may request a variance at any time by
158 filing the request in writing with the commissioner. The request for a variance shall include:

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

160 2. The nature and duration of the variance requested;

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

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

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

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

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

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

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

173 1. Shall identify:

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

175 b. To whom the variance applies; and

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

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

179 G. The requester shall comply with the standard or requirement to which a variance has been
180 requested unless a variance has been granted.

181 H. The commissioner may rescind or modify a variance if:

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

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

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

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

189 I. If a variance is denied, expires, or is rescinded, the commissioner, the department, or the
190 NDSO, as applicable, shall enforce the standard or requirement to which the variance was
191 granted.

192 **Statutory Authority**

193 § 32.1-23.4 of the Code of Virginia.

194 Part II

195 Reporting Requirements

196 **12VAC5-219-50. Carrier reporting requirements.**

197 A. Every carrier offering a health benefit plan shall report annually by April 1 to the NDSO the
198 information required in this subsection on total annual spending on prescription drugs, before
199 enrollee cost sharing, for each health benefit plan offered by the carrier in the Commonwealth:

200 1. For covered outpatient prescription drugs that were prescribed to enrollees during the
201 immediately preceding calendar year:

202 a. The names of the 25 most frequently prescribed outpatient prescription drugs;

- 203 b. The names of the 25 outpatient prescription drugs covered at the greatest cost,
 204 calculated using the total annual spending by such health benefit plan for each
 205 outpatient prescription drug covered by the health benefit plan; and
 206 c. The names of the 25 outpatient prescription drugs that experienced the greatest
 207 year-over-year increase in cost, calculated using the total annual spending by a health
 208 benefit plan for each outpatient prescription drug covered by the health benefit plan;
 209 2. The percent increase in annual net spending for prescription drugs after accounting for
 210 aggregated discounts;
 211 3. The percent increase in premiums that were attributable to each health care service,
 212 including prescription drugs;
 213 4. The percentage of specialty drugs with utilization management requirements; and
 214 5. The premium reductions that were attributable to specialty drug utilization management.
 215 B. In determining which outpatient prescription drugs are reportable under subdivision A 1 of
 216 this section, the carrier shall:
 217 1. Average the frequency of prescription for all drug products of an outpatient prescription
 218 drug for such health benefit plan to determine which outpatient prescription drugs are
 219 reportable under subdivision A 1 a of this section;
 220 2. Average the cost, calculated using the total annual spending by such health benefit plan
 221 for all drug products of an outpatient prescription drug covered by the health benefit plan,
 222 to determine which outpatient prescription drugs are reportable under subdivision A 1 b of
 223 this section; and
 224 3. Average the year-over-year increase in cost, calculated using the total annual spending
 225 by a health benefit plan for all drug products of an outpatient prescription drug covered by
 226 the health benefit plan, to determine which outpatient prescription drugs are reportable
 227 under subdivision A 1 c of this section.
 228 C. When submitting a report pursuant to this section, a carrier:
 229 1. May not disclose the identity of a specific health benefit plan or the price charged for a
 230 specific prescription drug or class of prescription drugs;
 231 2. Shall use a health benefit plan unique identifier as described in subsection E of this
 232 section in lieu of the health benefit plan's identity; and
 233 3. Shall report on all drug products of an outpatient prescription drug determined to be
 234 reportable pursuant to subsections A and B of this section.
 235 D. Every carrier offering a health benefit plan shall require each PBM with which it enters into
 236 a contract for pharmacy benefits management to comply with 12VAC5-219-60.
 237 E. Every carrier shall provide the information specified in subsections A and B of this section
 238 on a form prescribed by the department that includes the following data elements:

<u>Data Element</u> <u>Name</u>	<u>Data Element Definition</u>
<u>Carrier tax</u> <u>identification</u> <u>number</u>	<u>The nine-digit tax Taxpayer Identification Number used by the IRS.</u>
<u>Carrier name</u>	<u>The legal name of the reporting entity.</u>
<u>Health benefit plan</u> <u>category</u>	<u>The two-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).</u>

<u>Health benefit plan unique identifier</u>	<u>A unique five-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.</u>
<u>Proprietary drug name</u>	<u>The brand or trademark name of the prescription drug reported to the FDA.</u>
<u>Non-proprietary drug name</u>	<u>The generic name of the prescription drug assigned by the USAN Council.</u>
<u>WAC unit</u>	<u>The lowest identifiable quantity of the prescription drug that is dispensed, exclusive of any diluent without reference to volume measures pertaining to liquids.</u>
<u>NDC</u>	<u>The NDC assigned to each drug product of an outpatient prescription drug.</u>
<u>Brand-name or generic</u>	<u>Whether the prescription drug is brand-name or generic.</u>
<u>Inclusion criteria</u>	<u>The criteria, as specified in subdivision A 1 of this section, that resulted in the outpatient prescription drug being determined to be reportable.</u>
<u>Net spending increase</u>	<u>The percent year-over-year increase in annual net spending for prescription drugs after accounting for aggregated discounts or other reductions in price.</u>
<u>Premium increase</u>	<u>The percent year-over-year increase in premiums that were attributable to each health care service, including prescription drugs.</u>
<u>Specialty drugs with utilization management</u>	<u>The percentage of specialty drugs with utilization management requirements.</u>
<u>Premium reductions</u>	<u>The percent year-over-year of premium reductions that were attributable to specialty drug utilization management.</u>
<u>Comments</u>	<u>A text field for any additional information the carrier wishes to provide.</u>

239 **Statutory Authority**

240 § 32.1-23.4 of the Code of Virginia.

241 **12VAC5-219-60. Pharmacy benefits manager reporting requirements.**

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

- 245 1. The aggregate amount of rebates received by the PBM;
 246 2. The aggregate amount of rebates distributed to the relevant health benefit plan; and
 247 3. The aggregate amount of rebates passed on to enrollees of each health benefit plan at
 248 the point of sale that reduced the enrollees' applicable deductible, copayment,
 249 coinsurance, or other cost-sharing amount.

250 B. A PBM shall report on all drug products of a prescription drug determined to be reportable
 251 pursuant to subsection A of this section.

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

<u>Data Element Name</u>	<u>Data Element Definition</u>
<u>PBM tax identification number</u>	<u>The nine-digit tax Taxpayer Identification Number used by the IRS.</u>
<u>PBM name</u>	<u>The legal name of the reporting entity.</u>

<u>Proprietary drug name</u>	<u>The brand or trademark name of the prescription drug reported to the FDA.</u>
<u>Non-proprietary drug name</u>	<u>The generic name of the prescription drug assigned by the USAN Council.</u>
<u>NDC</u>	<u>The NDC assigned to each drug product of a prescription drug.</u>
<u>Brand-name or generic</u>	<u>Whether the prescription drug is brand-name or generic.</u>
<u>Carrier name</u>	<u>The legal name of the carrier to whom rebates were distributed or passed on.</u>
<u>Total rebates</u>	<u>Total aggregate rebates received or negotiated directly with the manufacturer in the last calendar year, for business in the Commonwealth.</u>
<u>Total rebates distributed</u>	<u>Total aggregate rebates distributed to the relevant health benefit plan in the last calendar year, for business in the Commonwealth.</u>
<u>Total rebates passed on</u>	<u>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.</u>
<u>Comments</u>	<u>A text field for any additional information the PBM wishes to provide.</u>

254 **Statutory Authority**

255 § 32.1-23.4 of the Code of Virginia.

256 **12VAC5-219-70. Manufacturer reporting requirements.**

257 A. Except as provided in subsection D of this section, every manufacturer shall report annually
258 by April 1 to the NDSO on each of its:

- 259 1. Brand-name prescription drug and biologic, other than a biosimilar, with:
260 a. A WAC of \$100 or more for a 30-day supply or a single course of treatment; and
261 b. Any increase of 15% or more in the WAC of such brand-name drug or biologic over
262 the preceding calendar year;
263 2. Biosimilar with an initial WAC that is not at least 15% less than the WAC of the
264 referenced brand biologic at the time the biosimilar is launched and that has not been
265 previously been reported to the NDSO; and
266 3. Generic drug with a price increase that results in an increase in the WAC equal to 200%
267 or more during the preceding 12-month period, when the WAC of such generic drug is
268 equal to or greater than \$100, annually adjusted by the Consumer Price Index for All Urban
269 Consumers, for a 30-day supply.
270 For the purposes of this subdivision, a price increase is the difference between the WAC
271 of the generic drug after increase in the WAC and the average WAC of such generic drug
272 during the previous 12 months.

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

- 275 1. The name of the prescription drug;
276 2. Whether the prescription drug is a brand name or generic;
277 3. The effective date of the change in WAC;
278 4. Aggregate, company-level research and development costs for the most recent year for
279 which final audit data is available;
280 5. The name of each of the manufacturer's new prescription drugs approved by the FDA
281 within the previous three calendar years;
282 6. The name of each of the manufacturer's prescription drugs that, within the previous
283 three calendar years, became subject to generic competition and for which there is a
284 therapeutically equivalent generic version; and

- 285 7. A concise statement regarding the factors that caused the increase in WAC.
 286 C. A manufacturer shall report on all drug products of a prescription drug determined to be
 287 reportable pursuant to subsection A of this section.
 288 D. A manufacturer that does not own the NDC of a prescription drug or does not control the
 289 WAC of a prescription drug shall report annually by April 1 to the NDSO that it has no data
 290 responsive to the requirements of this section.
 291 E. Except as provided in subsection D of this section, every manufacturer shall provide the
 292 information specified in subsections A and B of this section on a form prescribed by the
 293 department that includes the following data elements:

<u>Data Element Name</u>	<u>Data Element Definition</u>
<u>Manufacturer tax identification number</u>	<u>The nine-digit tax Taxpayer Identification Number (TIN) used by the IRS.</u>
<u>Manufacturer name</u>	<u>The legal name of the reporting entity.</u>
<u>Proprietary drug name</u>	<u>The brand or trademark name of the prescription drug reported to the FDA.</u>
<u>Non-proprietary drug name</u>	<u>The generic name of the prescription drug assigned by the USAN Council.</u>
<u>WAC unit</u>	<u>The lowest identifiable quantity of the prescription drug that is dispensed, exclusive of any diluent without reference to volume measures pertaining to liquids.</u>
<u>NDC</u>	<u>The NDC assigned to each drug product of a prescription drug.</u>
<u>Brand-name drug or generic drug</u>	<u>Whether the report is about a brand-name drug or generic drug.</u>
<u>Subject to generic competition</u>	<u>The month and year of initial generic competition.</u>
<u>Date of market introduction</u>	<u>The year of market introduction of the prescription drug.</u>
<u>WAC at market introduction</u>	<u>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.</u>
<u>WAC on January 1 of the prior calendar year</u>	<u>The manufacturer's list price in United States 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.</u>
<u>WAC on December 31 of the prior calendar year</u>	<u>The manufacturer's list price in United States 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.</u>
<u>Effective date of change in WAC</u>	<u>The month and year that the WAC changed.</u>
<u>Justification for current-year WAC increase</u>	<u>The reason or reasons that the manufacturer increased the WAC of the prescription drug compared with last year.</u>
<u>Inclusion criteria</u>	<u>The criteria, as specified in subsection A of this section, that resulted in the prescription drug being determined to be reportable.</u>

<u>Research and development costs</u>	<u>Aggregate, company-level research and development costs in United States dollars for the most recent year for which final audit data is available.</u>
<u>Year of research and development costs</u>	<u>The year in which final audit data is available.</u>
<u>Comments</u>	<u>A text field for any additional information the manufacturer wishes to provide.</u>

294 F. To satisfy the reporting requirements of this section, a manufacturer may submit information
 295 and data that a manufacturer includes in its annual consolidation report on the U.S. Securities
 296 and Exchange Commission Form 10-K or any other public disclosure.

297 **Statutory Authority**

298 § 32.1-23.4 of the Code of Virginia.

299 **12VAC5-219-80. Wholesale distributor reporting requirements.**

300 A. For the purposes of this section, "cost" means the expense incurred and the monetary
 301 value of the resources used or consumed in the provision of a prescription drug by a wholesale
 302 drug distributor.

303 B. If the department determines that data received from carriers, PBMs, and manufacturers is
 304 insufficient, the department may request wholesale distributors to report the information specified
 305 in subsection C of this section.

306 1. The department shall publish a general notice in the Virginia Register of Regulations
 307 that contains its determination, the request for wholesale distributors reporting, and the
 308 deadline for wholesale distributors to report pursuant to subsection C of this section.

309 2. The NDSO shall notify every wholesale distributor of the department's determination
 310 and request by electronic mail at its electronic mailing address of record.

311 C. If requested by the department pursuant to subsection B of this section and no more than
 312 45 calendar days after the publication of the general notice pursuant to subdivision B 1 of this
 313 section, a wholesale distributor shall report for the 25 costliest prescription drugs dispensed in the
 314 Commonwealth, including each drug product of a reportable prescription drug:

315 1. The WAC directly negotiated with a manufacturer in the last calendar year;

316 2. The WAC directly negotiated with a manufacturer in the current calendar year;

317 3. Aggregate total discounts directly negotiated with a manufacturer in the last calendar
 318 year, for business in the Commonwealth, in total; and

319 4. Aggregate total discounts, dispensing fees, and other fees negotiated in the last
 320 calendar year with pharmacies, in total.

321 D. In determining which prescription drugs are reportable under subsection C of this section,
 322 the wholesale distributor shall average the cost for all drug products of a dispensed prescription
 323 drug.

324 E. A wholesale manufacturer shall report on all drug products of a prescription drug
 325 determined to be reportable pursuant to subsections C and D of this section.

326 F. Every wholesale distributor shall provide the information specified in subsection C of this
 327 section on a form prescribed by the department that includes the following data elements:

<u>Data Element Name</u>	<u>Data Element Description</u>
<u>Wholesale distributor tax identification number</u>	<u>The nine-digit tax Taxpayer Identification Number used by the IRS.</u>
<u>Wholesale distributor name</u>	<u>The legal name of the reporting entity.</u>
<u>Proprietary drug name</u>	<u>The brand or trademark name of the prescription drug reported to the FDA.</u>

<u>Non-proprietary drug name</u>	<u>The generic name of the prescription drug assigned by the USAN Council.</u>
<u>WAC unit</u>	<u>The lowest identifiable quantity of the prescription drug that is dispensed, exclusive of any diluent without reference to volume measures pertaining to liquids.</u>
<u>NDC</u>	<u>The NDC assigned to each drug product of a prescription drug.</u>
<u>Current year minus one WAC</u>	<u>WAC in United States 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.</u>
<u>Current year WAC</u>	<u>WAC in United States 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.</u>
<u>Total manufacturer discounts</u>	<u>Total aggregate discounts for each prescription drug directly negotiated with a manufacturer in the last calendar year, for business in the Commonwealth.</u>
<u>Total pharmacy discounts, dispensing fees, and other fees</u>	<u>Total aggregate discounts, dispensing fees, and other fees for each prescription drug negotiated in the last calendar year with a pharmacy.</u>
<u>Comments</u>	<u>A text field for any additional information the wholesale distributor wishes to provide</u>

- 328 G. The commissioner, the department, and the NDSO may not disclose:
329 1. The identity of a specific wholesale distributor;
330 2. The price charged for a specific prescription drug or class of prescription drugs; or
331 3. The amount of any discount or fee provided for a specific prescription drug or class of
332 prescription drugs.

333 **Statutory Authority**

334 § 32.1-23.4 of the Code of Virginia.

335 **12VAC5-219-90. Method of report submission.**

336 A. A reporting entity shall submit any report required by this part to the NDSO through the
337 NDSO's online collection tool.

338 B. A reporting entity shall submit any required report by uploading electronic spreadsheet files,
339 or other methods as determined by the NDSO, that include all required information for each report
340 and that comply with the NDSO's Prescription Drug Price Transparency Regulation (12VAC5-
341 219) Submission Manual, Version 1.1.

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

344 **Statutory Authority**

345 § 32.1-23.4 of the Code of Virginia.

346 Part III
347 Enforcement
348 Article 1

349 Data Validation and Audits

350 **12VAC5-219-100. Data validation; notification; response.**

351 A. The NDSO shall:

352 1. Validate that the data received from each reporting entity pursuant to a report required
 353 under Part II (12VAC5-219-50 et seq.) of this chapter is complete no more than 90
 354 calendar days after submission;

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

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

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

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

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

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

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

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

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

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

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

376 1. The NDSO shall provide to the commissioner within one business day of the second
 377 failure to correct:

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

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

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

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

384 **Statutory Authority**

385 § 32.1-23.4 of the Code of Virginia.

386 **12VAC5-219-110. Audit; corrective action plan.**

387 A. When submitting any notification or report to the NDSO, a reporting entity shall include:

388 1. A signed, written certification of the accuracy of any notification or report filed in a
 389 physical format; and

390 2. Electronic certification of the accuracy of any notification or report filed by email or
 391 through the NDSO's online collection tool.

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

395 C. The NDSO shall send a copy of the audit findings to the reporting entity no more than five
 396 business days after the conclusion of the audit at its email mailing address of record.

397 D. If any deficiencies are found during the audit:

398 1. The NDSO shall:

399 a. Notify a reporting entity by providing a copy of the audit findings no more than five
 400 business days after completion of the audit to the reporting entity's email address of
 401 record; and

- 402 b. Provide a copy of the notification to the commissioner at the same time it is sent to
403 the reporting entity.
- 404 2. The reporting entity shall prepare a written corrective action plan addressing each
405 deficiency cited at the time of audit as specified in subsection E of this section.
- 406 E. The reporting entity shall submit to the NDSO and the commissioner a corrective action
407 plan no more than 10 business days after receipt of the audit findings and shall include in the
408 corrective action plan:
- 409 1. A description of the corrective action to be taken for each deficiency and the position
410 title of the employees to implement the corrective action;
- 411 2. The deadline for completion of all corrective action, not to exceed 45 business days
412 from the receipt of the audit findings; and
- 413 3. A description of the measures implemented to prevent a recurrence of the deficiency.
- 414 F. The reporting entity shall ensure that the person responsible for the implementation of the
415 corrective action plan signs, dates, and indicates their title on the corrective action plan.
- 416 G. The NDSO shall:
- 417 1. Notify the reporting entity if the NDSO determines any item in the corrective action plan
418 is unacceptable;
- 419 2. Grant the reporting entity two opportunities to revise and resubmit a corrective action
420 plan that the NDSO initially determines to be unacceptable. If the reporting entity revises
421 and resubmits the corrective action plan, the revision is due to the NDSO and the
422 commissioner no more than 15 business days after the NDSO has notified the reporting
423 entity pursuant to subdivision 1 of this subsection.
- 424 H. If a reporting entity fails to comply with the corrective action plan:
- 425 1. The NDSO shall provide to the commissioner any correspondence between the NDSO
426 and the reporting entity after the notification sent pursuant to subsection D of this section;
427 and
- 428 2. The commissioner shall deem the failure to comply as a failure to report pursuant to
429 Part II (12VAC5-219-50 et seq.) of this chapter.

Statutory Authority

430 § 32.1-23.4 of the Code of Virginia.

Article 2**Administrative Process****12VAC5-219-120. Sanctions.**

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

436 B. The commissioner may:

- 437 1. Petition an appropriate court for an injunction, mandamus, or other appropriate remedy
438 or imposition of a civil penalty against the reporting entity pursuant to subsection B or C
439 of § 32.1-27 of the Code of Virginia for each violation of this chapter; and
- 440 2. Levy a civil penalty upon the reporting entity as specified in subsection B of 12VAC5-
441 219-130 and pursuant to subsection C of § 32.1-23.4 of the Code of Virginia, in
442 accordance with the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia)
443 for each violation of Part II (12VAC5-219-50 et seq.).

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

Statutory Authority

448 § 32.1-23.4 of the Code of Virginia.

450 **12VAC5-219-130. Civil penalty.**

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

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

456 1. For the first offense:

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

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

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

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

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

463 2. For the second offense:

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

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

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

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

470 The commissioner shall assess civil penalties in the aggregate on a per day basis.

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

472 1. April 2 for a reporting entity that fails to submit any information or documentation
473 pursuant to 12VAC5-219-50, 12VAC5-219-60, or 12VAC5-219-70 or for a reporting entity
474 that knowingly submits false, inaccurate, or misleading data pursuant to 12VAC5-219-50,
475 12VAC5-219-60, or 12VAC5-219-70;

476 2. The 46th calendar day after the publication of the general notice pursuant to subdivision
477 A 1 of 12VAC5-219-80 for a wholesale distributor that that fails to submit any information
478 or documentation or that knowingly submits false, inaccurate, or misleading data;

479 3. The 16th calendar day after notification pursuant to subdivision C 1 of 12VAC5-219-
480 100 for a reporting entity that fails to correct its report submitted pursuant to Part II
481 (12VAC5-219-50 et seq.) of this chapter; and

482 4. The calendar day immediately succeeding the deadline of a corrective action plan for a
483 reporting entity that fails to comply with its corrective action plan approved pursuant to
484 12VAC5-219-110.

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

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

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

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

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

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

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

- 501 b. An additional amount that approximates the administrative costs arising under §
502 2.2-4806 of the Code of Virginia; and
503 c. Late penalty fees of 10% of the past due civil penalties.
504 2. The commissioner may refer a past due civil penalty for collection by the Division of
505 Debt Collection of the Office of the Attorney General.

506 **Statutory Authority**

507 §§ 2.2-4805 and 32.1-23.4 of the Code of Virginia.

508 **12VAC5-219-140. Informal fact-finding proceeding.**

509 A. A reporting entity may dispute the imposition of a civil penalty pursuant to subdivision B 2
510 of 12VAC5-219-120 by requesting an informal fact finding proceeding pursuant to § 2.2-4019 of
511 the Code of Virginia:

512 1. In writing to the commissioner; and

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

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

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

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

521 C. The request for an informal fact finding proceeding:

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

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

526 D. If a reporting entity does not request an informal fact finding proceeding pursuant to
527 subsection A of this section, the civil penalty imposed pursuant to subdivision B 2 of 12VAC5-
528 219-120 shall be final on the 15th calendar day after the date of receipt of the notice of civil penalty
529 imposition.

530 E. If a reporting entity remains aggrieved by a case decision after an informal fact finding
531 proceeding, it may seek review of the case decision in accordance with Article 5 (§ 2.2-4025 et
532 seq.) of Chapter 40 of Title 2.2. of the Code of Virginia.

533 **Statutory Authority**

534 § 32.1-23.4 of the Code of Virginia.

535 **Documents Incorporated by Reference (12VAC5-219)**

536 [Prescription Drug Price Transparency Regulation Submission Manual, Version 1.1, 2022,](#)

537 [Virginia Health Information \(rev. 9/2022\)](#)



COMMONWEALTH of VIRGINIA

Department of Health
P O BOX 2448
RICHMOND, VA 23218

Colin M. Greene, MD, MPH
State Health Commissioner

TTY 7-1-1 OR
1-800-828-1120

MEMORANDUM

DATE: September 22, 2022

TO: Virginia State Board of Health

FROM: Julie Henderson, Director, Office of Environmental Health Services

SUBJECT: Final Private Well Regulations, 12VAC5-630

The Private Well Regulations (regulations) establish the minimum location and construction requirements for private wells installed in the Commonwealth. The Board of Health (the Board) has not made significant revisions to the regulations since their adoption in 1990. On August 17, 2016, the Virginia Department of Health began a periodic review of the regulations, which led to the effort culminating in this planned regulatory action. The final regulations before the Board include minor revisions in response to public comment on the draft regulations published in the Virginia Register of Regulations in January 2022.

The planned regulatory action provides amendments to the regulations based on current industry standards and public comments received during all phases of the regulatory process. The purpose is to ensure the regulations (i) are protective of public health and the environment, (ii) address changes in current standards and practices, (iii) clarify regulatory language, (iv) provide private well owners greater flexibility in well locations, and (v) exhibit improved consistency with the Code of Virginia and other regulations related to wells and groundwater resources.

Upon approval by the Board, the proposed final regulations will be submitted for executive branch review and, upon approval by the Governor, will be published in the Virginia Register of Regulations with provision for a 30-day final adoption period before the regulatory action becomes effective.



townhall.virginia.gov

Final Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12-VAC-5-630
VAC Chapter title(s)	Private Well Regulations
Action title	Amendments to Private Well Regulations
Date this document prepared	

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

Brief Summary

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

The Board of Health (Board) has not made significant revisions to the Private Well Regulations (Regulations) since their adoption in 1990. The Regulations establish the minimum location and construction requirements for private wells installed in the Commonwealth. In August 2016, the Virginia Department of Health (VDH) began a periodic review of the Regulations and formed a Private Well Regulations Workgroup. The purpose of the workgroup was to assist VDH in the development of proposed revisions to the Regulations. The Proposed Regulations were published in Volume 38 Issue 11 of the *Virginia Register of Regulations* on January 17, 2022, and advertised a public comment period ending March 18, 2022. The intent of this regulatory action is to explore amendments to the Regulations based on current industry standards, all public comments received, and feedback received from the Private Well Regulations Workgroup. The purpose is to ensure the Regulations (i) are protective of public health and the environment, (ii) address changes in current standards and practices, (iii) clarify regulatory language, and (iv) exhibit improved consistency with other regulations related to private wells and

groundwater resources. No substantive changes have been made between the Proposed and Final Stages.

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.

- ASTM – American Society of Testing and Materials
- AWWA – American Waterworks Association
- DHCD – Department of Housing and Community Development
- DEQ – Department of Environmental Quality
- DPOR – Department of Professional and Occupational Regulation
- NGWA – National Groundwater Association
- NSF – National Sanitation Foundation
- ODW – Office of Drinking Water
- SHDR – Sewage Handling and Disposal Regulations
- SWCB – State Water Control Board
- VDH – Virginia Department of Health
- USGS – United States Geological Survey
- VWWA – Virginia Water Well Association
- WWSP – Water Well Systems Provider

Statement of Final Agency Action

Provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

The Board approved these Final Regulations for the Private Well Regulations (12VAC5-635) on (DATE)

Mandate and Impetus

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

In accordance with Virginia Code §2.2-4017 and Executive Order 14 (2018) (amended), the Department conducted a periodic review of the Regulations. In a January 27, 2017, memorandum to the Commissioner of the Department, Grant Kronenberg, Assistant Attorney General offered opinion that certain exemptions from regulatory requirements provided to dewatering wells in the existing regulations are not supported under the statutory authority given in the Code of Virginia §§ 32.1-176.4(A) and 32.1-176.5(A). The Assistant Attorney General therefore recommended that VDH amend the Regulation so that statutory requirements with respect to construction permits apply to private dewatering wells. This opinion, along with the periodic review of the Regulations, provided impetus to update the Regulations such that they (i) are protective of public health and the environment, (ii) address changes in current standards and practices, (iii) clarify regulatory language, and (iv) exhibit improved consistency with other regulations related to private wells and groundwater resources.

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.

Section 32.1-12 of the Code of Virginia authorizes the Board to “make, adopt, promulgate and enforce such regulations and provide for reasonable variances and exemptions therefrom as may be necessary to carry out the provisions of [Title 32.1.]” § 32.1-176.4 requires the Board to promulgate regulations “pertaining to the location and construction of private wells,” including “minimum storage capacity and yield requirements for residential drinking wells.” The Board has the duty to protect the public health and to ensure that ground water resources are not adversely affected by the construction and location of private wells.

Purpose

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

The private well industry has experienced significant advancements since promulgation of the Regulations in 1990, including improvements in the materials and equipment used to construct private wells, changes in the regulatory oversight of Water Well Systems Providers (WWSP) from VDH to the Department of Professional and Occupational Regulation (DPOR), and changes in other regulations which relate to these Regulations. New information and research has improved understanding of the risk to public health and groundwater resources with regards to the location and construction of private wells. Examples include advancements in alternative onsite sewage treatment system design, promulgation of standards related to reclaimed water, federal guidelines related to emerging contaminants, regulation of groundwater withdrawal by the Virginia Department of Environmental Quality (DEQ), and activities such as hydraulic fracturing and underground injection of treated effluent. Stakeholders have also identified inconsistencies between the Regulations and other regulations related to private wells and groundwater resources, including references to repealed sections of the Code of Virginia, and the need for the Regulations to correlate to other regulatory requirements for wells constructed in designated Groundwater Management Areas. The amendments to the Regulations propose updated private well location and construction criteria recognizing current industry standards, improve consistency with other regulations, and improve protection of public health and groundwater resources. This regulatory change is essential to public health and safety because there are currently requirements in the Regulation that are based on outdated well location and construction standards. Without the proposed amendments, Virginians will have to comply with regulations that are not informed by current, up to date research and industry practices. Additionally, inconsistencies between the Regulations and other regulations related to private wells and groundwater resources will persist.

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 following substantive changes to existing sections, and new substantive provisions, are proposed to the existing regulatory language:

- Revisions of definitions, and additional definitions, as necessary for consistency with the Code of Virginia, other regulations related to private wells and groundwater resources, and current industry standards.
- Revision of administrative processes to reflect current law and to improve consistency with other Department regulations.
- Clarification of grout materials and procedures approved for well abandonment.
- Improvement of standards regarding well abandonment protocols.
- Revision of the separation distance requirements between sources of contamination and wells abandoned in accordance with the Regulations.
- Improvement of consistency between the Regulations and other regulations, such as the Sewage Handling and Disposal Regulations (12VAC5-610), which establish minimum separation distance from private wells.
- Improvement of consistency between private well construction reporting requirements in the Regulations and well construction and reporting requirements in the Groundwater Withdrawal Regulations (9VAC25-610).
- Removal or revision of references to obsolete or repealed regulations and laws.
- Revision of current construction standard exemptions for Class IIIC and Class IV wells.
- Clarification of disinfection procedures.
- Clarification of standards for yield and storage requirements.
- Revision of private well classification system so that Class IV well construction standards mirror Class III wells.
- Establishment of a standard procedure for converting existing Class IV wells to Class III wells.
- Identification of reasonable exemptions from the Regulations (e.g., dewatering wells).
- Clarification of regulatory authority relative to observation wells.
- Establishment of minimum private well construction criteria based on geologic conditions, such as requiring a mechanical seal at the termination of well casing into bedrock.
- Requirement that all private well components meet national lead-free standards.
- Establishment of criteria to acknowledge nationally recognized standards and certifications (e.g., National Sanitation Foundation) for approval of private well components (including, but not limited to, standard methods, materials, products, analytical, and permeability standards).
- Establishment of a minimum separation distance from utilities, property lines, permanently abandoned onsite sewage systems, reuse water lines, and other potential sources of contamination.
- Establishment of quality standards for water used during well construction.

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.

Primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions

Advantages include clarity in requirements for well location and construction, which benefit both WWSP and well owners, and enhanced protection of public health and groundwater quality by means of improved setback distance requirements. VDH has not identified any disadvantages in the proposed revisions.

Primary advantages and disadvantages to the agency or Commonwealth

The revisions will assist the Department in making improvements to the permitting process by addressing inconsistencies in the existing Regulations. The revisions will assist the Commonwealth by enhanced protection of public health and the environment. VDH has not identified any disadvantages in the proposed revisions.

Other pertinent matters to the regulated community, government officials, and the public

The revisions eliminate static references to well construction materials and procedures and replace them with reference to national standards and accreditations (e.g., ASTM, NSF). This provides WWSP the ability to apply professional judgment rather than forced reliance on obsolete specifications and standards included in the existing Regulations.

Requirements More Restrictive than Federal

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

There are no federal requirements, other than non-enforceable general guidance, addressing the location and construction of private wells.

Agencies, Localities, and Other Entities Particularly Affected

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

Other State Agencies Particularly Affected

DEQ, DPOR, DHCD

Localities Particularly Affected

The Regulations apply equally throughout the Commonwealth. Localities named in VA Code §§ 32.1-176.4.A and 32.1-176.5.B and C and having authority to adopt ordinances establishing standards pertaining to private well location, testing of water, and well abandonment may need to modify ordinances to be consistent with the regulatory changes.

Other Entities Particularly Affected

WWSP, Homebuilders, Onsite Soil Evaluators, Realtors, Commercial Laboratories.



Public Comment

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

Commenter	Comment	Agency response
Virginia Onsite Soil Evaluators	<p>Title: "drilling fluids unsuitable for potable water development." Comment ID: 119191 Concern: widespread practice of withdrawal and injection into wells under development of uncharacterized surface waters obtained from streams, farm ponds, or rivers while drilling or boring drinking water wells contaminates groundwater with materials (see pollutants), and/or pathological organisms (bacteriological, viral & parasitic) which could threaten public health on or adjacent to permit holder's property. Reference: "G. Water used during well construction shall be obtained from a suitable source or the well being constructed. A suitable source means a pure water source, or, when a pure water source is not locally available, water taken from another source then disinfected using compounds meeting NSF/ANSI Standard 60 environmental specifications." Private sanitary standards do not meet requirements of Code citation. Therefore it is recommended requirement for disinfection be specified.</p>	<p>The Department agrees that disinfection of water used in well construction is necessary when the water is not from a pure water source, which is the purpose of the new regulatory language referenced. The Department does not agree that "private sanitary standards do not meet requirements of Code citation." (§§ 32.1-12 and 32.1-176.2 through -176.8:1 of the Code of Virginia). The existing revision language requires disinfection of water not from a pure water source using compounds meeting NSF/ANSI Standard 60 environmental specifications.</p> <p>The Department is sympathetic to the commenter's concern regarding uncharacterized surface waters. In discussion with representatives of the Virginia Water Well Association, the parties discussed the subsection language but were not able to agree on a suitable text revision.</p> <p>In the majority of well construction events the matter will not come up because water hauled to well construction sites by the driller comes from pure water sources. The purpose of the language is to provide water well system providers an option in the rare case that additional water is needed and there is no nearby pure water source available.</p>
John Public	<p>Title: "Minimum yield" Comment ID: 119207 Minimum yield requirements increase cost to consumer, role of health officials should not include bullying citizens into drilling additional wells. The regulations are silent on the accepted means of determining well yield or storage capacity; thus the driller who has several conceivable conflicts of interest, is left to advise the property owner whether the yield is "sufficient." Water use is one parameter which is completely at the</p>	<p>The inclusion of minimum yield requirements in the regulations is required by the Code of Virginia. Section 32.1-176.4.A. states, in relevant part, that the private well "regulations shall include minimum storage capacity and yield requirements for residential drinking wells. The certified water well systems provider shall certify the storage capacity and the yield of the well on a form provided by the Department at the time the well is completed."</p> <p>Other than style modifications to improve consistency with the <i>Form and Style Requirements for the Virginia Register of</i></p>

Commenter	Comment	Agency response
	<p>discretion of the homeowner. Is there any data suggesting that 1/2 gpm well yield is insufficient for a 3BR home? A sewage permit would anticipate discharge of 450 gallons/day, while 1440 minutes/day gives 720 gallons from a so-called low yield well. The existing regulation has not proven problematic, and is certainly not a threat to public health or welfare. Leave well enough alone.</p> <p>Reference: 12VAC5-630-460. Water system yields for residential use wells.</p> <p>A. All drinking Drinking water systems that utilize one or more Class III wells shall be capable of supplying water in adequate quantity for the intended usage. All such systems, with Systems with a capacity <u>less than under</u> three gallons per minute, shall have a <u>capacity ability</u> to produce and store 150 gallons per bedroom per day and be capable of delivering a sustained flow of five gallons per minute per connection <u>for 10 minutes for ordinary residential use</u>. Systems with a capacity of three gallons per minute or more do not require additional storage.</p> <p>B. The certified water well systems provider shall certify the storage capacity and the yield of the well on the Uniform Water Well Completion Report.</p>	<p><i>Regulations and Virginia Administrative Code</i>, the sole change to the existing section is clarification of the length of time that sustained flow of 5 gallons per minute per connection is required, which will eliminate confusion for the regulated community.</p> <p>Modification to Regulations in response to comment: No.</p>
<p>JT Walker</p>	<p>Title: "licensure" Comment ID: 120641 Please clarify who is licensed to design and permit construction of water wells. Although VDH regulations require acceptance of well site design applications endorsed by PE, OSE or certified well driller the proposed regulations are silent on the vital issue of site plan, certification of meeting horizontal standoffs to easements, boundaries, and existing or proposed improvements. Reference: 12VAC5-630-80. Relationship to the Department of Professional and Occupational Regulation. <u>Persons engaged in the construction, repair, or alteration of a private well shall be licensed and</u></p>	<p>The Code of Virginia § 32.1-176.5:2.A states "(t)he Department shall accept private site evaluations and designs, in compliance with the Board's regulations for the construction of private wells, designed and certified by a licensed professional engineer, in consultation with a licensed onsite soil evaluator, or by a licensed onsite soil evaluator." Further, Acts of the Assembly Chapter 831 (2018) states that "Beginning July 1, 2018, (the Department shall) accept private evaluations and designs for private wells, in compliance with the State Board of Health Regulations for construction of private wells, designed and certified by a certified master water well system provider pursuant to § 54.1-1129.1 of the Code of Virginia."</p> <p>These sections of the Code of Virginia clearly distinguish between <i>site evaluation</i> and <i>design</i>.</p>

Commenter	Comment	Agency response
	<p>certified in accordance with § 54.1-1100 §§ 54.1-1103 and 54.1-1129.1 of the Code of Virginia. any contractor constructing a water well to reach ground water shall possess, as a minimum, a valid Class B contractors license.</p>	<p>Site evaluation (i.e., determining the proposed location of a well) is not a function of design. This is supported by academic and industry standards and practices (e.g., Groundwater and Wells, 2nd edition, Fletcher G. Driscoll, Ph.D.), which clearly differentiate identification of the intended location of a well from design functions pertaining to the construction of the well (such as casing diameter, well depth, screen length, and so on).</p> <p>Site evaluation (referred to in the Regulations as a sanitary survey) is a matter of adhering to a prescribed standard. In the case of 12VAC5-630, the prescribed standard is presented in Section 380, and the expectation placed on the party completing the sanitary survey is that the location of the well must meet required separation distances and be documented in detail sufficient that a person unfamiliar with the property can properly locate the well site.</p> <p>Private well design requirements are presented in Part III of the Regulations, which identify the classes of private wells and the minimum casing and grout requirements relative to each class. It is a generally accepted practice (Driscoll) that in the design of domestic, or residential, wells a “compromise is necessary between well cost and well efficiency.” For this reason, well depth and screen interval for domestic wells is typically determined on site at the time of drilling rather than on the basis of a documented design completed prior to drilling.</p> <p>When owners of non-domestic private wells (e.g. irrigation or industrial) require detailed well design specifications prior to drilling, VDH is not involved beyond the issuance of a construction permit based on the well class. Questions regarding licensure to design water wells fall under the purview of the Department of Professional and Occupational Regulation.</p> <p>With respect to permitting of construction, the Department issues permits for the construction of water wells, including private wells and wells supplying waterworks.</p> <p>Modification to Regulations in response to comment: No.</p>
William Johnson	Comment by Email.	The commenter has identified a lack of clarity in the proposed revision of the Regulations

Commenter	Comment	Agency response
	<p>Our concern originates in 12VAC5-640-10 Definitions.</p> <p>The definition “Biosolids” means solid, semisolid, or liquid materials removed from municipal sewage and treated to be suitable for recycling as fertilizer. This definition seems innocuous enough...however...</p> <p>There are no mentions of Class A, Class B, or EQ biosolids.</p> <p>There are no mentions of 40CFR-anything.</p> <p>There are no mentions of other VAC-anything.</p> <p>Because the definition is in the regulation and does not reference any other definitions, or any regulatory definitions, or any other regulations, or any other regulatory guidance, all of the other things that we know to be TRUE about Biosolids do not exist within the eyes of this regulation or within the context of the definition herein. By being in the regulation as is, this definition closes the door with respect to referencing everything else known about biosolids.</p> <p>The Virginia Department of Health in the Private Well Regulations is defining the term Biosolids in twenty words or less for the purpose of regulating private wells in the Commonwealth of Virginia.</p> <p>As well-meaning and important as these regulations are, they do not have the mandate nor authority to define biosolids, regardless of how good their intentions are...</p> <p>We are hoping to get your specific reference for the words used to define biosolids in the proposed regulations; our Googling found:</p> <p>The words (“solid, semisolid, or liquid materials removed from municipal sewage and treated to be suitable for recycling as fertilizer) suggests these words are often used in the public advertisements for land application of biosolids permits (reference Nutri-Blend 2009, Cumberland and reference Synagro Central 2010 Surry)</p> <p>DEQ FAQ Pamphlet from 2015 (see attached) uses these words.</p>	<p>with respect to separation distance from locations subject to the application of biosolids. Specifically, the term “biosolids” as presented in the draft Regulations is non-specific and does not align with requirements in the DEQ regulations that address their beneficial use. The Department agrees with the commenter that the draft language is subject to potential conflicting interpretations.</p> <p>Modification to Regulations in response to comment: Yes</p>

Commenter	Comment	Agency response
	<p>We found 9VAC25-32-10 (VPA Permit Regulation) Definitions: "Biosolids" means a sewage sludge that has received an established treatment and is managed in a manner to meet the required pathogen control and vector attraction reduction, and contains concentrations of regulated pollutants below the ceiling limits established in 40 CFR Part 503 and 9VAC25-32-356, such that it meets the standards established for use of biosolids for land application, marketing, or distribution in accordance with this regulation. Liquid biosolids contains less than 15% dry residue by weight. Dewatered biosolids contains 15% or more dry residue by weight.</p> <p>With respect to 12VAC5-630-380 Well location:</p> <p>Paragraph A says (whole new paragraph): A. The private well shall be sited for the protection of public health and the aquifer, with appropriate consideration given to distance from potential contamination sources; vulnerability to known or suspected natural risks (e.g., flooding); potential for interference with utilities; accessibility for drilling machinery and support equipment; and safety of the public and well construction personnel.</p> <p>Paragraph B says (underlined parts are new): B. Sanitary survey. Any obvious source Obvious sources of potentially toxic or dangerous substances within 200 feet of the proposed private well shall be investigated as part of the sanitary survey by the district or local health department. Sources of contamination may include, but are not limited to, items listed in Table 3.1.; abandoned wells.; pesticide treated soils, underground; petroleum or chemical storage tanks, drums, totes or other storage containers (aboveground and underground); and other sources of physical, chemical or biological contamination. If the source</p>	

Commenter	Comment	Agency response
	<p>of contamination could affect the well adversely, and preventive measures are not available to protect the ground water groundwater, the well shall be prohibited. The minimum separation distance between a private well and structures, topographic features, or sources of pollution shall comply with the minimum distances shown in Table 3.1.</p> <p>The words 'items listed in Table 3.1' originate in the 'old regulations' that describe structures and topographic features...the update to Table 3.1 describes more than 'structures or topographic features'?</p> <p>This regulation says that 'the well shall be prohibited within 100 feet of Biosolids application sites, no exceptions'. This regulation (unintentionally?) puts an X over every single biosolids application site in the Commonwealth of Virginia for the location or development of a private well; there are no preventative measures that can un-apply biosolids from a site. Every single site has been permitted by the Virginia Department of Environmental Quality. Every single site has been declared off-limits by the Virginia Department of Health in the Private Well Regulations (unintentionally?). Who will the property owners hold liable for their land being forever marked by an X by the Commonwealth of Virginia and Virginia Department of Health? No well equals not development potential, which means no development potential value; can the Commonwealth of Virginia be held financially liable for marking an X over property that was permitted by the Commonwealth of Virginia?</p> <p>We do not believe that VDH intends this consequence; we do not believe that VDH would enforce this consequence even though it is written in its own Private Well Regulations...we believe that VDH intends to direct the application of Biosolids to have a 100' buffer around the new well to protect the new well. HOWEVER, the way the regulation is</p>	

Commenter	Comment	Agency response
	<p>drafted, a very savvy commenter in a public forum will stand up and point to the words in the new PRIVATE WELL REGULATIONS and say that VDH says no new wells within 100 feet of a Biosolids application site, no exceptions. We do not want to have to argue that this is not what the regulation says...we want the VDH, the DEQ, the Commonwealth of Virginia, and the Biosolids industry to work together to revise the proposed language to head this type of public argument off at the pass, especially since we do not believe that VDH intends to put an X over every piece of property that is a Biosolids Application site.</p> <p>Paragraph I says: <u>Biosolids application site. No private well shall be placed closer than 100 feet from land on which biosolids are applied.</u></p> <p>Just to make the case for the 'savvy commenter' more straight forward, paragraph I says in no uncertain terms that no private well shall be placed on land on which biosolids are applied...we believe that the intent is to make sure that the application of biosolids in the vicinity of a new well backs off the expected 100 feet, but the words say much more than what seems to have been intended? Again, VDH does not intend the interpretations articulated herein, but a plain straight-faced reading of the words may conclude otherwise.</p>	
<p>Brian Campbell (DEQ)</p>	<p>Comments by Email</p> <ol style="list-style-type: none"> Specify "GW-2" when referencing Uniform Water Well Completion Report for clarity and consistency 	<p>The term GW-2 is not universally used in reference to the Uniform Water Well Completion Report. The Department therefore believes removal of all references to GW-2 will provide clarity and consistency, as opposed to the action recommended by the commenter. In addition, because the Uniform Water Well Completion Report is addressed in Section 310, Section 440 will be repealed to avoid duplication.</p> <p>Modification to Regulations in response to comment: Yes</p>

Commenter	Comment	Agency response
	<p>2. Incorrect reference in 12VAC5-630-410.</p> <p>3. Suggested clarifications regarding placement of grout in Section 12VAC5-630-410. Commenter is concerned that the methodology of pouring grout or bentonite chips/pellets is subject to failure if the annular space or interior of tremie pipe is not dry. The presence of moisture can lead to swelling and bridging, preventing effective application.</p> <p>4. The hyperlink to the Uniform Water Well Completion Report in the Forms Section is Obsolete</p>	<p>The Department agrees that the reference is incorrect.</p> <p>Modification to Regulations in response to comment: Yes</p> <p>The Department agrees with this comment.</p> <p>Modification to Regulations in response to comment: Yes</p> <p>The Department agrees with this comment.</p> <p>Modification to Regulations in response to comment: Yes</p>

Detail of Changes Made Since the Previous Stage

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

Current chapter-section number	New chapter-section number, if applicable	New requirement from previous stage	Updated new requirement since previous stage	Change, intent, rationale, and likely impact of updated requirements
10	na	No	Yes	CHANGE: The definition of Biosolids is changed as follows: "Biosolids" means solid, semisolid, or liquid materials removed from municipal sewage and treated to be suitable for recycling as fertilizer, as defined in <u>9VAC25-31-10 and 9VAC25-32-10</u> . For the purpose of these

Current chapter-section number	New chapter-section number, if applicable	New requirement from previous stage	Updated new requirement since previous stage	Change, intent, rationale, and likely impact of updated requirements
				<p><u>regulations, biosolids do not include exceptional quality biosolids as that term is defined in 9VAC25-32-10.</u></p> <p>INTENT: The intent of the change is to provide clarity to the definition of biosolids.</p> <p>RATIONALE: The rationale for the revision of the definition of biosolids is that 9VAC25-31 and 9VAC25-32 provide definitions of biosolids and the intention of the proposed amendment is to achieve consistency with those definitions.</p> <p>LIKELY IMPACT: The likely impact of the change is that separation distance of a well from a biosolids application field will be in harmony with DEQ’s regulation of biosolids application.</p>
310	na	No	Yes	<p>CHANGE: Remove two references to GW-2 form, further, the term GW-2 is replaced with uniform water well completion report wherever it occurs in the Regulations.</p> <p>INTENT: The intent of the change is to discontinue use of the term “GW-2” relative to the Uniform Water Well Completion Report.</p> <p>RATIONALE: The rationale for the change is that “GW-2”</p>

Current chapter-section number	New chapter-section number, if applicable	New requirement from previous stage	Updated new requirement since previous stage	Change, intent, rationale, and likely impact of updated requirements
				is not universally used by the regulated community and regulators, whereas “Uniform Water Well Completion Report” is. LIKELY IMPACT: The likely impact is to reduce confusion for the regulated community and regulators with other state and federal agencies regarding the name of the document completed following well construction.
380	na	No	Yes	CHANGE: Table 3.1 is renumbered as Table 1 (note: references to Table 3.1 throughout the Regulations are revised accordingly). INTENT: To improve clarity RATIONALE: This is the only table in the Regulations. LIKELY IMPACT: The likely impact of the change is consistency with the <i>Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code</i> . Further, the regulated community will not attempt to find tables numbered lower than Table 3.1.
380	na	No	Yes	CHANGE: The Title of Table 3.1 is changed from “Distances (in feet) between a well and a structure or topographic feature” to “Separation

Current chapter-section number	New chapter-section number, if applicable	New requirement from previous stage	Updated new requirement since previous stage	Change, intent, rationale, and likely impact of updated requirements
				<p>Distances (in feet),” and the Table 3.1 Column 1 Row 2 legend is changed from “Structure or Topographic Feature” to “Feature”</p> <p>INTENT: The intent of the change is improve the clarity and readability of the table.</p> <p>RATIONALE: The features requiring separation distances listed in the table include more than “structures and topographic features.”</p> <p>LIKELY IMPACT: the likely impact of the change is to eliminate confusion for the regulated community regarding table contents.</p>
380	na	No	Yes	<p>CHANGE: Item 10 in Table 3.1 (renumbered Table 1) is changed as follows: “Biosolids application sites <u>fields (as field is defined in 9VAC25-32-10).</u>” In addition, the following language is added to Exceptions: “<u>No separation distance applies if biosolids have not been applied within the 12 months preceding well construction.</u>”</p> <p>INTENT: The intent of the change is to achieve consistency with 9VAC25-32.</p> <p>RATIONALE: The rationale for the change is that an application “site” is not</p>

Current chapter-section number	New chapter-section number, if applicable	New requirement from previous stage	Updated new requirement since previous stage	Change, intent, rationale, and likely impact of updated requirements
				<p>defined, but an application "field" is, per the DEQ regulation that is referenced. Also, because a purpose is to protect groundwater resources during well construction, the exclusion allows well siting when the threat to groundwater is mitigated by time.</p> <p>LIKELY IMPACT: The likely impact of the change is that the regulated community will understand that a biosolids application field has the same meaning as in the DEQ regulation governing biosolids application, and that the separation distance will not apply if biosolids have not been applied within the previous 12 months.</p>
380	na	No	Yes	<p>CHANGE: Subsection I is changed as follows: "<u>Biosolids application site field</u>. No private well shall be placed closer than 100 feet from <u>land a field, as defined in 9VAC25-32-10</u>, on which biosolids are <u>being applied or have been applied within the previous twelve months</u>."</p> <p>INTENT: The intent of the change is to achieve consistency with 9VAC25-32.</p>

Current chapter-section number	New chapter-section number, if applicable	New requirement from previous stage	Updated new requirement since previous stage	Change, intent, rationale, and likely impact of updated requirements
				<p>RATIONALE: To clarify both the location of and conditions associated with (i.e., one year since application) biosolids application. LIKELY IMPACT: The likely impact of the change is clarity for regarding separation distance from a biosolids application field, including conditions when the separation distance does not apply.</p>
410	na	No	Yes	<p>CHANGE: Subsection C.4.d. is revised to update reference. INTENT: The intent of the change is to correct a typographic error. RATIONALE: The rationale for the change is to ensure that the reference to the applicable subsection is correct. LIKELY IMPACT: The likely impact of the change is to reduce confusion regarding the referenced subsection.</p>
410	na	No	Yes	<p>CHANGE: Added language to F.6.b: "Pouring of grout is acceptable for bored wells whenever <u>when</u> the grouting depth does not exceed 30 <u>20</u> feet provided there is a minimum of a 3-inch annular space <u>[and the annular space is free of standing water.]</u>" INTENT: To clarify the conditions when it</p>

Current chapter-section number	New chapter-section number, if applicable	New requirement from previous stage	Updated new requirement since previous stage	Change, intent, rationale, and likely impact of updated requirements
				<p>is permissible to pour grout. RATIONALE: The rationale for the change is to mitigate potential for improper placement of grout during well construction. LIKELY IMPACT: To reduce the chance of bridging or other failure during the grout placement phase of well construction.</p>
410	na	na	na	<p>CHANGE: Added language to F.6.c: <u>“Bentonite chips or pellets are acceptable for bored wells when the grouting depth does not exceed 20 feet provided the annular space is at least four (4) inches greater than the outside diameter of the casing or coupling and the casing [and the annular space is free of standing water].”</u> INTENT: To clarify the conditions when it is permissible to place bentonite chips or pellets. RATIONALE: The rationale for the change is to mitigate potential for improper placement of grout during the grouting phase of well construction. LIKELY IMPACT: To reduce the chance of bridging or other failure during grout placement with</p>

Current chapter-section number	New chapter-section number, if applicable	New requirement from previous stage	Updated new requirement since previous stage	Change, intent, rationale, and likely impact of updated requirements
				bentonite chips or pellets.
440	na	No	Yes	<p>CHANGE: This section is repealed.</p> <p>INTENT: To improve clarity.</p> <p>RATIONALE: The repeal of this section eliminates duplication within the chapter, given that Section 310 addresses the Uniform Water Well Completion Report.</p> <p>LIKELY IMPACT: The change to this section will reduce confusion for the regulated community by eliminating duplicate sections having the same requirement.</p>
FORMS	na	na	na	<p>CHANGE: Update hyperlink to Uniform Water Well Completion Report.</p> <p>INTENT: To provide the regulated community with the current form.</p> <p>RATIONALE: The rationale for the change is to ensure that forms required by the Regulations are accurate and current.</p> <p>LIKELY IMPACT: To allow the regulated community to access the currently-used form.</p>

Detail of All Changes Proposed in this Regulatory Action

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

Current section number	New section number, if applicable	Current requirement	Change, intent, rationale, and likely impact of new requirements
Throughout all sections			<p>CHANGE: The following changes were made throughout the document:</p> <ul style="list-style-type: none"> ● “any” deleted or replaced with “a”; ● “all” deleted or replaced with “a”; ● “such” deleted or replaced with “the”; ● “ground water” replaced with “groundwater”; ● “driller” replaced with “water well systems provider”; ● “sanitarian” replaced with “environmental health specialist”; ● Words not capitalized unless they are proper nouns (e.g., “department, board, commissioner”); and ● Male pronouns deleted and replaced with gender neutral terms. <p>In subsequent rows, changes as described above are summarized as “amended for clarity.”</p> <p>INTENT: To remove obsolete references and unnecessary terms which can lead to multiple interpretations.</p> <p>RATIONALE: Conformance to the Virginia Register of Regulations Form, Style, and Procedure Manual for Publication of Virginia Regulations.</p> <p>LIKELY IMPACT: Consistency in style with other Virginia regulations will reduce confusion for the regulated community.</p>
10		Definitions*	<p>CHANGE: The following definitions were amended: “Abandoned well,” “Aquifer,” “Bedrock,” “Closed Loop ground-source heat pump well,” “Commissioner,” “Construction of wells,” “Disinfection,” “Division,” “Emergency Well Replacement,” “Gravel Pack,” “Groundwater,” “Observation Well or Monitoring Well,” “Sanitary Survey,” “Screen,” “Sewer,” “Water table,” and “Water Well.”</p> <p>The following definitions were added: “Agricultural operation,” “Beneficial use,” “Bioretention pond,” “Biosolids,” “Casing,” “Cathodic protection well,” “Clean fill,” “Coliform,” “Contaminated media,” “Controlled low strength material,” “Cuttings,” “Department,” “DEQ,” “Development or well development,” “Groundwater management area,” “Human consumption,” “Injection well,” “Lead free,” “Nonpublic water,” “Pollutant,” “Pure water,” “Reclaimed water,” “Remediation well,” “Tremie pipe,” “Water quality,” “Water well systems,” “Water well systems provider,” “Waterworks,” “Well</p>

Current section number	New section number, if applicable	Current requirement	Change, intent, rationale, and likely impact of new requirements
			<p>area,” “Well bore,” “Well site,” and Withdrawal system.” One definition was deleted: “Confined aquifer.” INTENT: To provide clarity to the Regulations. RATIONALE: To ensure consistency in relation to agency practices, and to be consistent with the definition of the same term in other regulations (ODW, DEQ, DPOR, DCHD) or industry standard (AWWA, NGWA, USGS). The deleted definition is for a term no longer used in the regulations. LIKELY IMPACT: The amended, added, and deleted definitions will aid the regulated community’s understanding of terms used in the Regulations.</p>
30		Purpose and applicability of regulations	<p>CHANGE: This section is amended to include a reference to well abandonment. A new section (B.) is added to clarify exemptions from the regulations, which were previously presented in the Definitions section, or were non-explicit. INTENT: To correct the language by which, in the opinion of the Office of the Attorney general, certain exemptions from regulatory requirements provided to dewatering wells in the existing regulations are not supported under the statutory authority given in the Code of Virginia §§ 32.1-176.4(A) and 32.1-176.5(A). RATIONALE: §§ 32.1-12 of the Code of Virginia authorizes the Board to provide for reasonable exemptions from regulations. LIKELY IMPACT: The changes in the section will reduce confusion for the regulated community regarding the applicability of the Regulations to certain wells.</p>
40		Relationship to Virginia Sewage Handling and Disposal Regulations	<p>CHANGE: The section is repealed. INTENT: To establish consistency between the Private Well Regulations and the Sewage Handling and Disposal Regulations. RATIONALE: The section became unnecessary following an update to the Sewage Handling and Disposal Regulations. LIKELY IMPACT: The repeal of this section will reduce confusion for the regulated community regarding the relation of private wells to onsite sewage systems.</p>
50		Relationship to State Water Control Board	<p>CHANGE: This section is amended to clarify reference to additional requirements applying to private wells in groundwater management areas under VA Code 62.1-258 and 9VAC25-610.</p>

Current section number	New section number, if applicable	Current requirement	Change, intent, rationale, and likely impact of new requirements
			<p>INTENT: To establish consistency between the Private Well Regulations and the Groundwater Management Act of 1992.</p> <p>RATIONALE: WWSP's must register with the SWCB private wells constructed in a groundwater management area within 30 days of the completion of construction.</p> <p>LIKELY IMPACT: The change to this section will reduce confusion for the regulated community with respect to SWCB authority relative to groundwater withdrawal in designated groundwater management areas.</p>
60		Relationship to DEQ	<p>CHANGE: This section is amended to delete the reference to Waste Management Division of DEQ as it pertains to observation, monitoring, and remediation wells.</p> <p>INTENT: The reference to the Waste Management Division is obsolete.</p> <p>RATIONALE: The use of monitoring wells may occur pursuant to a variety of DEQ regulatory programs, not just waste management.</p> <p>LIKELY IMPACT: The change to this section will reduce confusion for the regulated community regarding observation, monitoring, and remediation wells.</p>
70		Relationship to Uniform Statewide Building Code	<p>CHANGE: This section is amended to change "sampled" to "sampled and tested."</p> <p>INTENT: To improve clarity.</p> <p>RATIONALE: Sampling in the absence of testing does not demonstrate compliance.</p> <p>LIKELY IMPACT: The change to this section will clarify the information to be provided to building officials in order to obtain an occupancy permit.</p>
80		Relationship to DPOR	<p>CHANGE: This section is amended to identify the license and certification of persons engaged in the construction, repair, or alteration of a private well and to remove reference to the class of contractor license needed.</p> <p>INTENT: To establish consistency between the Private Well Regulations and the regulation of tradesmen by the Board of Contractors.</p> <p>RATIONALE: §§ 54.1-1103 and 54.1-1129.1 of the Code of Virginia address DPOR regulatory authority over WWSP.</p> <p>LIKELY IMPACT: The change to this section will provide clarity to the regulated community regarding who is authorized to engage in the construction, repair, or alteration of a private well.</p>
90		Administration of regulations	<p>CHANGE: This section is amended for clarity.</p>

Current section number	New section number, if applicable	Current requirement	Change, intent, rationale, and likely impact of new requirements
			<p>INTENT: Conformance to the Virginia Register of Regulations Form, Style, and Procedure Manual for Publication of Virginia Regulations.</p> <p>RATIONALE: § 2.2-4000 et seq. of the Code of Virginia</p> <p>LIKELY IMPACT: Consistency in style with all Virginia regulations provides clarity for the regulated community.</p>
100		Right of entry and inspections	<p>CHANGE: Addition of “In accordance with the provisions of § 32.1-176.6 of the Code of Virginia, the department has the authority to conduct such inspections as it may find reasonably necessary to ensure that construction work conforms to applicable construction standards.”</p> <p>INTENT: To clarify the Department’s right to inspect private well construction.</p> <p>RATIONALE: Inspection of well construction protects public health and groundwater resources by ensuring that requirements of Part III of the Regulations are achieved.</p> <p>LIKELY IMPACT: Improved quality of private well construction throughout the Commonwealth.</p>
170		Variances	<p>CHANGE: Subsection headings are revised. Section B. clarifies the requirements of a variance application for consistency with 12VAC5-610. Subsections C through G amended for clarity</p> <p>INTENT: To conform to the <i>Virginia Register of Regulations Form, Style, and Procedure Manual for Publication of Virginia Regulations</i> and to realize consistency with 12VAC5-610.</p> <p>RATIONALE: § 2.2-4000 et seq. of the Code of Virginia</p> <p>LIKELY IMPACT: Consistency in style with all Virginia regulations will reduce confusion for the regulated community.</p>
180		Hearing Types	<p>CHANGE: Deletion of discussion of components of adjudicatory hearing pursuant to § 2.2-4000 et seq. of the Code of Virginia.</p> <p>INTENT: To improve clarity of the Regulations.</p> <p>RATIONALE: It is not necessary to duplicate the APA in the Regulations.</p> <p>LIKELY IMPACT: Consistency in style with all Virginia regulations will reduce confusion for the regulated community.</p>
210		Appeals	<p>CHANGE: Deletion of discussion of hearings and variances discussed in other sections.</p> <p>INTENT: To reduce confusion by not duplicating requirements in different sections.</p>

Current section number	New section number, if applicable	Current requirement	Change, intent, rationale, and likely impact of new requirements
			<p>RATIONALE: The elimination of duplication mitigates the chance of inconsistent interpretation of the Regulations.</p> <p>LIKELY IMPACT: To reduce confusion for the regulated community regarding the appeals process.</p>
220		Permits & Inspection Statements: General	<p>CHANGE: This section is amended to remove exemption from permitting for dewatering wells.</p> <p>INTENT: To avoid duplication with Section 30 which exempts dewatering wells from all parts of the chapter except abandonment.</p> <p>RATIONALE: In a January 27, 2017, memorandum to the Commissioner of VDH, Grant Kronenberg, Assistant Attorney General offered opinion that certain exemptions from regulatory requirements provided to dewatering wells in the existing regulations are not supported under the statutory authority given in the Code of Virginia §§ 32.1-176.4(A) and 32.1-176.5(A).</p> <p>LIKELY IMPACT: The change to this section will reduce confusion for the regulated community regarding requirements pertaining to dewatering wells.</p>
230		Application for a Construction Permit	<p>CHANGE: A requirement is added that the owner provide a statement indicating whether the adjacent property is used for an agricultural operation and, if so, to provide additional information (identified in Sub-section 380.E) if necessary.</p> <p>INTENT: To address additional requirements on well owners pursuant to § 32.1-176.5:2 of the Code of Virginia.</p> <p>RATIONALE: § 32.1-176.5:2 of the Code of Virginia prohibits construction of a private well within 50 feet of the property line with an adjacent property of three acres or larger that is used for an agricultural operation, as defined in § 3.2-300.</p> <p>LIKELY IMPACT: The change to this section will reduce confusion for the regulated community regarding information to be included on the application for a construction permit.</p>
240		Issuance of Construction Permit	<p>CHANGE: This section is amended to allow designation of well area or well site on construction permits.</p> <p>INTENT: To reduce the need for permit revisions or issuance of a second permit to address issues encountered during well construction.</p> <p>RATIONALE: In the event that site-specific conditions place limitation on well construction, the designation of a well area allows the WWSP to relocate within the area</p>

Current section number	New section number, if applicable	Current requirement	Change, intent, rationale, and likely impact of new requirements
			<p>without risk of non-compliance with the permit. LIKELY IMPACT: The change to this section will reduce the number of denials of inspection statements resulting from the relocation of a well to avoid an onsite obstacle or limitation.</p>
250		Emergency procedures	<p>CHANGE: This section is amended to recognize that private sector professionals may perform sanitary surveys for emergency well replacements. INTENT: To update the outdated reference to local health departments being the sole provider of well location services. RATIONALE: § 32.1-176.5:2.B. and 2018 Acts of the Assembly Chapter 831 authorize the Department to accept private site evaluations and designs from licensed onsite soil evaluators, professional engineers, and water well systems providers. LIKELY IMPACT: The change to this section will reduce confusion for the regulated community regarding the conducting of sanitary surveys for emergency well replacements.</p>
290		Revocation of permits or inspection statements	<p>CHANGE: This section is amended to add a reference to new section 331. INTENT: To improve clarity. RATIONALE: Section 331 discusses enforcement, notices, and informal conferences. LIKELY IMPACT: The change to this section will reduce confusion for the regulated community regarding permit revocation.</p>
300		Voidance of construction permits	<p>CHANGE: This section is amended to clarify that the commissioner may declare permit documents null and void on the basis of changed conditions, and to add a reference to new section 331. INTENT: To improve clarity. RATIONALE: As originally written, the section could be interpreted to state that permit documents would become null and void without action. LIKELY IMPACT: The change to this section will reduce confusion for the regulated community regarding voidance of construction permits.</p>
310		Statement required upon completion of construction	<p>CHANGE: This section is amended to specify the deadline for submission of a uniform water well completion report and to clarify that it shall be signed. INTENT: To clarify responsibilities of the water well systems provider. RATIONALE: To ensure proper documentation of well construction.</p>

Current section number	New section number, if applicable	Current requirement	Change, intent, rationale, and likely impact of new requirements
			<p>LIKELY IMPACT: The change to this section will provide clarity the regulated community regarding uniform water well completion reports.</p>
330		Issuance of Inspection Statement	<p>CHANGE: This section is amended to clarify that the issuance of the inspection statement by VDH does not denote or imply a warranty or guarantee of water quality or quantity. INTENT: To improve clarity. RATIONALE: The inspection statement confirms that a private well meets the minimum location and construction requirements of the chapter; it is not an assurance of well performance. LIKELY IMPACT: The regulated community will understand that water quality and quantity is not something VDH can assure through means of the Regulations.</p>
NA	331	Enforcement, Notices, Informal Conferences.	<p>CHANGE: This section provides language regarding the citation of regulatory violations, remediating such violations, the addition of language regarding informal fact finding conferences, and the Commissioner’s authority to take action in cases of threats to public health as it pertains to private wells. INTENT: The intent of the change is to inform the regulated community of rights and responsibilities and the Department’s administration of the APA. RATIONALE: §§ 32.1-12, 32.1-176.2, and 2.2-4000 et seq. of the Code of Virginia. LIKELY IMPACT: The change to this section will provide clarity to the regulated community regarding enforcement, notices, and informal conferences.</p>
350		General	<p>CHANGE: This section is amended to clarify the applicability of the regulations to existing private wells. INTENT: The intent is to clarify the effective date of the chapter. RATIONALE: §§ 32.1-12 and 32.1-176.2 of the Code of Virginia. LIKELY IMPACT: The change to this section will reduce confusion for the regulated community regarding the effective date of the regulations.</p>
360		Classes of water wells*	<p>CHANGE: This section is amended to create Class IV well subclasses that mirror Class III well subclasses, and to provide method to convert a Class IV well to a Class III well. INTENT: To provide well owners a simplified pathway to change a well from non-potable to potable use, provided that separation distance criteria are met. RATIONALE: To prevent abandonment or replacement of Class IV wells intended to be repurposed for potable water supply when</p>

Current section number	New section number, if applicable	Current requirement	Change, intent, rationale, and likely impact of new requirements
			<p>well construction does not conform to a Class III standard. LIKELY IMPACT: The change to this section will assist the regulated community and the Department to alter well classifications when situations warrant.</p>
370	431	Water quality	<p>CHANGE: Section 370 is repealed. INTENT: The information is presented in new section 431. RATIONALE: The rationale is to list requirements related to the construction of a private well in the order in which they occur. LIKELY IMPACT: The change to this section will provide clarity to the regulated community by listing well construction activities in the regulation consistent with the order in which they occur when a well is constructed.</p>
380		Well Location and Separation Distances*	<p>CHANGE: This section is amended to:</p> <ul style="list-style-type: none"> ● Clarify separation distance criteria; ● Simplify Table 3.1 by removing footnotes and incorporating footnoted conditions in the table itself; ● Add additional separation distance criteria for: <ul style="list-style-type: none"> - Permanently abandoned onsite sewage disposal systems. - Reclaimed water distribution pipelines. - Biosolids application sites. - Bioretention ponds. ● Improve consistency of separation criteria with similar criteria in 12VAC5-610 and various DEQ regulations and guidance documents; ● Establish criteria for certification required by VA Code 32.1-176.5:2.; and ● Eliminate the required separation distance from termite treated building foundation. <p>INTENT: To protect public health and groundwater resources by the adoption of clearer and more comprehensive well location requirements. RATIONALE: To incorporate current agency policies, separation distances applicable in other regulations, and industry standards. The amendment regarding termite treated foundations is based on a joint investigation conducted by the Office of Environmental Health Services and the Office of Epidemiology, and will provide owners with greater flexibility with regards to</p>

Current section number	New section number, if applicable	Current requirement	Change, intent, rationale, and likely impact of new requirements
			<p>placement of private wells near building foundations. LIKELY IMPACT: The change to this section will provide clarity to the regulated community and make more of a property available for the siting of a well.</p>
400		Well construction material specifications*	<p>CHANGE: This section is amended to:</p> <ul style="list-style-type: none"> ● Replace prescriptive standards with reference to nationally recognized standards such as ASTM and NSF; ● Relocate “Joints” to section 410; ● Relocate grout specifications from Section 410 to this section; ● Add requirement that water used for well construction shall be pure water; and ● Add requirement that compounds used in disinfection shall meet NSF environmental specifications. <p>INTENT: To protect public health and groundwater resources by the adoption of clearer and more comprehensive material specifications. RATIONALE: To incorporate current industry standards and agency policies. LIKELY IMPACT: The change to this section will provide clarity to the regulated community regarding materials standards and requirements.</p>
410		Well construction*	<p>CHANGE: This section is amended to:</p> <ul style="list-style-type: none"> ● Provide requirement that WWSP notify the agency prior to initiation of well construction; ● Relocate “Joints” from section 400 to this section; ● Add subsections addressing: <ul style="list-style-type: none"> - Well bore. - Filter pack. - Well development. - Well maintenance and repair. ● Relocate grout specifications to Section 400; and ● Delete prescriptive standards pertaining to well casing. <p>It is important to note the Waterworks Regulations reference AWWA A-100, a nationally recognized standard for construction of public water supply wells. The A-100 standard is too rigid for most private wells, and reference to that standard in the Private Well Regulations would place an undue technical and financial burden on private well owners and WWSP. In the absence of a similar nationally recognized well construction standard applicable to private wells, this section provides more details regarding finished well construction</p>

Current section number	New section number, if applicable	Current requirement	Change, intent, rationale, and likely impact of new requirements
			<p>than do the sections pertaining to well construction included in the Waterworks Regulation.</p> <p>INTENT: To clarify the minimum construction standards for private wells.</p> <p>RATIONALE: To incorporate current agency policy and industry standards.</p> <p>LIKELY IMPACT: The change to this section will provide clarity to the regulated community regarding well construction.</p>
420		Observation wells*	<p>CHANGE: This section is amended to clarify that test and exploration wells are not observation or monitoring wells. It is also amended to clarify that permanent abandonment of observation or monitoring wells is required following cessation of use and that temporary abandonment may only occur under the terms of a permit issued by the DEQ.</p> <p>INTENT: To enhance protection of public health and groundwater resources.</p> <p>RATIONALE: To address a loophole in the existing regulations by which wells installed for Preliminary Engineering Reports and similar studies are not permitted as private wells, and to ensure permanent abandonment of unused observation and monitoring wells.</p> <p>LIKELY IMPACT: The change to this section will result in test and exploration wells being permitted as private wells. It will also increase permanent abandonment of observation and monitoring wells.</p>
430		Disinfection	<p>CHANGE: This section is amended to provide the option for an alternate method of well disinfection endorsed by the NGWA.</p> <p>INTENT: To protect public health and groundwater resources by increasing options by which WWSP disinfect wells.</p> <p>RATIONALE: To provide greater flexibility for WWSP to disinfect wells under a variety of schedules rather than limiting all disinfection to a 24 hour method.</p> <p>LIKELY IMPACT: The change to this section will increase options for the regulated community regarding private well disinfection.</p>
370	431	Water quality	<p>CHANGE: Replaces section 370.</p> <p>INTENT: To improve clarity.</p> <p>RATIONALE: The rationale is to list requirements related to the construction of a private well in the order in which they occur.</p> <p>LIKELY IMPACT: The change to this section will reduce confusion for the regulated community by listing water quality requirements after well construction and disinfection.</p>

Current section number	New section number, if applicable	Current requirement	Change, intent, rationale, and likely impact of new requirements
440		Uniform Water Well Completion Reports	<p>CHANGE: This section is repealed. INTENT: To improve clarity. RATIONALE: The repeal of this section eliminates duplication within the chapter, given that 310 addresses the Uniform Water Well Completion Report. LIKELY IMPACT: The change to this section will reduce confusion for the regulated community by eliminating duplicate sections having the same requirement.</p>
450		Well abandonment*	<p>CHANGE: This section is amended to:</p> <ul style="list-style-type: none"> ● Provide clarity; ● Provide requirement that WWSP notify the agency prior to initiation of well abandonment; ● Add subsection on materials prohibited from use in well abandonment; and ● Provide additional method to abandon a bored well so that it is no longer a well with respect to separation distances. <p>INTENT: To enhance protection of public health and protection of groundwater resources. RATIONALE: To provide the regulated community with greater flexibility regarding well abandonment methods, which in turn will allow the placement of onsite sewage systems near abandoned bored wells. Further, to protect groundwater by restricting the use of coal combustion by-products in materials used to abandon wells. LIKELY IMPACT: The change to this section will protect public health and groundwater by improved well abandonment practices, and provide means to increase usable land for onsite sewage system siting and repairs.</p>
460		Yield for residential wells	<p>CHANGE: This section is amended to clarify the time period necessary for sustained flow of five gallons per minute per connection when well capacity is under three gallons per minute. INTENT: To eliminate ambiguity. RATIONALE: The existing wording of the section could not be enforced because it did not clearly describe the minimum standard to be achieved. LIKELY IMPACT: The change to this section will provide clarity to the regulated community regarding yield for residential wells.</p>
480		Well casing specifications	<p>CHANGE: The section is repealed. INTENT: To reduce duplication in the chapter.</p>

Current section number	New section number, if applicable	Current requirement	Change, intent, rationale, and likely impact of new requirements
			<p>RATIONALE: The revision of section 400 eliminated the need for this section.</p> <p>LIKELY IMPACT: The change to this section will reduce confusion for the regulated community regarding well casing specifications.</p>

Office of Regulatory Management
Economic Review Form

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12 VAC 5 - 630
VAC Chapter title(s)	Private Well Regulations
Action title	Amended regulations
Date this document prepared	August 18, 2022

Cost Benefit Analysis

Table 1a must be completed for all actions. Tables 1b and 1c must be completed for actions (or portions thereof) where the agency is exercising discretion, including those where some of the changes are mandated by state or federal law or regulation. Tables 1b and 1c are not needed if **all** changes are mandated, and the agency is not exercising any discretion. In that case, enter a statement to that effect.

- (1) Direct Costs & Benefits: Identify all specific, direct economic impacts (costs and/or benefits), anticipated to result from the regulatory change. (A direct impact is one that affects entities regulated by the agency and which directly results from the regulatory change itself, without any intervening steps or effects. For example, the direct impact of a regulatory fee change is the change in costs for these regulated entities.) When describing a particular economic impact, specify which new requirement or change in requirement creates the anticipated economic impact. Keep in mind that this is the proposed change versus the status quo. One bullet has been provided, add additional bullets as needed.
- (2) Quantitative Factors:
 - (a) Enter estimated dollar value of total (overall) direct costs described above.
 - (b) Enter estimated dollar value of total (overall) direct benefits described above.
 - (c) Enter the present value of the direct costs based on the worksheet.
 - (d) Enter the present value of the direct benefits based on the worksheet.
- (3) Benefits-Costs Ratio: Calculate d divided by c OR enter it from the worksheet.
- (4) Net Benefit: Calculate d minus c OR enter it from the worksheet.
- (5) Indirect Costs & Benefits: Identify all specific, indirect economic impacts (costs and/or benefits), anticipated to result from the regulatory change. (An indirect impact is one that results from responses to the regulatory change, but which are not directly required by the regulation. Indirect impacts of a regulatory fee change on regulated entities could include a change in the prices they charge, changes in their operating procedures or employment levels, or decisions to enter or exit the regulated profession or market. Indirect impacts also include responses by other entities that have close economic ties to the regulated entities, such as suppliers or partners.) If there are no indirect costs or benefits, include a specific statement to that effect.

- (6) Information Sources: Describe the sources of information used to determine the benefits and costs, including the source of the Quantitative Factors. If dollar amounts are not available, indicate why they are not.
- (7) Optional: Use this space to add any further information regarding the data provided in this table, including calculations, qualitative assessments, etc.

Table 1a: Costs and Benefits of the Proposed Changes (Primary Option)

<p>(1) Direct Costs & Benefits</p>	<p>VDH does not anticipate that the proposed changes will alter the cost to locate, permit, design or construct a private well, or have any other direct cost for well owners or water well system providers. There is one proposed change that is anticipated to eliminate a common variance request:</p> <ul style="list-style-type: none"> ● Section 380 and Table 1: reducing the separation distance from termite treated structures (reduction based on toxicological assessment of currently used termiticides). <p>Direct Costs: The direct costs (e.g., permitting, site inspection) for the proposed change are not anticipated to change for Local Health Departments or private sector providers. The proposed change is anticipated to reduce the number of variances submitted and processed for separation distance from termite-treated foundations and for abandonment of bored/hand-dug wells.</p> <p>The direct costs incorporate time required of EH Managers (District), OEHS and OCOM personnel (Central Office) to process a variance. From 2019 to 2021, the average number of variances processed related to the separation distance from termite treated foundations was five per year. The total personnel costs to process a variance is estimated to average \$650.00 (LHD up to Commissioner of Health).</p> <p>Direct Benefits: The direct benefits of this proposed change are elimination of variances regarding the separation distance between termite treated foundations and private wells. This provides a direct benefit to builders and homeowners who would have otherwise had to wait 30 to 60 days for a variance to be processed.</p>	
<p>(2) Quantitative Factors</p>	<p>Estimated Dollar Amount</p>	<p>Present Value</p>
<p>Direct Costs</p>	<p>(a) \$0</p>	<p>(c) \$0</p>

Direct Benefits	(b) \$3,250 per year (5 per year variances at \$650 each)	(d) \$3,250	
(3) Benefits-Costs Ratio	1	(4) Net Benefit	\$28,555
(5) Indirect Costs & Benefits	<p>All indirect costs and benefits. VDH has not identified any indirect costs that will result from the changes. The following indirect benefits of the regulatory changes have been identified.</p> <ul style="list-style-type: none"> ● Section 10 includes definition for lead free. The indirect benefit is protection of public health, especially for children, by reduction of the risk of exposure to lead. ● Section 240 allows for the designation of a well area on private well construction permits. The indirect benefit is a reduction of the wells which have to be abandoned and replaced because they were installed in the wrong location. ● Section 360 creates Class IV subclasses that mirror Class III well subclasses. The indirect benefit is to prevent abandonment or replacement of Class IV wells intended to be repurposed for potable water supply when well construction does not conform to a Class III standard. ● Section 400 includes provisions of well construction material specifications consistent with current industry standards. The indirect benefit is enhanced protection of public health and groundwater resources via clearer and more comprehensive material specification. ● Section 410 decreases depth when pouring of grout is acceptable in bored wells from 30 feet to 20 feet. The indirect benefit is protection of public health and groundwater resources by reducing changes of bridging or other failure during well construction. ● Section 410 adds subsections pertaining to the well bore, filter pack well development, and well maintenance and repair. The indirect benefit is protection of public health and groundwater resources by clarification of the minimum construction standards for private wells. ● Section 420 clarifies that test and exploration wells are not observation/monitoring wells and further clarifies that permanent abandonment of observation/monitoring wells is required following cessation of use. The indirect benefit is protection of public health and groundwater resources by encouraging abandonment of unused wells. Further, it eliminates a loophole by which certain wells bypass permitting as private wells. ● Section 430 is amended to provide the option for an alternate method of well disinfection endorsed by the National Groundwater Association. The indirect benefit is to protect public health and 		

	<p>groundwater resources by allowance for well disinfection methodology consistent with site specific considerations.</p> <ul style="list-style-type: none"> Section 450 includes provision that the Water Well System Provider notify VDH prior to well abandonment, identifies materials prohibited from use in well abandonment (e.g. coal ash), and identifies a method to abandon a bored well such that it no longer needs to be considered a well with respect to separation distances. The indirect benefit is enhanced protection of public health and groundwater resources by improved well abandonment practices.
(6) Information Sources	Section 380 and Table 1 revision to reduce the setback from termite treated structures. Variance costs determined by review of agency variance tracking log, and hours expended by involved staff and average hourly rates (HR).
(7) Optional	

Table 1b: Costs and Benefits under the Status Quo (No change to the regulation)

This table addresses current requirements and the implications of not making any changes. In other words, describe the costs and benefits of maintaining the current regulatory requirements as is.

(1) Direct Costs & Benefits	<ul style="list-style-type: none"> Section 380 and Table 1: maintain 50 foot separation distance from all termite treated structures. <p>Direct Costs: The direct costs of maintaining the status quo is \$3,250 per year. The direct costs incorporate time required of EH Managers (District), OEHS and OCOM personnel (Central Office) to process a variance. Based on the number of variances related to termite treatment from 2019 to 2021, the average number of variances processed related to the separation distance from termite treated foundations was five per year. The total personnel costs to process a variance is estimated to average \$650.00 per variance (LHD up to Commissioner of Health).</p> <ul style="list-style-type: none"> Direct Benefits: Maintaining the status quo provides no benefits. It delays action on permits, and increases agency cost. 	
(2) Quantitative Factors	Estimated Dollar Amount	Present Value

Direct Costs	(a) \$3,250 per year (5 less variances at \$650 each)	(c) \$3,250	
Direct Benefits	(b) \$0.00	(d) \$0.00	
(3) Benefits-Costs Ratio	NA	(4) Net Benefit	-\$3,250
(5) Indirect Costs & Benefits	<p>All indirect costs and benefits. There are no indirect benefits of maintaining the status quo. The indirect cost of the status quo regulations are not quantifiable because every application for a private well construction permit is unique. The specific cost incurred by each applicant is unknown until such time that a permit request is received and a site assessment conducted.</p> <p>Maintaining the status quo would eliminate the indirect benefits identified in Row (6) of Table 1a.</p>		
(6) Information Sources	<p>Section 380 and Table 1 revision to reduce the setback from termite treated structures. Variance costs determined by review of agency variance tracking log, and hours expended by involved staff and average hourly rates (HR).</p>		
(7) Optional			

Table 1c: Costs and Benefits under an Alternative Approach

This table addresses an alternative approach to accomplishing the objectives with different requirements. These alternative approaches may include the use of reasonably available alternatives in lieu of regulation, or information disclosure requirements or performance standards instead of regulatory mandates.

(1) Direct Costs & Benefits	<p>Section 380 and Table 1 maintain 25 foot separation distance from all termite treated structures.</p> <p>Direct Costs: This alternative approach increases the safety factor for the separation distance from 50% to 150%. The direct costs (e.g., permitting, site inspection) for the alternative approach are not anticipated to change for Local Health Departments or private sector providers based on historical variances. The alternative approach is anticipated to reduce the number of variances submitted and</p>
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	<p>processed for separation distance from termite-treated foundations and for abandonment of bored/hand-dug wells</p> <p>The direct costs incorporate time required of EH Managers (District), OEHS and OCOM personnel (Central Office) to process a variance. Based on the number of variances related to termite treatment from 2019 to 2021, the average number of variances processed related to the separation distance from termite treated foundations is five per year. The total personnel costs to process a variance is estimated to average \$650.00 (LHD up to Commissioner of Health).</p> <p>Direct Benefits: The direct benefits of this proposed change is reduction of variances regarding the separation distance between termite treated foundations and private wells for these purposes. However, owners seeking to install a well between 15 feet and 24 feet from a termite treated foundation would still need a variance. This provides a direct benefit builders and homeowners that would have otherwise had to wait 30 to 60 days for a variance to be processes.</p>		
(2) Quantitative Factors	Estimated Dollar Amount	Present Value	
Direct Costs	(a) \$3,000 (year 1)	(c) \$0	
Direct Benefits	(b) \$3,250 per year (5 less variances at \$650 each)	(d) \$3,250	
(3) Benefits-Costs Ratio		(4) Net Benefit	\$25,555
(5) Indirect Costs & Benefits	There are no additional indirect costs, as VDH is not proposing other alternatives to the status beyond those provided above.		
(6) Information Sources	Section 380 and Table 1 revision to reduce the setback from termite treated structures. Variance costs determined by review of agency variance tracking log, and hours expended by involved staff and average hourly rates (HR).		
(7) Optional			

Impact on Local Partners

- (1) Describe the direct costs and benefits (as defined on page 1) for local partners in terms of real monetary costs and FTEs. Local partners include local or tribal governments, school divisions, or other local or regional authorities, boards, or commissions. If local partners are not affected, include a specific statement to that effect and a brief explanation of the rationale.
- (2) Quantitative Factors:
 - (a) Enter estimated dollar value of total (overall) direct costs described above.
 - (b) Enter estimated dollar value of total (overall) direct benefits described above.
- (3) Indirect Costs & Benefits: Describe any indirect benefits and costs (as defined on page 1) for local partners that are associated with all significant changes. If there are no indirect costs or benefits, include a specific statement to that effect.
- (4) Information Sources: describe the sources of information used to determine the benefits and costs, including the source of the Quantitative Factors. If dollar amounts are not available, indicate why they are not.
- (5) Assistance: Identify the amount and source of assistance provided for compliance in both funding and training or other technical implementation assistance.
- (6) Optional: Use this space to add any further information regarding the data provided in this table, including calculations, qualitative assessments, etc.

Note: If any of the above information was included in Table 1, use the same information here.

Table 2: Impact on Local Partners

(1) Direct Costs & Benefits	There are not anticipated direct costs or benefits to local partners. Localities having ordinances pertaining to private wells may need to revise ordinances to maintain consistency with the revised regulations. VDH anticipates that this effort will be absorbed in existing locality budgets.
(2) Quantitative Factors	Estimated Dollar Amount
Direct Costs	(a) \$0
Direct Benefits	(b) \$0
(3) Indirect Costs & Benefits	There are no anticipated indirect costs or benefits to local partners.
(4) Information Sources	NA
(5) Assistance	NA

(6) Optional	
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Economic Impacts on Families

- (1) Describe the direct costs and benefits (as defined on page 1) to a typical family of three (average family size in Virginia according to the U. S. Census) arising from any proposed regulatory changes that would affect the costs of food, energy, housing, transportation, healthcare, and education. If families are not affected, include a specific statement to that effect and a brief explanation of the rationale.
- (2) Quantitative Factors:
 - (a) Enter estimated dollar value of direct costs.
 - (b) Enter estimated dollar value of direct benefits.
- (3) Indirect Costs & Benefits: Describe any indirect costs and benefits (as defined on page 1) to a typical family of three that are most likely to result from the proposed changes.
- (4) Information Sources: describe the sources of information used to determine the benefits and costs, including the source of the Quantitative Factors. If dollar amounts are not available, indicate why not.
- (5) Optional: Use this space to add any further information regarding the data provided in this table, including calculations, qualitative assessments, etc.

Note: If any of the above information was included in Table 1, use the same information here.

Table 3: Impact on Families

(1) Direct Costs & Benefits	There are not anticipated direct costs or benefits to families. The cost for private well installation is not anticipated to be affected by this regulatory change.
(2) Quantitative Factors	Estimated Dollar Amount
Direct Costs	(a) \$0
Direct Benefits	(b) \$0
(3) Indirect Costs & Benefits	The indirect costs and the indirect benefits of the regulatory changes on families are not quantifiable because every application for a private well construction permit is unique. The specific benefits received by a family is unknown until such time that a permit request is received and a site assessment conducted. In general, the proposed changes incorporate standard industry practice which ensure the protection of family’s health by ensuring properly constructed private wells.

(4) Information Sources	NA
(5) Optional	

Impacts on Small Businesses

- (1) Describe the direct costs and benefits (as defined on page 1) for small businesses. For purposes of this analysis, “small business” means the same as that term is defined in § 2.2-4007.1. If small businesses are not affected, include a specific statement to that effect and a brief explanation of the rationale.
- (2) Quantitative Factors:
 - (a) Enter estimated dollar value of direct costs.
 - (b) Enter estimated dollar value of direct benefits.
- (3) Indirect Costs & Benefits: Describe the indirect benefits and costs (as defined on page 1) for small businesses that are most likely to result from the proposed changes.
- (4) Alternatives: Add a qualitative discussion of any equally effective alternatives that would make the regulatory burden on small business more equitable compared to other affected business sectors, and how those alternatives were identified.
- (5) Information Sources: describe the sources of information used to determine the benefits and costs, including the source of the Quantitative Factors. If dollar amounts are not available, indicate why not.
- (6) Optional: Use this space to add any further information regarding the data provided in this table, including calculations, qualitative assessments, etc.

Note: If any of the above information was included in Table 1, use the same information here.

Table 4: Impact on Small Businesses

(1) Direct Costs & Benefits	There are not anticipated direct costs or benefits to small businesses. The primary small businesses using the Private Well Regulations are Water Well Systems Providers, Onsite Soil Evaluators, and Professional Engineers. The regulatory change is not anticipated to affect the cost of permitting or construction of private wells.
(2) Quantitative Factors	Estimated Dollar Amount
Direct Costs	(a) \$0
Direct Benefits	(b) \$0

(3) Indirect Costs & Benefits	The indirect benefits of the regulatory changes on small businesses is not quantifiable because every application for a private well construction permit is unique. The specific benefits received by small businesses is unknown until such time that a permit request is received and a site assessment conducted.
(4) Alternatives	There are no anticipated direct costs or benefits to small businesses; therefore, alternatives other than maintaining the status quo were not considered.
(5) Information Sources	None anticipated
(6) Optional	

Changes to Number of Regulatory Requirements

For each individual VAC Chapter amended, repealed, or promulgated by this regulatory action, list (a) the initial requirement count, (b) the count of requirements that this regulatory package is adding, (c) the count of requirements that this regulatory package is reducing, (d) the net change in the number of requirements. This count should be based upon the text as written when this stage was presented for executive branch review. Five rows have been provided, add or delete rows as needed.

Table 5: Total Number of Requirements

Section number	Number of Requirements			
	Initial Count	Additions	Subtractions	Net Change
10	0	0	0	0
20	1	0	0	0
30	4	0	0	0
40	1	0	0	0
50	1	0	0	0
60	1	0	0	0
70	2	0	0	0
80	1	0	0	0
90	5	0	0	0
100	1	0	0	0
110	1	0	0	0
120	2	0	0	0
130	0	0	0	0
140	4	0	0	0
150	21	0	0	0
160	1	0	0	0
170	16	0	0	0

180	17	0	0	0
190	3	0	0	0
200	2	0	0	0
210	5	0	0	0
220	6	0	0	0
230	8	1	0	1
240	2	0	0	0
250	11	0	0	0
260	11	0	0	0
270	6	0	0	0
271	9	0	0	0
272	4	0	0	0
280	2	0	0	0
290	3	0	0	0
300	4	0	0	0
310	1	0	0	0
320	1	0	0	0
330	2	0	0	0
331	0	0	0	0
340	1	0	0	0
350	1	0	0	0
360	0	0	0	0
370	9	0	4	-4
380	26	7	0	7
390	3	0	0	0
400	10	4	1	3
410	45	9	4	5
420	2	1	0	1
430	2	1	0	1
431	0	4	0	4
440	1	0	1	-1
450	12	2	0	2
460	4	0	0	0
470	0	0	1	-1
480	1	0	1	-1
TOTAL:	276	29	12	17

1 **Project 5654 - Proposed**

2 **Department of Health**

3 **Amend Regulations Following Periodic Review**

4 **12VAC5-630-10. Definitions.**

5 The following words and terms, when used in this chapter, shall have the following meanings
6 unless the context clearly indicates otherwise.

7 "Abandoned well" means a private well ~~whose~~ from which the pump has been disconnected
8 for reasons other than repair or replacement, or ~~whose~~ the use of which has been discontinued
9 or which has been pronounced abandoned by the owner. A temporarily abandoned well is a well
10 that is intended to be returned to service as a source of water at some future time. A permanently
11 abandoned well is a well that is not intended to be used ~~as a source of water at any future time.~~
12 ~~Abandoned wells must meet the requirements of 12VAC5-630-450.~~

13 "Agent" means a legally authorized representative of the owner.

14 "Agricultural operation" means an operation devoted to the bona fide production of crops,
15 animals, or fowl, including the production of fruits and vegetables of all kinds; meat, dairy, and
16 poultry products; nuts, tobacco, nursery and floral products; and the production and harvest of
17 products from silviculture activity.

18 "Annular space" means the space between the well bore hole wall and the outside of a water
19 well casing pipe, or between a casing pipe and a liner pipe.

20 "Aquifer" means a geologic formation, group of formations, or part of a formation, that
21 ~~transmits water~~ has the capability to store and transmit water in sufficient quantity to constitute a
22 usable supply source.

23 "Bedrock" means ~~any solid rock underlying soil, sand, or clay~~ the solid, potentially fractured
24 and fissured rock formations that occur beneath soils, underlying sediment deposits, or weathered
25 material.

26 "Beneficial use" means use of water that includes domestic, agricultural, commercial,
27 industrial, and investigative purposes.

28 "Bioretention pond" means a best management practice structure engineered for the purpose
29 of reducing the pollutant load in storm water runoff to surface water and groundwater systems.

30 "Biosolids" means solid, semisolid, or liquid materials removed from municipal sewage and
31 treated to be suitable for recycling as fertilizer, as defined in 9VAC25-31-10 and 9VAC25-32-10.
32 For the purpose of these regulations, biosolids do not include exceptional quality biosolids as that
33 term is defined in 9VAC25-32-10].

34 "Board" means the State Board of Health.

35 "Bored well" means a well that is excavated by means of a soil auger (hand or power) as
36 distinguished from a well which is drilled, driven, dug, or jetted.

37 "Casing" means a hollow cylindrical device (typically steel, plastic, or concrete) that is installed
38 in a well to maintain the well opening and to provide a seal.

39 "Clean fill" means any combination of undisturbed soil and natural earth material,
40 commercially available quarried sand or gravel product, and cuttings from the well being
41 constructed, provided that the materials do not contain contaminated media. In this context,
42 undisturbed soil and natural earth materials refers to unconsolidated mineral and organic material
43 on the immediate surface of the Earth that developed naturally on the property on which it
44 originates.

45 "Closed-loop ground-source heat pump well" means a well consisting of a sealed loop of
46 plastic pipe buried vertically beneath the earth's surface to allow heat transfer between the fluid
47 in the pipe and the earth. Horizontal closed-loop ground source heat pump pipe configurations
48 installed in trenches, including those which may intercept shallow groundwater, are excluded.

49 "Coliform" means a broad group of naturally occurring bacteria species found in soils and
50 rocks. Coliform bacteria are more prevalent in near surface soils, and their presence in well water
51 may indicate the possible presence of more harmful pathogens.

52 "Collapsing material" means any soil or gravel material which that collapses upon itself
53 forming a seal with the casing and leaves no voids around the casing.

54 "Commercially dependent well" means a well that is the sole source of water for a commercial
55 facility that requires the water from the well for continued operation. Examples include wells
56 serving an ice plant, a car wash facility, or as irrigation for commercial nurseries, or agricultural
57 wells that provide water for livestock or irrigation.

58 "Commissioner" means the State Health Commissioner, who is the chief executive officer of
59 the board, a deputy commissioner, or his a subordinate who has been delegated powers in
60 accordance with subdivision 2 of 12VAC5-630-90 B of this chapter.

61 "Confined aquifer" means an aquifer that is confined by an overlying impermeable formation.

62 "Consolidated rock" means a formation consisting entirely of a natural rock formation that
63 contains no soil and does not collapse against the well casing.

64 "Construction dewatering" means the process of draining an excavated area that is flooded
65 with rain water or groundwater before construction can start.

66 "Construction of wells" means acts necessary to locate and construct private wells, ~~including~~
67 ~~the location of private wells, the boring, digging, drilling, or otherwise excavating of a well hole~~
68 ~~and the installation of casing with or without well screens, or well curbing.~~

69 "Contaminated media" means soil, sediment, dredged material, or debris that, as a result of a
70 release or human use, has absorbed or adsorbed physical, chemical, or radiological substances
71 at concentrations above those consistent with nearby or undisturbed soil or natural earth
72 materials.

73 "Controlled low strength material" or "flowable fill" means a slurry comprised of cement, water,
74 and fine aggregate or filler (including coal ash, foundry sand, quarry fines, and baghouse dust in
75 any combination).

76 "Cuttings" means the solid material, saturated or unsaturated, removed from a borehole drilled
77 by rotary, percussion, or auger methods.

78 "Deep well ejector pump system" means a well that utilizes a casing adapter and a deep well
79 ejector. These wells must maintain a constant vacuum to operate.

80 "~~Dewatering well~~" means a driven well constructed for the sole purpose of lowering the water
81 ~~table and kept in operation for a period of 60 days or less. Dewatering wells are used to allow~~
82 ~~construction in areas where a high water table hinders or prohibits construction and are always~~
83 ~~temporary in nature.~~

84 "Department" means the Virginia Department of Health.

85 "Deputy commissioner" means a person who serves as a deputy commissioner in accordance
86 with § 32.1-22 of the Code of Virginia.

87 "DEQ" means the Virginia Department of Environmental Quality.

88 "Disinfection" means ~~the destruction of all~~ a process that inactivates or destroys pathogenic
89 organisms in water by use of a disinfectant.

90 "Division" means the Division of On-Site Sewage and Water Services, Environmental
91 Engineering, and Marina Programs within the department.

92 "District health department" means a consolidation of local health departments as authorized
93 in § 32.1-31 C of the Code of Virginia.

94 "DPOR" means the Virginia Department of Professional and Occupational Regulation.

95 "Drilled shallow well suction pump system" means a drilled well two inches or less in diameter
96 that utilizes an offset pump to draw water from the well through the casing. These wells must
97 maintain a constant vacuum in order to operate.

98 "Drilled well" means a well that is excavated wholly or in part by means of a drill (either
99 percussion or rotary) ~~which~~ that operates by cutting or abrasion.

100 "Driven well" means a well that is constructed by driving a pipe, at the end of which there is a
101 drive point and screen, without the use of ~~any a~~ a drilling, boring, or jetting device.

102 "Dug well" means a well that is excavated by means of picks, shovels, or other hand tools, or
103 by means of a power shovel or other dredging or trenching machinery, as distinguished from a
104 bored, drilled, driven, or jetted well.

105 "Emergency well replacement" means the replacement of an existing private drinking water
106 well, heat pump well, or commercially dependent well that has failed to deliver the water needed
107 for its intended use. ~~Such~~ The failure requires the drilling of a new well or extensive modifications
108 to the existing well. The replacement of failed noncommercial irrigation wells, and other types of
109 private wells are not considered emergencies.

110 "Gravel pack" means sand or gravel placed outside a well screen in a well to assist the flow
111 of water into the well screen and to inhibit clogging of the screen.

112 ~~"Ground water"~~ "Groundwater" means ~~any~~ water, except capillary moisture, beneath the land
113 surface in the zone of saturation or beneath the bed of ~~any a~~ a stream, lake, reservoir or other body
114 of surface water within the boundaries of this Commonwealth, whatever may be the subsurface
115 geologic structure in which ~~such~~ the water stands, flows, percolates, or otherwise occurs.

116 "Groundwater management area" means a geographically defined groundwater area in which
117 the State Water Control Board has deemed the levels, supply, or quality of groundwater to be
118 adverse to public welfare, health, and safety pursuant to 9VAC25-600.

119 "Grout" means ~~any a~~ a stable, impervious bonding material, reasonably free of shrinkage, ~~which~~
120 that is capable of providing a watertight seal in the annular spaces of a water well throughout the
121 depth required, to protect against the intrusion of objectionable matter.

122 "Human consumption" means drinking, food preparation, dishwashing, bathing, showering,
123 hand washing, teeth brushing, and maintaining oral hygiene.

124 "Jetted well" means a well that is excavated using water pumped under pressure through a
125 special washing point to create a water jet ~~which~~ that cuts, abrades, or erodes material to form
126 the well.

127 "Lead free" means the following:

128 1. When used with respect to solders and flux, refers to solder and flux containing not
129 more than 0.2% lead.

130 2. When used with respect to pipes, pipe fittings, plumbing fittings, and plumbing fixtures,
131 refers to the weighted average of wetted surfaces of pipes, pipe fittings, plumbing fittings,
132 and plumbing fixtures containing not more than 0.25% lead.

133 "Local health department" means the department established in each city and county in
134 accordance with § 32.1-30 of the Code of Virginia.

135 "Noncollapsing material" means soil or gravel material ~~which that~~ can maintain an open well
136 bore ~~hole~~ long enough to grout the annular space between a well and the well bore hole. For the
137 purpose of this chapter, soil or gravel material ~~which that~~ collapsed upon itself but created voids
138 around the casing is considered noncollapsing material.

139 "Nonpublic water" means pure water that is not provided by a waterworks.

140 "Observation well" or "monitoring well" means a well constructed to measure hydrogeologic
141 parameters, ~~such as the fluctuation of water levels,~~ or for scientific monitoring of the quality of
142 ground water groundwater, or for both purposes.

143 "Owner" means ~~any person, who owns, leases, the Commonwealth or any of its political~~
144 subdivisions, including sanitary districts, sanitation district commissions and authorities, an
145 individual, a group of individuals acting individually or as a group, a public or private institution,
146 corporation, company, partnership, firm, or association that owns or proposes to own or lease a
147 private well.

148 "Person" means ~~any and all persons, including individuals, firms, partnerships, associations,~~
149 ~~public or private institutions, municipalities or political subdivisions, governmental agencies, or~~
150 ~~private or public corporations organized under the law of this Commonwealth or any other state~~
151 ~~or country~~ an individual, corporation, partnership, association, or any other legal entity.

152 "Pollutant" means substances, including solid waste, sewage, effluent, radioactive materials,
153 petroleum products, manufactured chemical products, and industrial byproducts, that can
154 detrimentally affect the quality of water.

155 "Private well" means any a water well constructed for a person on land ~~which that~~ is owned
156 or leased by that person and is usually intended for household, ~~ground water~~ groundwater source
157 heat pump, agricultural use, industrial use, or other nonpublic water well.

158 "Pure water" means water of a quality suitable for human consumption that is (i) sanitary and
159 normally free of minerals, organic substances, and toxic agents in excess of reasonable amounts
160 and (ii) adequate in quantity and quality for the minimum health requirements of the persons
161 served.

162 "Reclaimed water" means treated wastewater that can be used for beneficial purposes,
163 determined by the degree of treatment achieved.

164 "Remediation well" means an observation or monitoring well in use for recovery or treatment
165 of one or more pollutants.

166 "Replacement well" means a well being constructed to take the place of an existing well that
167 is being taken out of service and is being abandoned.

168 "Sanitary survey" means an investigation of ~~any condition that may affect public health~~
169 obvious sources of potentially toxic or dangerous substances within 200 feet of a proposed private
170 well.

171 "Screen" means the intake section of a well casing that obtains water from an unconsolidated
172 aquifer providing for the water to flow freely and adding structural support to the bore hole.
173 Screens are used to increase well yield or prevent the entry of sediment, or both.

174 "Sewage" means water carried and nonwater carried human excrement, kitchen, laundry,
175 shower, bath, or lavatory wastes separately or together with ~~such~~ underground, surface, storm
176 and other water and liquid industrial wastes as may be present from residences, buildings,
177 vehicles, industrial establishments, or other places.

178 "Sewage disposal system" means a sewerage system or treatment works designed not to
179 result in a point source discharge.

180 "Sewer" means ~~any sanitary or combined sewer~~ a pipe or conduit used to convey sewage or
181 ~~municipal or industrial wastes~~ waste streams.

182 "Sewerage system" means pipelines or conduits, pumping stations and force mains, and all
183 other construction, devices, and appliances appurtenant thereto, used for the collection and
184 conveyance of sewage to a treatment works or point of ultimate disposal.

185 "Subsurface soil absorption" means a process ~~which~~ that utilizes the soil to treat and dispose
186 of sewage effluent.

187 "Treatment works" means ~~any a~~ a device or system used in the storage, treatment, disposal, or
188 reclamation of sewage or combinations of sewage and industrial wastes, including ~~but not limited~~
189 ~~to~~ pumping, power, and other equipment and appurtenances, septic tanks, and ~~any~~ works,
190 including land, that are or will be (i) an integral part of the treatment process or (ii) used for the
191 ultimate disposal of residues or effluents resulting from ~~such~~ the treatment.

192 "Tremie pipe" means a tube through which grout, filter media, or other flowing material is
193 placed by gravity feed or pumping. The pipe is placed at the lowermost part of the well feature
194 being treated (inner casing or annular space), and the bottom of the pipe remains submerged in
195 the material being placed as the pipe is raised in order to prevent uneven distribution or bridging.

196 "Variance" means a conditional waiver of a specific regulation ~~which~~ that is granted to a
197 specific owner relating to a specific situation or facility and may be for a specified time period.

198 "Water quality" means the chemical, physical, bacteriological, and radiological characteristics
199 of water with respect to its suitability for a particular purpose.

200 "Water table" means the uppermost surface of ~~ground water~~ groundwater saturation in an
201 unconfined aquifer. The level in the saturated zone at which the pressure is equal to atmospheric
202 pressure.

203 "Water well" or "well" means ~~any an~~ an artificial opening or artificially altered natural opening,
204 however made, by which ~~ground water~~ groundwater is sought or through which ~~ground water~~
205 groundwater flows under natural pressure or is intended to be artificially drawn; ~~provided this~~
206 ~~definition shall not include wells drilled for the following purposes: (i) exploration or production of~~
207 ~~oil or gas, (ii) building foundation investigation and construction, (iii) elevator shafts, (iv) grounding~~
208 ~~of electrical apparatus, or (v) the modification or development of springs.~~

209 "Water well systems" means the water well to reach groundwater and the well pump and tank,
210 including pipe and wire, up to and including the pint of connection to plumbing and electrical
211 systems.

212 "Water well systems provider" means the person certified by DPOR to provide the drilling,
213 installation, maintenance, or repair of a water wells or water well systems.

214 "Waterworks" means a system that serves piped water for human consumption to at least 15
215 service connections or 25 or more individuals for at least 60 days out of the year. "Waterworks"
216 includes all structures, equipment, and appurtenances used in the storage, treatment, and
217 distribution of pure water except the piping and fixtures inside the building where the water is
218 delivered.

219 "Well area" means an area designated on a construction permit as appropriate for the
220 construction of a private well.

221 "Well bore" means a vertical hole advanced into the earth, however created, by a water well
222 system provider, in which a well is constructed.

223 "Well site" means the location on the ground surface of a property designated on a
224 construction permit for the construction of a private well.

225 "Work days" or "working days" means days on which the department, the district health
226 department, or the local health department, as applicable in context, is open for business,
227 excluding holidays and closures."

228 "Yield" means the quantity of water, usually measured in volume of water per unit time, which
229 may flow or which may be pumped, from a well or well field.

230 **Statutory Authority**

231 §§ 32.1-12 and 32.1-176.4 of the Code of Virginia.

232 **Historical Notes**

233 Derived from VR355-34-100 § 1.1, eff. April 1, 1992.

234 **12VAC5-630-20. Authority for regulations.**

235 Title 32.1 of the Code of Virginia, and specifically §§ 32.1-12 and ~~32.1-176.4~~ 32.1-176.2 of
236 the Code of Virginia, provide that the ~~State Board of Health~~ board has the duty to protect the
237 public health and to ensure that ~~ground water~~ groundwater resources are not adversely affected
238 by the construction and location of private wells. In order to discharge this duty, the board is
239 empowered, pursuant to §§ 32.1-12 and 32.1-176.4 of the Code of Virginia, to ~~supervise and~~
240 regulate the construction and location of private wells within the Commonwealth.

241 **Statutory Authority**

242 §§ 32.1-12 and 32.1-176.4 of the Code of Virginia.

243 **Historical Notes**

244 Derived from VR355-34-100 § 1.3, eff. April 1, 1992.

245 **12VAC5-630-30. Purpose and applicability of regulations.**

246 ~~These regulations have~~ A. Purpose. This chapter has been promulgated by the State Board
247 of Health board to:

- 248 1. Ensure that all private wells are located, constructed, and maintained in a manner which
249 that does not adversely affect ~~ground water~~ groundwater resources, or the public welfare,
250 safety, and health;
- 251 2. Guide the ~~State Health Commissioner~~ commissioner in ~~his determination of~~ determining
252 whether a permit for construction of a private well should be issued or denied;
- 253 3. Guide the owner or ~~his~~ the owner's agent in the requirements necessary to secure a
254 permit for construction of a private well; ~~and~~
- 255 4. Guide the owner or ~~his~~ the owner's agent in the requirements necessary to secure an
256 inspection statement following construction; ~~and~~
- 257 5. Guide the owner or the owner's agent in the requirements necessary to abandon a
258 private well (temporarily or permanently) when the well is not in use.

259 B. Applicability. This chapter applies to owners of a private well. The following wells are
260 excluded from the requirements of this chapter:

- 261 1. Wells constructed as a groundwater source for a waterworks as regulated by 12VAC5-
262 590.
- 263 2. Wells constructed for the purpose of building, roadway, or other geotechnical foundation
264 investigation, design, or construction, provided that the well, including an unimproved well
265 bore, is abandoned in such a manner as to prevent it from being a channel of vertical
266 movement of surface water or a source of contamination into the ground.
- 267 3. Wells constructed for the purpose of an elevator shaft.
- 268 4. Wells constructed for the purpose of constructing an extensometer or similar scientific
269 instrument.
- 270 5. Wells constructed for the purpose of grounding of electrical apparatus.
- 271 6. Wells constructed for the purpose of the modification or development of springs.

272 7. Wells constructed for the purpose of underground injection as regulated by 40 CFR Part
273 144.

274 8. Wells constructed for the purpose of the observation or monitoring of groundwater
275 elevation or quality, except as governed by 12VAC5-630-420 B and C.

276 9. Well bores, including direct push well bores and hand tool made well bores, advanced
277 for the purpose of collecting soil or groundwater samples for analysis with or without
278 temporary installation of casing or screen, provided that the well bore is abandoned after
279 the sample is collected in such a manner as to prevent it from being a channel of vertical
280 movement of surface water or a source of contamination into groundwater.

281 10. Wells constructed for the purpose of construction dewatering, provided that the well is
282 abandoned within 60 days of construction by the removal of the well point, well casing,
283 screening, and other appurtenances associated with the construction and operation of the
284 well and completion of abandonment in such a manner as to prevent it from being a
285 channel of vertical movement of surface water or a source of contamination into
286 groundwater.

287 11. Wells constructed to provide cathodic protection, provided that the well is abandoned
288 after use in such a manner as to prevent it from being a channel of vertical movement of
289 surface water or a source of contamination into groundwater.

290 **Statutory Authority**

291 §§ 32.1-12 and 32.1-176.4 of the Code of Virginia.

292 **Historical Notes**

293 Derived from VR355-34-100 § 1.3, eff. April 1, 1992.

294 **~~12VAC5-630-40. Relationship to Virginia Sewage Handling and Disposal Regulations.~~**
295 **~~(Repealed.)~~**

296 ~~This chapter supersedes 12VAC5-610-1150 of the Virginia Sewage Handling and Disposal~~
297 ~~Regulations, and 12VAC5-610-1140 B and C of the Virginia Sewage Handling and Disposal~~
298 ~~Regulations which address private wells, and were adopted by the State Board of Health pursuant~~
299 ~~to Title 32.1 of the Code of Virginia.~~

300 **~~Statutory Authority~~**

301 ~~§§ 32.1-12 and 32.1-176 of the Code of Virginia.~~

302 **~~Historical Notes~~**

303 ~~Derived from VR355-34-100 § 1.4, eff. April 1, 1992.~~

304 **12VAC5-630-50. Relationship to the State Water Control Board.**

305 This chapter is independent of all regulations promulgated by the State Water Control Board.
306 ~~Ground-water~~ Groundwater users located in a ~~ground-water~~ groundwater management area may
307 be required to obtain a permit from the State Water Control Board in addition to obtaining a permit
308 from the Department of Health. In addition to the reporting requirements contained in this chapter,
309 § 62.1-258 of the Code of Virginia requires that private wells constructed in a groundwater
310 management area be registered by the water well systems provider with the State Water Control
311 Board within 30 days of the completion of construction. Private wells constructed in groundwater
312 management areas are subject to 9VAC25-610.

313 **Statutory Authority**

314 §§ 32.1-12 and 32.1-176.4 of the Code of Virginia.

315 **Historical Notes**

316 Derived from VR355-34-100 § 1.5, eff. April 1, 1992.

317 **12VAC5-630-60. Relationship to the Department of Environmental Quality, Waste**
318 **Management Division.**

319 This chapter establishes minimum standards for the protection of public health and ground
320 water groundwater resources. Observation wells, monitoring wells, and remediation wells
321 constructed under the supervision of the ~~Virginia Department of Environmental Quality, Waste~~
322 ~~Management Division, DEQ~~ are governed by 12VAC5-630-420.

323 **Statutory Authority**

324 §§ 32.1-12 and 32.1-176.4 of the Code of Virginia.

325 **Historical Notes**

326 Derived from VR355-34-100 § 1.6, eff. April 1, 1992.

327 **12VAC5-630-70. Relationship to the Uniform Statewide Building Code.**

328 This chapter is independent of and in addition to the requirements of the Uniform Statewide
329 Building Code (13VAC5-63). ~~All persons~~ Persons required to obtain a well permit by this chapter
330 shall furnish a copy of the permit to the local building official, upon request, when making
331 application for a building permit. Prior to obtaining an occupancy permit, an applicant shall furnish
332 the local building official with a copy of the inspection statement demonstrating the water supply
333 has been inspected, sampled and tested (when applicable), and approved by the district or local
334 health department.

335 **Statutory Authority**

336 §§ 32.1-12 and 32.1-176.4 of the Code of Virginia.

337 **Historical Notes**

338 Derived from VR355-34-100 § 1.7, eff. April 1, 1992.

339 **12VAC5-630-80. Relationship to the Department of Professional and Occupational**
340 **Regulation.**

341 ~~Persons engaged in the construction, repair, or alteration of a private well shall be licensed~~
342 ~~and certified in accordance with § 54.1-1100 §§ 54.1-1103 and 54.1-1129.1 of the Code of~~
343 ~~Virginia, any contractor constructing a water well to reach ground water shall possess, as a~~
344 ~~minimum, a valid Class B contractors license.~~

345 **Statutory Authority**

346 §§ 32.1-12 and 32.1-176.4 of the Code of Virginia.

347 **Historical Notes**

348 Derived from VR355-34-100 § 1.8, eff. April 1, 1992.

349 **12VAC5-630-90. Administration of regulations.**

350 This chapter is administered by the following:

351 A. 1. The ~~State Board of Health, hereinafter referred to as the board,~~ board has the
352 responsibility to promulgate, amend, and repeal regulations necessary to ensure the
353 proper location, construction ~~and location, repair, and abandonment~~ of private wells.

354 B. 2. The ~~State Health Commissioner, hereinafter referred to as the commissioner,~~ is the
355 chief executive officer of the ~~State Department of Health~~ department. The commissioner
356 has the authority to act, within the scope of regulations promulgated by the board, and for
357 the board when it is not in session. The commissioner may delegate his powers under this
358 chapter in writing to ~~any a subordinate, with the exception of (i) his; however, the power~~
359 to (i) issue variances under § 32.1-12 of the Code of Virginia and 12VAC5-630-170, and
360 (ii) his power to issue orders under § 32.1-26 of the Code of Virginia and 12VAC5-630-
361 140 and 12VAC5-630-150 B and (iii) the power to revoke permits or inspection statements

362 under ~~12VAC5-630-290~~, which may only not be delegated pursuant to ~~§ 32.1-22~~ of the
363 Code of Virginia.

364 The commissioner has final authority to adjudicate contested case decisions of
365 subordinates delegated powers under this section prior to appeal of such case decisions
366 to the circuit court.

367 ~~C. 3.~~ The State Department of Health hereinafter referred to as department is designated
368 as the primary agent of the commissioner for the purpose of administering this chapter.

369 ~~D. 4.~~ The district or local health departments are responsible for implementing and
370 enforcing the regulatory activities required by this chapter.

371 **Statutory Authority**

372 §§ 32.1-12 and 32.1-176.4 of the Code of Virginia.

373 **Historical Notes**

374 Derived from VR355-34-100 § 1.9, eff. April 1, 1992.

375 **12VAC5-630-100. Right of entry and inspections.**

376 In accordance with the provisions of ~~§§ § 32.1-25 and 32.1-12 and 32.1-176.6~~ of the Code of
377 Virginia, the commissioner or ~~his~~ the commissioner's designee shall have the right to enter any
378 property to ensure compliance with this chapter. In accordance with the provisions of § 32.1-176.6
379 of the Code of Virginia, the department has the authority to conduct such inspections as it may
380 find reasonably necessary to ensure that the construction work conforms to applicable
381 construction standards.

382 **Statutory Authority**

383 §§ 32.1-12 and 32.1-176.4 of the Code of Virginia.

384 **Historical Notes**

385 Derived from VR355-34-100 § 1.10, eff. April 1, 199.

386 **12VAC5-630-110. Compliance with the Administrative Process Act.**

387 The provisions of the Virginia Administrative Process Act (~~§ 9-6.14:1~~ 2.2-4000 et seq. of the
388 Code of Virginia) shall govern the promulgation and administration of this chapter, including
389 governing the procedures for rendering case decisions as defined in § 2.2-4001 of the Code of
390 Virginia, and shall be applicable to the appeal of ~~any~~ a case decision based upon this chapter.

391 **Statutory Authority**

392 §§ 32.1-12 and 32.1-176.4 of the Code of Virginia.

393 **Historical Notes**

394 Derived from VR355-34-100 § 2.1, eff. April 1, 1992.

395 **12VAC5-630-120. Powers and procedures of regulations not exclusive.**

396 The commissioner may enforce this chapter through ~~any~~ means lawfully available.

397 **Statutory Authority**

398 §§ 32.1-12 and 32.1-176.4 of the Code of Virginia.

399 **Historical Notes**

400 Derived from VR355-34-100 § 2.2, eff. April 1, 1992.

401 **12VAC5-630-140. Emergency order.**

402 If an emergency exists the commissioner may issue an emergency order as is necessary for
403 preservation of public health, safety, and welfare or to protect ~~ground-water~~ groundwater
404 resources. The emergency order shall state the reasons and precise factual basis upon which the
405 emergency order is issued. The emergency order shall state the time period for which it is

406 effective. Emergency orders will be publicized in a manner deemed appropriate by the
407 commissioner. The provisions of 12VAC5-630-150 C and D shall not apply to emergency orders
408 issued pursuant to this section.

409 **Statutory Authority**

410 §§ 32.1-12 and 32.1-176.4 of the Code of Virginia.

411 **Historical Notes**

412 Derived from VR355-34-100 § 2.4, eff. April 1, 1992.

413 **12VAC5-630-150. Enforcement of regulations.**

414 A. Notice. Subject to the exceptions ~~below in this section~~, whenever the commissioner or the
415 district or local health department has reason to believe a violation of any of this chapter has
416 occurred or is occurring, the alleged violator shall be notified. ~~Such~~ The notice shall be made in
417 writing, shall be delivered personally or sent by certified mail, shall cite the regulation ~~or~~
418 ~~regulations that are~~ allegedly being violated, shall state the facts ~~which that~~ form the basis for
419 believing the violation has occurred or is occurring, shall include a request for a specific action by
420 the recipient by a specified time, and shall state the penalties associated with such violation.
421 ~~When the~~ The commissioner ~~deems~~ may deem it necessary, ~~he may~~ to initiate criminal
422 prosecution or seek civil relief through mandamus ~~or~~, injunction, or other appropriate remedy prior
423 to giving notice.

424 B. Orders. Pursuant to the authority granted in § 32.1-26 of the Code of Virginia, the
425 commissioner may issue orders to require ~~any an~~ owner, or other person, to comply with the
426 provisions of this chapter. The order shall be signed by the commissioner and may require:

- 427 1. The immediate cessation and correction of the violation;
- 428 2. Appropriate remedial action to ensure that the violation does not recur;
- 429 3. The submission to the commissioner for review and approval of a plan to prevent future
430 violations to the commissioner for review and approval;
- 431 4. The submission of an application for a variance; or
- 432 5. ~~Any other~~ Other corrective action deemed necessary for proper compliance with the
433 chapter.

434 C. Hearing before the issuance of an order. Before the issuance of an order described in
435 ~~12VAC5-630-150~~ this section, a hearing must be held, with at least 30 days of notice by certified
436 mail to the affected owner or other person of the time, place, and purpose thereof, for the purpose
437 of adjudicating the alleged violation ~~or violations~~ of this chapter. The procedures at the hearing
438 shall be in accordance with 12VAC5-630-180 A or B ~~of this chapter and with §§ 9-6.14:11 through~~
439 ~~9-6.14:14 of the Code of Virginia~~ the Virginia Administrative Process Act (§ 2.2-4000 et seq. of
440 the Code of Virginia).

441 D. Order; when effective. ~~All orders~~ Orders issued pursuant to ~~12VAC5-630-150~~ this section
442 shall become effective not less than 15 days after mailing a copy thereof by certified mail to the
443 last known address of the owner or person violating this chapter. ~~Violation of an order is a Class~~
444 ~~1 misdemeanor. See § 32.1-27 of the Code of Virginia.~~

445 E. Compliance with effective orders. The commissioner may enforce ~~all~~ orders. Should any
446 owner or other person fail to comply with any order, the commissioner may:

- 447 1. Apply to an appropriate court for an injunction or other legal process to prevent or stop
448 any practice in violation of the order;
- 449 2. Commence administrative proceedings to suspend or revoke the construction permit;
- 450 3. Request the Attorney General to bring an action for civil penalty, injunction, or other
451 appropriate remedy; or

452 4. Request the Commonwealth's Attorney to bring a criminal action.

453 F. Not exclusive means of enforcement. Nothing contained in 12VAC5-630-140 or ~~12VAC5-~~
454 ~~630-150~~ this section shall be interpreted to require the commissioner to issue an order prior to
455 commencing administrative proceedings or seeking enforcement of ~~any~~ regulations or statute
456 through an injunction, mandamus, other appropriate remedy, or criminal prosecution.

457 **Statutory Authority**

458 §§ 32.1-12 and 32.1-176.4 of the Code of Virginia.

459 **Historical Notes**

460 Derived from VR355-34-100 § 2.5, eff. April 1, 1992.

461 **12VAC5-630-160. Suspension of regulations during disasters.**

462 If in the case of a man-made or natural disaster, the commissioner finds that certain
463 regulations cannot be complied with and that the public health is better served by not fully
464 complying with this chapter, ~~he~~ the commissioner may authorize the suspension of the application
465 of the chapter for specifically affected localities and institute a provisional regulatory plan until the
466 disaster is abated.

467 **Statutory Authority**

468 §§ 32.1-12 and 32.1-176.4 of the Code of Virginia.

469 **Historical Notes**

470 Derived from VR355-34-100 § 2.6, eff. April 1, 1992.

471 **12VAC5-630-170. Variances.**

472 ~~Only the~~ A. ~~The commissioner or the deputy commissioners~~ may grant a variance to this
473 chapter. (~~See §§ 32.1-12 and 32.1-22 of the Code of Virginia and 12VAC5-630-90 B.~~) The
474 commissioner ~~or the deputy commissioners~~ shall follow the appropriate procedures set forth in
475 this ~~subsection~~ section in granting a variance.

476 A. B. Requirements for a variance. The commissioner may grant a variance if a thorough
477 investigation reveals that the hardship imposed by this chapter (may be economic) outweighs the
478 benefits that may be received by the public. ~~Further, and that~~ the granting of such a variance shall
479 not subject the public to unreasonable health risks or jeopardize ~~ground water~~ groundwater
480 resources.

481 ~~Exception:~~ The commissioner shall not grant a variance for an improperly located Class IV
482 well that was located pursuant to an express Class IV permit, as described under 12VAC5-630-
483 260 and 12VAC5-630-270, if the improper location of the well is a result of the failure by the
484 owner, ~~his~~ the owner's agent, or the ~~well driller~~ water well systems provider to provide complete
485 or accurate information on the site plan submitted with the application or to install the well in
486 accordance with the permit.

487 B. C. Application for a variance. Any owner who seeks a variance shall apply in writing within
488 the time period specified in 12VAC5-630-210 ~~B.~~ The application shall be signed by the owner,
489 addressed, and sent to the commissioner ~~at the State Department of Health in Richmond.~~ The
490 application shall include:

- 491 1. A citation to the section from which a variance is requested;
- 492 2. The nature and duration of the variance requested;
- 493 3. Any relevant analytical results, including results of relevant tests conducted pursuant to
494 the requirements of this chapter;
- 495 4. The hardship imposed by the specific requirement of this chapter;
- 496 5. Statements or evidence why the public health and welfare as well as the ~~ground water~~
497 groundwater resources would not be degraded if the variance were granted;

498 ~~5.~~ 6. Suggested conditions that might be imposed on the granting of a variance that would
499 limit the detrimental impact on the public health and welfare or ~~ground-water~~ groundwater
500 resources;

501 ~~6.~~ 7. Other information, if any, believed pertinent by the applicant; and

502 ~~7.~~ Such other 8. Other information as that the district or local health department or
503 commissioner may require.

504 ~~C.~~ D. Evaluation of a variance application.

505 1. The commissioner shall act on ~~any a~~ a variance request submitted pursuant to ~~12VAC5-~~
506 ~~630-170-B~~ subsection C of this section within 60 calendar days of receipt of the request.

507 2. In the evaluation of a variance application, the commissioner shall consider the following
508 factors:

509 a. The effect that ~~such a~~ the variance would have on the construction, location, or
510 operation of the private well;

511 b. The cost and other economic considerations imposed by this requirement;

512 c. The effect that ~~such a~~ the variance would have on protection of the public health;

513 d. The effect that ~~such a~~ the variance would have on protection of ~~ground-water~~
514 groundwater resources;

515 e. Relevant analytical results, including results of tests conducted pursuant to the
516 requirements of this chapter;

517 f. The hardship imposed by enforcing the specific requirements of this chapter;

518 g. Suggested conditions that might be imposed on the granting of a variance that would
519 limit detrimental impact on the public health and welfare;

520 h. Other information, if any, believed pertinent by the applicant; and

521 ~~e.~~ Such other i. Other factors as the commissioner may deem appropriate.

522 ~~D.~~ E. Disposition of a variance request.

523 1. The commissioner may deny ~~any an~~ an application for a variance by sending a denial
524 notice to the applicant by certified mail. The notice shall be in writing and shall state the
525 reasons for the denial.

526 2. If the commissioner proposes to grant a variance request submitted pursuant to
527 ~~12VAC5-630-170-B~~ subsection C of this section, the applicant shall be notified in writing
528 of this decision. ~~Such~~ The notice shall identify the variance, any conditions to the variance,
529 and private well covered, and shall specify the period of time for which the variance will
530 be effective. The effective date of a variance shall be as stated in the variance.

531 3. No owner may challenge the terms or conditions set forth in the variance after 30
532 calendar days have elapsed from the effective date of the variance.

533 ~~E.~~ F. Posting of variances. ~~All variances~~ Variances granted to ~~any~~ private wells are
534 transferable from owner to owner unless otherwise stated, but not transferable to another private
535 well. ~~Each~~ The variance shall be attached to the permit to which it is granted. ~~Each~~ The variance
536 is revoked when the permit to which it is attached is revoked.

537 ~~F.~~ G. Hearings on disposition of variances. Subject to the time limitations specified in 12VAC5-
538 630-210, hearings on denials of an application for a variance or on challenges to the terms and
539 conditions of a granted variance may be held pursuant to subdivision 1 or 2 of 12VAC5-630-180
540 ~~A or B~~, except that informal hearings under subdivision 1 of 12VAC5-630-180 A shall be held by
541 the commissioner or ~~his~~ the commissioner's designee.

542 **Statutory Authority**

543 §§ 32.1-12 and 32.1-176.4 of the Code of Virginia.

544 **Historical Notes**

545 Derived from VR355-34-100 § 2.7, eff. April 1, 1992.

546 **12VAC5-630-180. Hearing types.**

547 Hearings before the commissioner or the commissioner's designees shall include any of the
548 following forms depending on the nature of the controversy and the interests of the parties
549 involved.

550 A. 1. Informal hearings. An informal hearing is a meeting with a district or local health
551 department with the district or local health director presiding and held in conformance with
552 ~~§ 9-6.14:11~~ § 2.2-4019 of the Code of Virginia. The district or local health department
553 director shall consider all evidence presented at the meeting ~~which~~ that is relevant to the
554 issue in controversy. Presentation of evidence, however, is entirely voluntary. The district
555 or local health department shall have no subpoena power. No verbatim record need be
556 taken at the informal hearing. The local or district health director shall review the facts
557 presented and based on those facts render a decision. A written copy of the decision and
558 the basis for the decision shall be sent to the appellant within 15 work days of the hearing,
559 unless the parties mutually agree to a later date in order to allow the department to
560 evaluate additional evidence. If the decision is adverse to the interests of the appellant,
561 an aggrieved appellant may request an adjudicatory hearing pursuant to ~~12VAC5-630-~~
562 ~~180-B~~ below subdivision 2 of this section.

563 B. 2. Adjudicatory hearing. The adjudicatory hearing is a formal, public adjudicatory
564 proceeding ~~before the commissioner, or a designated hearing officer, and held in~~
565 ~~conformance with § 9-6.14:12~~ conducted pursuant to § 2.2-4020 of the Code of Virginia.
566 An adjudicatory hearing includes the following features:

567 1. Notice. ~~Notice which states the time and place and the issues involved in the~~
568 ~~prospective hearing shall be sent to the owner or other person who is the subject of the~~
569 ~~hearing. Notice shall be sent by certified mail at least 15 calendar days before the hearing~~
570 ~~is to take place.~~

571 2. Record. ~~A record of the hearing shall be made by a court reporter. A copy of the~~
572 ~~transcript of the hearing, if transcribed, will be provided within a reasonable time to any~~
573 ~~person upon written request and payment of the cost.~~

574 3. Evidence. ~~All interested parties may attend the hearing and submit oral and~~
575 ~~documentary evidence and rebuttal proofs, expert or otherwise, that are material and~~
576 ~~relevant to the issues in controversy. The admissibility of evidence shall be determined in~~
577 ~~accordance with § 9-6.14:12 of the Code of Virginia.~~

578 4. Counsel. ~~All parties may be accompanied by and represented by counsel and are~~
579 ~~entitled to conduct such cross examination as may elicit a full and fair disclosure of the~~
580 ~~facts.~~

581 5. Subpoena. ~~Pursuant to § 9-6.14:13 of the Code of Virginia, the commissioner or hearing~~
582 ~~officer may issue subpoenas on behalf of himself or any person or owner for the~~
583 ~~attendance of witnesses and the production of books, papers or maps. Failure to appear~~
584 ~~or to testify or to produce documents without adequate excuse may be reported by the~~
585 ~~commissioner to the appropriate circuit court for enforcement.~~

586 6. Judgment and final order. ~~The commissioner may~~ shall designate a hearing officer or
587 ~~subordinate~~ to conduct the hearing as provided in ~~§ 9-6.14:12~~ § 2.2-4024 of the Code of
588 Virginia, and to make written recommended findings of fact and conclusions of law to be
589 submitted for review and final decision by the commissioner. The final decision of the
590 commissioner shall be reduced to writing and will contain the explicit findings of fact upon
591 which ~~his~~ the decision is based. Certified copies of the decision shall be delivered to the

592 owner affected by it. Notice of a decision will be served upon the parties and become a
593 part of the record. Service may be by personal service or certified mail return receipt
594 requested.

595 **Statutory Authority**

596 §§ 32.1-12 and 32.1-176.4 of the Code of Virginia.

597 **Historical Notes**

598 Derived from VR355-34-100 § 2.8, eff. April 1, 1992.

599 **12VAC5-630-190. Request for hearing.**

600 A request for an informal hearing shall be made by sending the request in writing to the district
601 or local health department. A request for an adjudicatory hearing shall be made in writing and
602 directed to the commissioner ~~at the State Department of Health in Richmond~~. Requests for
603 hearings shall cite the ~~reason(s)~~ reason for the hearing request and shall cite ~~the section(s)~~ any
604 section of this chapter involved.

605 **Statutory Authority**

606 §§ 32.1-12 and 32.1-176.4 of the Code of Virginia.

607 **Historical Notes**

608 Derived from VR355-34-100 § 2.9, eff. April 1, 1992.

609 **12VAC5-630-200. Hearing as a matter of right.**

610 ~~Any~~ An owner or other person whose rights, duties, or privileges have been, or may be
611 affected by ~~any~~ a decision of the board or its subordinates in the administration of this chapter
612 shall have a right to both informal and adjudicatory hearings. The commissioner may require
613 participation in an informal hearing before granting the request for a full adjudicatory hearing.
614 ~~Exception:~~ No person other than an owner shall have the right to an adjudicatory hearing to
615 challenge the issuance of either a construction permit or inspection statement unless the person
616 can demonstrate at an informal hearing that the minimum standards contained in this chapter
617 have not been applied and that ~~he~~ the person will be injured in some manner by the issuance of
618 the permit or that ~~ground water~~ groundwater resources will be damaged by the issuance of the
619 permit.

620 **Statutory Authority**

621 §§ 32.1-12 and 32.1-176.4 of the Code of Virginia.

622 **Historical Notes**

623 Derived from VR355-34-100 § 2.10, eff. April 1, 1992.

624 **12VAC5-630-210. Appeals.**

625 ~~Any~~ An appeal from a denial, revocation, or voidance of a construction permit, inspection
626 statement, or request for variance for a private well must be made in writing and received by the
627 department within ~~60~~ 30 days of the date of the denial, revocation, or voidance.

628 ~~A. Any request for hearing on the denial of an application for a variance pursuant to 12VAC5-~~
629 ~~630-170-D 1 must be made in writing and received within 60 days of receipt of the denial notice.~~

630 ~~B. Any~~ A request for a variance must be made in writing and received by the department prior
631 to the denial of the private well permit, or within 60 days after such denial.

632 ~~C. In the event a person applies for a variance within the 60-day period provided by subsection~~
633 ~~B above, the date for appealing the denial of the permit, pursuant to subsection A above, shall~~
634 ~~commence from the date on which the department acts on the request for a variance.~~

635 ~~D. Pursuant to the Administrative Process Act (§ 9-6.14:1 (§ 2.2-4000~~ et seq. of the Code of
636 Virginia) an aggrieved ~~owner~~ party may appeal a final decision of the commissioner to an
637 appropriate circuit court.

638 **Statutory Authority**

639 §§ 32.1-12 and 32.1-176.4 of the Code of Virginia.

640 **Historical Notes**

641 Derived from VR355-34-100 § 2.11, eff. April 1, 1992.

642 **12VAC5-630-220. Permits and inspection statement; general.**

643 A. All private wells shall be constructed and located in compliance with the requirements as
644 set forth in this chapter.

645 ~~A. Except as provided in 12VAC5-630-220 B below, after~~ B. After the effective date of this
646 chapter, no person shall construct, alter, ~~rehabilitate~~, abandon, or ~~extend~~ increase the depth of a
647 private well, or allow the construction, alteration, ~~rehabilitation~~, abandonment, or extension activity
648 to increase the depth of a private well, without a written construction permit from the
649 commissioner. Conditions may be imposed on the issuance of ~~any~~ a permit and no private well
650 shall be constructed or modified in violation of those conditions. The replacement of a well pump,
651 ~~or~~ the replacement of a well seal or cap with an equivalent well seal or cap, or the vertical
652 extension of the well casing above the ground surface shall not be considered a well ~~modification~~
653 alteration.

654 ~~B. No permit shall be required for the construction, operation, or abandonment of dewatering~~
655 ~~wells. Furthermore, dewatering wells are exempted from the construction requirements found in~~
656 ~~12VAC5-630-410. All dewatering wells shall be abandoned within 60 days of construction.~~
657 ~~Abandonment in this case means the removal of the well point, well casing, screening, and other~~
658 ~~appurtenances associated with the construction and operation of the well.~~

659 C. Except as provided in 12VAC5-630-320, no person shall place a private well in operation,
660 or cause or allow a private well to be placed in operation, without obtaining a written inspection
661 statement pursuant to 12VAC5-630-310 and 12VAC5-630-330.

662 D. Except as provided in 12VAC5-630-270, 12VAC5-630-290, and 12VAC5-630-300,
663 construction permits for a private well shall be deemed valid for a period of ~~54~~ 18 months from
664 the date of issuance, with provision for one 18-month renewal.

665 **Statutory Authority**

666 §§ 32.1-12 and 32.1-176.4 of the Code of Virginia.

667 **Historical Notes**

668 Derived from VR355-34-100 § 2.12, eff. April 1, 1992.

669 **12VAC5-630-230. Procedures for obtaining a construction permit for a private well.**

670 A. Construction permits are issued by the authority of the commissioner. ~~All requests~~
671 Requests for a private well construction permit shall be by written application, signed by the owner
672 or ~~his~~ the owner's agent, and shall be directed to the district or local health department. ~~All~~
673 ~~applications~~ Applications shall be made on an application form provided by the district or local
674 health department and approved by the commissioner.

675 B. An application shall be deemed completed upon receipt by the district or local health
676 department of a signed and dated application, together with the appropriate fee, containing the
677 following information:

- 678 1. The property owner's name, address, and telephone number;
- 679 2. The applicant's name, address, and phone number (if different from subdivision 1 ~~above~~
680 of this subsection);
- 681 3. A statement signed by the property owner, or ~~his~~ the owner's agent, granting the ~~Health~~
682 ~~Department~~ department access to the site for the purposes of evaluating the suitability of
683 the site for a well and allowing the department access to inspect the well after it is installed;

- 684 4. A statement indicating whether the adjacent property is used for an agricultural
685 operation;
686 5. Information required per 12VAC5-630-380 E if necessary.
687 6. A site plan showing the proposed well site, property boundaries, accurate locations of
688 actual or proposed sewage disposal systems, recorded easements, and other sources of
689 contamination within 100 feet of the proposed well site, and at the option of the applicant
690 a proposed well design; and
691 5. 7. When deemed necessary because of geological or other natural conditions, plans
692 and specifications detailing how the well will be constructed.

693 **Statutory Authority**

694 §§ 32.1-12 and 32.1-176.4 of the Code of Virginia.

695 **Historical Notes**

696 Derived from VR355-34-100 § 2.13, eff. April 1, 1992.

697 **12VAC5-630-240. Issuance of the construction permit.**

698 A. A construction permit shall be issued to the owner by the commissioner no later than 60
699 days after receipt of a complete and approvable application submitted under 12VAC5-630-230
700 that meets requirements for issuance of the permit. If applicable, the applicant shall comply with
701 12VAC5-630-340 prior to issuance of the permit.

702 B. The permit shall indicate a well site or a well area.

703 1. A well site shall be designated as a specific location that can be identified on the
704 property by means of measurement from identified fixed points on the property.

705 2. A well area may be designated as a polygon or as a defined radius around a proposed
706 well site. The well area shall be described in sufficient detail that it can be identified on the
707 property by means of measurement from identified fixed points on the property.

708 **Statutory Authority**

709 §§ 32.1-12 and 32.1-176.4 of the Code of Virginia.

710 **Historical Notes**

711 Derived from VR355-34-100 § 2.14, eff. April 1, 1992.

712 **12VAC5-630-250. Emergency procedures.**

713 Applications for replacement wells that meet the definition of an emergency well replacement
714 (12VAC5-630-10) shall have priority over normal applications for private well permits. Emergency
715 procedures are as follows:

716 A. 1. Drinking water wells. In the event ~~When~~ a private drinking water well has failed and
717 must be replaced, ~~the local health department will~~ a licensed onsite soil evaluator,
718 professional engineer, or licensed water well systems provider shall conduct a sanitary
719 survey of the property and surrounding area to determine the most suitable location. If a
720 site is found that meets the minimum site requirements of this chapter, including the
721 minimum separation distances contained in Table 3-1 and 12VAC5-630-380 F H, the local
722 health department will issue a permit for that site. If a site cannot be located that meets
723 the minimum separation distances listed in Table 3-1 and 12VAC5-630-380 F H, the local
724 health department shall identify a site that complies with the minimum separation
725 distances to the greatest extent possible. However, the replacement well shall not be
726 located closer to ~~any~~ a source of contamination than the existing well it is replacing.
727 Replacement drinking water wells must meet the sampling requirements of 12VAC5-630-
728 370 D and E 12VAC5-630-431 E and F.

729 B. 2. Heat pump wells or commercially dependent wells. If a heat pump well or
730 commercially dependent well must be replaced, the applicant shall propose a replacement
731 site based on the technical requirements of the heat pump system or commercial
732 establishment. ~~The local health department will conduct a sanitary survey of the property~~
733 ~~and surrounding area to determine if the site meets the minimum site requirements of this~~
734 ~~chapter including the minimum separation distances contained in Table 3.1 and 12VAC5-~~
735 ~~630-380 F. A licensed onsite soil evaluator, professional engineer, or water well systems~~
736 ~~provider shall conduct a sanitary survey of the property and surrounding area to determine~~
737 ~~the most suitable location.~~ If the site meets the minimum requirements of this chapter, the
738 local health department will issue a permit for that site. If a site cannot be located that
739 meets the minimum separation distances listed in Table 3.1 ~~and 12VAC5-630-380 F~~, the
740 local health department shall identify a site that complies with the minimum separation
741 distances to the greatest extent possible. However, the replacement well shall not be
742 located closer to ~~any~~ a source of contamination than the existing well it is replacing. If the
743 replacement heat pump well or commercially dependent well must be placed closer to a
744 sewage disposal system (but no closer than the existing well it is replacing) the well shall
745 be sampled for fecal coliforms. If fecal coliforms are present in the sample and further
746 investigation reveals that the groundwater is contaminated, the well shall be abandoned.

747 **Statutory Authority**

748 §§ 32.1-12 and 32.1-176.4 of the Code of Virginia.

749 **Historical Notes**

750 Derived from VR355-34-100 § 2.15, eff. April 1, 1992.

751 **12VAC5-630-260. Express Class IV construction permits.**

752 If A. When a Class IV well is proposed for property that does not have an onsite sewage
753 disposal system, either active or inactive, an application may be made for an express Class IV
754 construction permit. An application for an express Class IV construction permit shall be made on
755 a form provided by the district or local health department and approved by the commissioner.

756 B. An application shall be deemed completed upon receipt by the district or local health
757 department of a signed and dated application, together with the appropriate fee, containing the
758 following information:

- 759 1. The property owner's name, address, telephone number, and personal signature. The
760 owner's signature will acknowledge that the permit will be issued without the benefit of a
761 site visit by the local health department prior to the issuance of the construction permit;
762 that the permit is being issued based upon the information provided on the accompanying
763 site plan; that the property owner also acknowledges that if the well is found not to comply
764 with the minimum separation distances or ~~any~~ other provision of this chapter, the well must
765 be abandoned at the direction of the local or district health director; and that a variance
766 will not be considered if the improper location of the well is a result of the failure by the
767 owner, ~~his~~ the owner's agent, or the ~~well driller~~ water well systems provider to provide
768 complete or accurate information on the site plan submitted with the application or to install
769 the well in accordance with the permit.;
- 770 2. Address and directions to the property;
- 771 3. The proposed use of the well;
- 772 4. The name, address, telephone number, ~~Class B (minimum)~~ license number, and
773 signature of the ~~well driller~~ water well systems provider who is to construct the well;
- 774 5. A statement signed by the property owner (and not ~~his~~ the owner's agent) granting the
775 department access to the site for the purposes of inspecting the property and the well

776 during and after its installation until the well is approved by the department or ~~any a~~
777 required abandonment is completed; and

778 6. A site plan showing the proposed well site, property boundaries, recorded easements,
779 and accurate locations of actual or proposed sources of contamination (including, ~~but not~~
780 ~~limited to~~ those listed in Table 3-1 of 12VAC5-630-380) within 100 feet of the proposed
781 well site, and at the option of the applicant a proposed well design. If the proposed well
782 site is located on or at the base of sloping topography, the minimum separation distances
783 shown on the site plan for ~~any~~ sources of contamination within a 60 degree arc slope of
784 the proposed well site must be increased 25 feet for every 5.0% slope.

785 **Statutory Authority**

786 §§ 32.1-12 and 32.1-176.4 of the Code of Virginia.

787 **Historical Notes**

788 Derived from VR355-34-100 § 2.16, eff. April 1, 1992.

789 **12VAC5-630-270. Issuance of express Class IV construction permits and final inspection.**

790 A. Issuance of express Class IV construction permit. Upon receipt of a complete and
791 approvable application, as defined in 12VAC5-630-260, by a local or district health department
792 with multiple ~~sanitarians~~ environmental health specialists, the department shall exercise ~~all~~ due
793 diligence to issue a permit either on the date of receipt or the following business day. If the local
794 or district office has only one assigned ~~sanitarian~~ environmental health specialist, the local or
795 district department will exercise ~~all~~ due diligence to issue the permit as soon as possible. Failure
796 by the department to issue the permit within the specified time does not authorize the construction
797 of the well without a permit. If applicable, the applicant shall comply with 12VAC5-630-340 prior
798 to the issuance of the permit.

799 B. Validity of express Class IV construction permits. Express Class IV construction permits
800 shall only be valid for a period of 30 days from the date of issuance.

801 C. Inspection. If, upon inspection of the well, it is found that the well location does not comply
802 with the minimum separation distances or ~~any~~ other provision of this chapter, no inspection
803 statement shall be issued and the well shall be immediately abandoned by the property owner in
804 accordance with 12VAC5-630-450 upon notification and direction by the local or district health
805 director. The commissioner shall not grant a variance if the improper location of the well is a result
806 of the failure by the owner, ~~his~~ the owner's agent, or the ~~well driller~~ water well systems provider
807 to provide complete or accurate information on the site plan submitted with the application or to
808 install the well in accordance with the permit.

809 The construction of the well shall also comply with this chapter.

810 **Statutory Authority**

811 §§ 32.1-12 and 32.1-176.4 of the Code of Virginia.

812 **Historical Notes**

813 Derived from VR355-34-100 § 2.17, eff. April 1, 1992.

814 **12VAC5-630-271. Express geothermal well permits.**

815 A. The issuance of an express geothermal permit is contingent upon proper registration and
816 payment of application fees and applies to the construction of wells used solely for a closed-loop
817 geothermal heating system.

818 B. A single application and a single fee are required for any geothermal well system. The fee
819 is the same as for a single private well. A registration statement for closed loop construction
820 permitting shall be made on a form provided and approved by the division. The registration shall
821 include the following information:

- 822 1. The property owner's name, address, and telephone number;
823 2. The address of and directions to the property;
824 3. The proposed use of the well;
825 4. The name, address, telephone number, and contractor license number of the ~~well driller~~
826 water well systems provider;
- 827 5. A statement signed by the property owner granting the department access to the site
828 for the purpose of inspecting the property and the well during and after the well installation
829 until the well is approved by the department or ~~any~~ required corrections are made;
- 830 6. A site plan, drawn to scale, showing the proposed well site ~~or sites~~, property boundaries,
831 recorded easements, and accurate locations of actual or proposed sources of
832 contamination (including ~~but not limited to~~ those listed in Table 3-1 of 12VAC5-630-380)
833 within 100 feet of the proposed well site ~~or sites~~; and
- 834 7. A statement signed by the licensed ~~well driller~~ water well systems provider that the
835 location and construction of the well ~~or wells~~ will comply with the requirements of this
836 chapter.

837 C. A single application fee is required for any geothermal well system, regardless of the
838 number of wells included in the system. The fee is the same as for a single private well.

839 **Statutory Authority**

840 §§ 32.1-12 and 32.1-176.4 of the Code of Virginia.

841 **Historical Notes**

842 Derived from Virginia Register Volume 28, Issue 22, eff. August 16, 2012.

843 **12VAC5-630-272. Issuance of express geothermal well construction permit, inspection,** 844 **and final approval.**

845 A. Issuance of the express geothermal well permit. Upon receipt of a complete registration
846 statement and the appropriate fee, the department will acknowledge receipt of the registration
847 statement and issue the permit with a copy given to the contractor. The construction of the
848 geothermal heating system may begin immediately upon submission of a complete registration
849 statement and counter-signature denoting receipt by the department.

850 B. Inspection. The department, at its sole discretion, may inspect the closed-loop geothermal
851 well ~~any time from~~ from after acceptance of the registration statement until after the installation is
852 approved. If, upon inspection of the well, it is found that the well location does not comply with the
853 minimum separation distances or ~~any~~ other provision of this chapter, no inspection statement
854 shall be issued until the deficiencies have been corrected.

855 C. Final approval. Upon receipt of the Uniform Water Well Completion Report [~~as required~~
856 ~~in 12VAC5-630-440~~] , and completion of ~~any~~ inspections deemed necessary to ensure
857 compliance with this chapter, ~~or~~ unless the department has evidence to indicate that the well is
858 not in compliance with the requirements of this chapter, the local health department will provide
859 the owner with a statement that the wells are approved for use.

860 **Statutory Authority**

861 §§ 32.1-12 and 32.1-176.4 of the Code of Virginia.

862 **Historical Notes**

863 Derived from Virginia Register Volume 28, Issue 22, eff. August 16, 2012.

864 **12VAC5-630-280. Denial of a construction permit.**

865 If it is determined that (i) the proposed design is inadequate ~~or that~~; (ii) site, geological,
866 hydrological, or other conditions exist that do not comply with this chapter or would preclude the
867 safe and proper operation of a private well system, ~~or that~~; (iii) the installation of the well would

868 create an actual or potential health hazard or nuisance; ~~or~~ or (iv) the proposed design would
869 adversely impact the ~~ground-water~~ groundwater resource, the permit shall be denied and the
870 owner shall be notified in writing, by certified mail, of the basis for the denial. The notification shall
871 also state that the owner has the right to appeal the denial.

872 **Statutory Authority**

873 §§ 32.1-12 and 32.1-176.4 of the Code of Virginia.

874 **Historical Notes**

875 Derived from VR355-34-100 § 2.18, eff. April 1, 1992.

876 **12VAC5-630-290. Revocation of construction permits or inspection statements.**

877 ~~The~~ In accordance with 12VAC5-630-331, the commissioner may revoke a construction
878 permit or inspection statement for any of the following reasons:

- 879 1. Failure to comply with the conditions of the permit;
880 2. Violation of ~~any~~ of this chapter for which no variance has been issued;
881 3. Facts become known which reveal that a potential health hazard would be created or
882 that the ~~ground-water~~ groundwater resources may be adversely affected by allowing the
883 proposed well to be installed or completed.

884 **Statutory Authority**

885 §§ 32.1-12 and 32.1-176.4 of the Code of Virginia.

886 **Historical Notes**

887 Derived from VR355-34-100 § 2.19, eff. April 1, 1992.

888 **12VAC5-630-300. Voidance of construction permits.**

889 ~~Null and void. All~~ A. In accordance with 12VAC5-630-331, the commissioner has authority to
890 declare well construction permits ~~are~~ or inspection statements null and void when (i) conditions
891 such as house location, sewage system location, sewerage system location, topography,
892 drainage ways, or other site conditions are changed from those shown on the application; or (ii)
893 conditions are changed from those shown on the construction permit; ~~or (iii).~~

894 B. Construction permits are null and void when more than ~~54~~ 18 months elapse from the date
895 the permit was issued or renewed. Reapplication for the purposes of having an expired permit
896 reissued shall be the responsibility of the owner, and ~~such~~ reapplication shall be handled as an
897 initial application and comply ~~fully~~ with 12VAC5-630-230.

898 **Statutory Authority**

899 §§ 32.1-12 and 32.1-176.4 of the Code of Virginia.

900 **Historical Notes**

901 Derived from VR355-34-100 § 2.20, eff. April 1, 1992.

902 **12VAC5-630-310. Statement required upon completion of construction.**

903 ~~Upon~~ Within 30 days of completion of the construction, alteration, ~~rehabilitation,~~
904 abandonment, ~~or extension~~ deepening of a private well, the owner ~~or, the owner's agent, or water~~
905 well systems provider shall ~~submit to~~ furnish the district or local health department a statement,
906 signed by the contractor, upon the form set out in 12VAC5-630-490, completed uniform water well
907 completion report [(GW-2)]. The [(GW-2) uniform water well completion report] shall be signed by
908 the water well systems provider and state that the well was installed, constructed, or abandoned
909 in accordance with the permit, and further that the well complies with all applicable state and local
910 regulations, ordinances, and laws.

911 **Statutory Authority**

912 §§ 32.1-12 and 32.1-176.4 of the Code of Virginia.

913 **Historical Notes**

914 Derived from VR355-34-100 § 2.21, eff. April 1, 1992.

915 **12VAC5-630-320. Inspection and correction.**

916 No well shall be placed in operation, except for the purposes of testing the mechanical
917 soundness of the system, until inspected by the district or local health department, corrections
918 are made if necessary, and the owner has been issued an inspection statement by the district or
919 local health department.

920 **Statutory Authority**

921 §§ 32.1-12 and 32.1-176.4 of the Code of Virginia.

922 **Historical Notes**

923 Derived from VR355-34-100 § 2.22, eff. April 1, 1992.

924 **12VAC5-630-330. Issuance of the inspection statement.**

925 Upon satisfactory completion of the requirements of 12VAC5-630-310, 12VAC5-630-320,
926 12VAC5-630-340, 12VAC5-630-370, [and] 12VAC5-630-430, [~~and 12VAC5-630-440~~], the
927 commissioner shall issue an inspection statement to the owner. The issuance of an inspection
928 statement does not denote or imply ~~any~~ a warranty or guarantee of the water quality or quantity
929 by the department or that the private well will function for ~~any~~ a specified ~~period~~ of time. It shall
930 be the responsibility of the owner or ~~any~~ subsequent owner to maintain, repair, replace, or to
931 comply with the requirements to abandon ~~any~~ a private well.

932 **Statutory Authority**

933 §§ 32.1-12 and 32.1-176.4 of the Code of Virginia.

934 **Historical Notes**

935 Derived from VR355-34-100 § 2.23, eff. April 1, 1992.

936 **12VAC5-630-331. Enforcement, notices, informal conferences.**

937 A. The commissioner may, after providing a notice of intent to revoke a construction permit or
938 inspection statement, and after providing an opportunity for an informal conference in accordance
939 with § 2.2-4019 of the Code of Virginia, revoke or declare null and void a construction permit or
940 inspection statement for flagrant or continuing violation of this chapter. Any person to whom a
941 notice of revocation or null and void is directed shall immediately comply with the notice. Upon
942 revocation, the former construction permit or inspection statement holder shall be given an
943 opportunity for appeal of the revocation in accordance with the Administrative Process Act (§ 2.2-
944 4000 et seq. of the Code of Virginia).

945 B. The commissioner may summarily suspend an inspection statement to operate a private
946 well if continued operation constitutes a substantial and imminent threat to public health. Upon
947 receipt of such notice that an inspection statement is suspended, the well owner shall cease
948 private well operations immediately. Whenever an inspection statement is suspended, the holder
949 of the inspection statement shall be notified in writing by certified mail or by hand delivery. Upon
950 service of notice that the inspection statement is immediately suspended, the former inspection
951 statement holder shall be given an opportunity for an informal conference in accordance with §
952 2.2-4019 of the Code of Virginia. The request for an informal conference shall be in writing and
953 shall be filed with the local health department by the former holder of the inspection statement. If
954 written request for an informal conference is not filed within 10 working days after the service of
955 notice, the suspension is sustained. Each holder of a suspended permit shall be afforded an
956 opportunity for an informal conference within three working days of receipt of a request for the
957 informal conference. The commissioner may end the suspension at any time if the reasons for
958 the suspension no longer exist.

959 C. Any person affected by a determination issued in connection with the enforcement of this
960 chapter may challenge such determination in accordance with the provisions of the Administrative
961 Process Act (§ 2.2-4000 et seq. of the Code of Virginia).

962 D. All private wells shall be constructed, operated, and maintained in compliance with the
963 requirements as set forth in this chapter. The commissioner may enforce this chapter through any
964 means lawfully available pursuant to § 32.1-27 of the Code of Virginia, and nothing in this chapter
965 shall be construed as preventing the commissioner from making efforts to obtain compliance
966 through warning, conference, or any other appropriate enforcement means.

967 **Statutory Authority**

968 §§ 32.1-12 and 32.1-176.4 of the Code of Virginia.

969 **12VAC5-630-340. Requirement for easement.**

970 Whenever a private well subject to this chapter is proposed to be installed on property other
971 than the owner's, an easement in perpetuity shall be recorded with the clerk of the circuit court
972 prior to issuance of a construction permit. The easement shall be of sufficient area to permit
973 access, construction, placement of the water line, and maintenance of the well.

974 **Statutory Authority**

975 §§ 32.1-12 and 32.1-176.4 of the Code of Virginia.

976 **Historical Notes**

977 Derived from VR355-34-100 § 2.24, eff. April 1, 1992.

978 **12VAC5-630-350. General.**

979 This chapter does not apply to private wells constructed, altered, ~~rehabilitated or extended or~~
980 ~~abandoned~~ prior to the effective date of these regulations September 1, 1990, unless the such
981 private well construction is modified or expanded subsequently altered or abandoned after the
982 effective date of these regulations September 1, 1990, in which case such alteration or
983 abandonment shall be performed in accordance with this chapter.

984 The class of well to be constructed shall be determined by the local or district health
985 department or the division.

986 **Statutory Authority**

987 §§ 32.1-12 and 32.1-176.4 of the Code of Virginia.

988 **Historical Notes**

989 Derived from VR355-34-100 § 3.1, eff. April 1, 1992.

990 **12VAC5-630-360. Classes of water wells.**

991 ~~The following classes~~ Classes of private wells ~~are~~ established for purposes of this chapter.
992 ~~These classes~~ are in addition to those established in the current Commonwealth of Virginia
993 Waterworks Regulations (~~12VAC5-590-10 et seq.~~) (12VAC5-590) and are intended for use for
994 private well systems:

995 1. Class III - Private wells constructed to be used as a source of drinking water. There are
996 three subclasses:

997 a. Class IIIA - Drilled wells in which the annular space around the casing is grouted to
998 a minimum depth of 20 feet.

999 (1) The well shall be drilled and cased to a depth of at least 100 feet.

1000 (2) The cased drill hole shall pass through at least 50 feet of collapsing material such
1001 as caving sand, gravel, or other material that will collapse against the casing.

1002 b. Class IIIB - Drilled wells in which the casing is installed to a minimum depth of 50
1003 feet and the annular space around the casing is grouted to at least 50 feet.

- 1004 c. Class IIIC - Drilled, bored, driven, or jetted wells other than Class IIIA and Class IIIB.
- 1005 2. Class IV - Private wells constructed for any a purpose other than use as a source of
- 1006 drinking water. There are three subclasses:
- 1007 a. Class IVA - Drilled wells in which the annular space around the casing is grouted to
- 1008 a minimum depth of 20 feet.
- 1009 (1) The well shall be drilled and cased to a depth of at least 100 feet.
- 1010 (2) The cased drill hole shall pass through at least 50 feet of collapsing material such
- 1011 as caving sand, gravel, or other material that will collapse against the casing.
- 1012 b. Class IVB - Drilled wells in which the casing is installed to a minimum depth of 50
- 1013 feet and the annular space around the casing is grouted to at least 50 feet.
- 1014 c. Class IVC - Drilled, bored, driven, or jetted wells other than Class IVA and Class
- 1015 IVB.
- 1016 3. Conversion of well class. A Class IV well may be converted to a corresponding Class
- 1017 III well provided the well meets (i) the location and construction standards set forth in this
- 1018 chapter and the water quality standards set forth in 12VAC5-630-431 and (ii) a
- 1019 construction permit application and a revised uniform water well completion report form
- 1020 are submitted to the department.

1021 **Statutory Authority**

1022 §§ 32.1-12 and 32.1-176.4 of the Code of Virginia.

1023 **Historical Notes**

1024 Derived from VR355-34-100 § 3.2, eff. April 1, 1992.

1025 **12VAC5-630-370. Water quality and quantity. (Repealed.)**

1026 ~~A. Class IV wells exempt. The water quality requirements contained in this section apply only~~

1027 ~~to Class III private wells. Class IV private wells (wells not constructed as a source of drinking~~

1028 ~~water) are not subject to any quality requirements. These regulations contain no well yield~~

1029 ~~requirements. See 12VAC5-630-460 for suggested minimum well yields for residential supplies.~~

1030 ~~B. Sample tap. A sample tap shall be provided at or near the water entry point into the system~~

1031 ~~so that samples may be taken directly from the source; this requirement may be met by utilizing~~

1032 ~~the first tap on a line near where the plumbing enters the house (may be a hose bib), provided~~

1033 ~~the tap precedes any water treatment devices.~~

1034 ~~C. Disinfection. The entire water system including the well shall be disinfected prior to use~~

1035 ~~(12VAC5-630-430 and 12VAC5-630-470).~~

1036 ~~D. Sampling. After operating the well to remove any remaining disinfectant, a sample of the~~

1037 ~~water from the well shall be collected for bacteriological examination. The sample may be~~

1038 ~~collected by the owner, well driller, or other person in accordance with procedures established by~~

1039 ~~the department and provided the sample is submitted to a private laboratory certified by the~~

1040 ~~Department of General Services, Division of Consolidated Laboratory Services, for analysis.~~

1041 ~~E. Test interpretation. A Class III private well shall be considered satisfactory if the water~~

1042 ~~sample(s) test(s) negative for coliform organisms as described in subdivision 1 or 2 below.~~

1043 ~~Sources with positive counts shall be tested as described in subdivision 3 below to determine if~~

1044 ~~the water supply is amenable to continuous disinfection (chlorination). Samples that exhibit~~

1045 ~~confluent growth shall be considered inconclusive and another sample shall be collected.~~

1046 ~~1. Where a private well has no unsatisfactory water sample within the previous 12 months,~~

1047 ~~one water sample which tests negative for coliform bacteria shall be considered satisfactory for~~

1048 ~~coliform organisms.~~

1049 2. Where a private well has had one or more positive water samples within the past 12 months
1050 for coliform bacteria, at least two consecutive samples must be collected and found negative for
1051 coliform organisms before the supply may be considered satisfactory for coliform organisms. The
1052 samples must be collected at least 24 hours apart and the well may not be disinfected between
1053 samples.

1054 3. When a private well does not test satisfactory for coliform organisms continuous disinfection
1055 may be recommended to the homeowner if the water supply is found to be suitable for continuous
1056 disinfection. A minimum of 10 samples shall be collected and tested for total coliform using an
1057 MPN methodology. The geometric mean of the samples shall be calculated and if the result is
1058 less than 100 organisms per 100 ml, the supply shall be considered satisfactory for continuous
1059 disinfection.

1060 F. Water treatment. If tests indicate that the water is unsatisfactory and no other approvable
1061 source is available, adequate methods of water treatment shall be applied and demonstrated to
1062 be effective pursuant to 12VAC5-630-370 E 3 prior to the issuance of an inspection statement.
1063 The district or local health department shall be consulted when treatment is necessary.

1064 **Statutory Authority**

1065 Statutory Authority §§ 32.1-12 and 32.1-176 of the Code of Virginia.

1066 **Historical Notes**

1067 Derived from VR355-34-100 § 3.3, eff. April 1, 1992.

1068 **12VAC5-630-380. Well location.**

1069 A. The private well shall be sited for the protection of public health and the aquifer, with
1070 appropriate consideration given to distance from potential contamination sources; vulnerability to
1071 known or suspected natural risks (e.g., flooding); potential for interference with utilities;
1072 accessibility for drilling machinery and support equipment; and safety of the public and well
1073 construction personnel.

1074 B. Sanitary survey. ~~Any obvious source~~ Obvious sources of potentially toxic or dangerous
1075 substances within 200 feet of the proposed private well shall be investigated as part of the sanitary
1076 survey by the district or local health department. Sources of contamination may include, ~~but are~~
1077 ~~not limited to,~~ items listed in Table 3.1; abandoned wells; pesticide treated soils, underground;
1078 petroleum or chemical storage tanks, drums, totes, or other storage containers (aboveground and
1079 underground); and other sources of physical, chemical, or biological contamination. If the source
1080 of contamination could affect the well adversely, and preventive measures are not available to
1081 protect the ~~ground water~~ groundwater, the well shall be prohibited. The minimum separation
1082 distance between a private well and structures, topographic features, or sources of pollution shall
1083 comply with the minimum distances shown in Table 3.1. ~~Where the minimum separation distances~~
1084 ~~for a Class IV well cannot be met, a permit may be issued under this chapter for a well meeting~~
1085 ~~all of the criteria in 12VAC5-630-400 and 12VAC5-630-410 and the separation distance~~
1086 ~~requirements for either a Class IIIA or IIIB well, without deviation, and such Class IV well shall not~~
1087 ~~be required to meet the water quality requirements of 12VAC5-630-370.~~

TABLE 3.1 DISTANCES (IN FEET) BETWEEN A WELL AND A STRUCTURE OR TOPOGRAPHIC FEATURE

Structure or Topographic Feature	Class IIIC or IV	Class IIIA or B
Building foundation	40	40
Building foundation (termite treated)	50 ¹	50 ¹
House sewer line	50 ²	50 ²

Sewer main, including force mains	50 ³	50 ³
Sewerage system	50	50
Pretreatment system (e.g. septic tank, aerobic unit, etc.)	50	50
Sewage disposal system or other contaminant source (e.g., drainfield, underground storage tank, barnyard, hog lot, etc.)	100	50
Cemetery	100	50
Sewage Dump Station	100	50 ⁴

⁴See 12VAC5-630-380

²Private wells shall not be constructed within 50 feet of a house sewer line except as provided below. Where special construction and pipe materials are used in a house sewer line to provide adequate protection, and the well is cased and grouted to the water bearing formation, all classes of private wells may be placed as close as 10 feet to the house sewer line. Special construction for house sewer lines constitutes cast iron pipe with water tight caulked joints or mechanical joints using neoprene gaskets, or solvent welded Schedule 40 or better polyvinyl chloride (PVC) pipe. It is the responsibility of the applicant to provide documentation from the contractor that such construction and pipe materials have been installed. In no case shall a private well be placed within 10 feet of a house sewer line.

³Private wells shall not be constructed within 50 feet of a sewer main except as provided below. Where special construction and pipe materials are used in a sewer main to provide adequate protection, and the well is cased and grouted to the water bearing formation, Class III wells may be placed as close as 35 feet to a sewer main and Class IV wells as close as 10 feet. Special construction for sewer mains constitutes ductile iron pipe with water tight joints, solvent welded Schedule 40 or better polyvinyl chloride (PVC) pipe (SDR 35 plastic PVC with neoprene gaskets). It is the responsibility of the applicant to provide documentation from the local building official or sanitary district that such construction and pipe materials have been installed. In no case shall a Class III well be placed within 35 feet of a sewer main. Likewise, in no case shall a Class IV well be placed within 10 feet of a sewer main.

TABLE [3.4.1] SEPARATION DISTANCES (IN FEET) [BETWEEN A WELL AND A STRUCTURE OR TOPOGRAPHIC FEATURE]

[<u>Structure or Topographic</u>] <u>Feature</u>	<u>Minimum Separation Distance</u>				<u>Exceptions</u>
	<u>Class IIIA/B</u>	<u>Class IIIC</u>	<u>Class IVA/B</u>	<u>Class IVC</u>	
<u>1. Building foundation</u>	<u>15</u>	<u>15</u>	<u>15</u>	<u>15</u>	<u>10 feet if structure is treated with borate based termite treatment</u>
<u>2. House sewer line</u>					
<u>a. Constructed of cast iron pipe with water-tight caulked joints; mechanical joints</u>	<u>10</u>	<u>10</u>	<u>10</u>	<u>10</u>	<u>None</u>

<u>using neoprene gaskets; or solvent welded Schedule 40 or better PVC pipe – provided the well is cased and grouted to water bearing formation</u>					
<u>b. Other or unknown construction; or if well is not cased and grouted to water bearing formation</u>	<u>50</u>	<u>50</u>	<u>50</u>	<u>50</u>	<u>None</u>
<u>3. Sewer main, including force main</u>					
<u>a. Constructed of ductile iron pipe with water-tight joints; solvent welded Schedule 40 or better PVC (SDR-35 plastic PVC with neoprene gaskets) – provided the well is cased and grouted to water bearing formation</u>	<u>35</u>	<u>35</u>	<u>35</u>	<u>35</u>	<u>None</u>
<u>b. Other or unknown construction; or if well is not cased and grouted to water bearing formation</u>	<u>50</u>	<u>50</u>	<u>50</u>	<u>50</u>	<u>None</u>
<u>4. Sewerage system</u>	<u>50</u>	<u>50</u>	<u>50</u>	<u>50</u>	<u>None</u>
<u>5. Active or permitted pretreatment system (e.g., septic tank or aerobic unit)</u>	<u>50</u>	<u>50</u>	<u>50</u>	<u>50</u>	<u>None</u>
<u>6. Active or permitted drainfield (including reserve drainfield).</u>	<u>50</u>	<u>100</u>	<u>50</u>	<u>100</u>	<u>None</u>
<u>7. Other contamination source (e.g., petroleum storage tank, drum, tote or other container [aboveground or underground], barnyard, landfill, animal lot, fertilizer or pesticide storage)</u>	<u>50</u>	<u>100</u>	<u>50</u>	<u>100</u>	<u>Tanks containing propane or other liquified petroleum gases are not deemed sources of contamination. However, the National Fire Protection Association Liquified Petroleum Gas Code (NFPA-58) recommends a minimum of 10 feet from sources of ignition.</u>

<u>8. Permanently abandoned sewage disposal systems</u>	<u>25</u>	<u>25</u>	<u>25</u>	<u>25</u>	<u>None</u>
<u>9. Reclaimed water distribution pipeline</u>	<u>50</u>	<u>50</u>	<u>50</u>	<u>50</u>	<u>35 feet if RWDP is constructed of water pipe material in accordance with 9VAC25-740-110.</u>
<u>10. Biosolids application [sites fields (as field is defined in 9VAC25-32-10).]</u>	<u>100</u>	<u>100</u>	<u>100</u>	<u>100</u>	<u>[No separation distance applies if biosolids have not been applied within the 12 months preceding well construction.]</u>
<u>11. Bioretention pond</u>					
<u>a. Unlined</u>	<u>50</u>	<u>50</u>	<u>50</u>	<u>50</u>	
<u>b. Lined</u>	<u>10</u>	<u>10</u>	<u>10</u>	<u>10</u>	
<u>12. Cemetery</u>	<u>50</u>	<u>100</u>	<u>50</u>	<u>100</u>	<u>None</u>
<u>13. Sewage dump station</u>	<u>50</u>	<u>100</u>	<u>50</u>	<u>100</u>	<u>None</u>
<u>14. Property line</u>					
<u>a. All properties except as described in subdivision 14 b of this table</u>	<u>5</u>	<u>5</u>	<u>5</u>	<u>5</u>	<u>None</u>
<u>b. With an adjacent property of three acres or larger used for an agricultural operation as defined in § 3.2-300 of the Code of Virginia.</u>	<u>50</u>	<u>50</u>	<u>50</u>	<u>50</u>	<u>Exemption for reduced distance applies if the adjacent property owner grants written permission for construction within 50 feet of the property line, or if it is certified that no other site on the property complies with the regulations for construction of a private well.</u>

1089 ~~B. C.~~ Downslope siting of wells from potential sources of pollution. Special precaution shall
1090 be taken when locating a well within a 60 degree arc directly downslope from any part of any an
1091 existing or intended onsite sewage disposal system or other known source of pollution, including,
1092 but not limited to, buildings subject to termite or vermin treatment, or used to store polluting
1093 substances or storage tanks or storage areas for petroleum products or other deleterious
1094 substances identified in subsection B of this section, including Table 1. The minimum separation
1095 distance shall be: (i) increased by 25 feet for every 5.0% of slope; or (ii) an increase shall be made
1096 to the minimum depth of grout and casing in the amount of five feet for every 5.0% of slope.

1097 ~~C. D.~~ Sites in swampy areas, low areas, or areas subject to flooding. No private well covered
1098 by this chapter shall be located in areas subject to the collection of pollutants such as swampy
1099 areas, low areas, or areas subject to flooding. Wells located in flood plains shall be adequately
1100 constructed so as to preclude the entrance of surface water during flood conditions. At a minimum,
1101 such construction will include extending the well terminus 18 inches above the annual flood level

1102 and grading to provide positive drainage in all directions. Other requirements may be made as
1103 determined on a case-by-case case-by-case basis by the division.

1104 ~~D. E. Property lines. There is no minimum separation distance between a private well and a~~
1105 ~~property line established by this chapter. The owner is responsible for establishing a separation~~
1106 ~~distance from property lines such that the construction and location of the well will be on the~~
1107 ~~owner's property and comply with any local ordinances. No private well shall be constructed within~~
1108 ~~five feet of a property line. If the proposed private well is on a property adjoining properties of~~
1109 ~~three acres or larger used for an agricultural operation, no private well shall be constructed within~~
1110 ~~50 feet of the property line except as exempted by the following:~~

1111 1. A notarized letter from the adjacent property owner grants permission to construct a
1112 well within 50 feet of the property line. The statement shall be recorded and indexed in the
1113 land records of the circuit court having jurisdiction over the property where the well is to
1114 be located, or

1115 2. A certification statement from a licensed onsite soil evaluator, professional engineer, or
1116 licensed water well systems provider confirms that no other well location on the property
1117 complies with this chapter. Reasons that a well location on a property may not comply with
1118 this chapter include:

1119 a. The property is not large enough to allow a location of a well 50 feet or more from
1120 the property line. In this case, the well should be located at the greatest distance from
1121 the property line consistent with this chapter.

1122 b. The location of a well 50 feet or more from the property line prevents separation
1123 distance requirements identified in 12VAC5-630-380 B being achieved on the
1124 property, provided that required separation distances can be achieved if the well is
1125 located fewer than 50 feet from the property line. In this case, the well should be
1126 located at the greatest distance from the property line consistent with this chapter. Well
1127 owners shall not be obligated to undertake otherwise optional actions, such as
1128 substitution of an alternative onsite sewage system in place of a conventional system
1129 where a conventional system is suitable, solely to comply with the requirement to
1130 maintain a 50 feet separation distance from an adjoining property of three acres or
1131 larger used for an agricultural operation.

1132 c. The location is inaccessible to well drilling equipment as a result of topography,
1133 surface water, structures, existing onsite sewage system components, overhead or
1134 buried utilities, or other obstacle.

1135 d. Other reasons that a well located greater than 50 feet from the property line may
1136 not comply with this chapter may be considered by the division on a case-by-case
1137 basis.

1138 ~~E. F. Utility lines. There is no minimum separation distance between a private well and~~
1139 ~~subsurface utility lines (electric, gas, water, cable, etc.). The minimum separation distance may,~~
1140 ~~however, be established by the individual utility company or local ordinance. Clearance distance~~
1141 ~~from overhead electrical utilities relative to drilling equipment is subject to an Occupational Safety~~
1142 ~~and Health Administration or related safety standard, and this factor shall be considered in~~
1143 ~~determination of well location. No private well shall be constructed within a utility easement~~
1144 ~~without documentation of permission from the utility.~~

1145 ~~F. Pesticide and termite treatment. No Class III private well shall be placed closer than 50 feet~~
1146 ~~from a building foundation that has been chemically treated with any termiticide or other pesticide.~~
1147 ~~No Class IV private well shall be placed closer than 50 feet to a building foundation that has been~~
1148 ~~chemically treated with any termiticide or other pesticide except as provided below. Further, no~~
1149 ~~termiticides or other pesticides shall be applied within five feet of an open water supply trench. A~~

1150 Class IV well may be placed as close as 10 feet to a chemically treated foundation if the following
1151 criteria are met:

1152 1. The aquifer from which the water is withdrawn must be a confined aquifer (i.e., there
1153 must be an impermeable stratum overlying the water bearing formation).

1154 2. The well must be cased and grouted a minimum of 20 feet or into the first confining
1155 layer between the ground surface and the water bearing formation from which water is
1156 withdrawn, whichever is greater. When the first confining layer is encountered at a depth
1157 greater than 20 feet, the well shall be cased and grouted to the first confining layer
1158 between the ground surface and the water bearing formation from which water is
1159 withdrawn.

1160 3. The material overlaying the confined aquifer must be collapsing material.

1161 G. Permanently abandoned sewage disposal systems.

1162 1. No private well shall be constructed within 25 feet of a permanently abandoned sewage
1163 disposal system. The following criteria is to determine if a sewage disposal system is
1164 permanently abandoned.

1165 a. The drainfield is no longer connected to a structure or other sewage source.

1166 b. The drainfield has been inactive for at least 24 consecutive months.

1167 c. The septic tank and distribution box have been pumped, limed, crushed, and either
1168 filled with an inert material or removed from the site.

1169 2. Documentation of disconnection may include:

1170 a. A statement from the owner of the drainfield.

1171 b. A notification of onsite sewage system abandonment recorded and indexed in the
1172 grantor index of the land records of the circuit court having jurisdiction over the site
1173 where the sewage system is located.

1174 c. A contractor invoice or other record documenting system disconnection, including
1175 disposition of septic tank and distribution box.

1176 d. Record from a public sewer operator indicating date of connection.

1177 3. Abandoned sewage disposal systems that do not meet the requirements of this
1178 subsection shall be treated as active systems with respect to determining the minimum
1179 separation distance to sources of contamination listed in Table 1.

1180 H. Reclaimed water distribution pipeline. No private well shall be placed closer than 50 feet
1181 from a reclaimed water distribution pipeline. This separation distance can be reduced to 35 feet
1182 provided that the reclaimed water distribution pipeline is constructed from a water pipe material
1183 in accordance with American Water Works Association (AWWA) specifications and pressure
1184 tested in place without leakage prior to backfilling. The hydrostatic test shall be conducted in
1185 accordance with the AWWA standard (ANSI/AWWA C-600-05) for the pipe material, with a
1186 minimum test pressure of 30 psi. A Class IV well located closer than 35 feet from a reclaimed
1187 water distribution pipeline shall not be converted to a Class III well.

1188 I. Biosolids application [site field] . No private well shall be placed closer than 100 feet from
1189 [land a field, as defined in 9VAC25-32-10,] on which biosolids are being applied [, or have been
1190 applied within the previous 12 months] .

1191 J. Bioretention pond. No private well shall be placed closer than 50 feet from an unlined
1192 bioretention pond or 10 feet from a lined bioretention pond. A Class IV well shall not be converted
1193 to a Class III well if the Class III well separation distance is not met.

1194 K. Exception for closed-loop ground-source heat pump wells. Closed-loop ground-source heat
1195 pump wells, depending upon construction, may not have to comply with the minimum separation

1196 distances for Class IV wells listed in Table 3-1. If the well is grouted 20 feet, the minimum
1197 separation distances must comply with those listed for Class IV wells. If the well is grouted a
1198 minimum of 50 feet, the separation distances shall be those listed for Class IIIA or IIIB wells. If
1199 the well is grouted the entire depth of the well, the well does not have to comply with the minimum
1200 separation distances contained in Table 3-1.

1201 **Statutory Authority**

1202 §§ 32.1-12 and 32.1-176.4 and 32.1-176.5:2 of the Code of Virginia.

1203 **Historical Notes**

1204 Derived from VR355-34-100 § 3.4, eff. April 1, 1992.

1205 **12VAC5-630-390. Site protection.**

1206 A. No objects, articles, or materials ~~of any kind which~~ that are not essential to the operation
1207 of the well shall be placed or stored in a well, well house, on the well head or well pump or water
1208 treatment system, or within close proximity to them.

1209 B. Fencing of an area around the well, or the placement of other barriers or restrictions, may
1210 be required as a condition of the permit under certain circumstances, such as to prohibit livestock
1211 access to the well head or to prohibit vehicles from damaging or polluting the area around the
1212 well head.

1213 C. The area around the well shall be graded to divert surface water away from the well.

1214 **Statutory Authority**

1215 §§ 32.1-12 and 32.1-176.4 of the Code of Virginia.

1216 **Historical Notes**

1217 Derived from VR355-34-100 § 3.5, eff. April 1, 1992.

1218 **12VAC5-630-400. Materials.**

1219 A. General. ~~All materials~~ Materials used in private wells shall be lead free, labeled as approved
1220 by the National Sanitation Foundation (NSF) for water well use, have long-term resistance to
1221 corrosion and sufficient strength to withstand hydraulic, lateral, and bearing loads.

1222 B. Drilling Fluids. Materials used for well bore stabilization and well development shall be
1223 labeled as meeting NSF/ANSI/CAN Standard 60-2020 environmental specifications.

1224 C. Casing. Materials used for casing shall be watertight and shall consist of wrought iron,
1225 concrete tile, clay tile, steel, stainless steel, fiberglass, or plastic, all designed for water well use
1226 or other suitable materials as determined by the division. The division shall maintain a list of
1227 approved casing materials. Materials used for casing shall be labeled as conforming to
1228 NSF/ANSI/CAN 61-2021 (Drinking Water System Components – Health Effects) and
1229 NSF/ANSI/CAN 372-2020 (Drinking Water System Components – Lead Content).

1230 1. Driven casings shall consist of ductile iron, steel or stainless steel and shall be equipped
1231 with a suitable drive boot.

1232 2. Casings used for ~~Class IIIA or IIIB~~ drilled wells shall be steel, stainless steel ~~or~~ plastic,
1233 or fiberglass.

1234 3. Casings used for bored Class IIIC and IVC wells shall be concrete.

1235 ~~C.~~ D. Screens. Where utilized, screens shall be constructed factory manufactured of stainless
1236 steel, plastic or other suitable materials as determined by the division. Screens shall be
1237 constructed of materials which that will not be damaged by any chemical or corrosive action of
1238 the ground-water groundwater or future cleaning operations. Additionally, screens shall be
1239 constructed of materials which that will not degrade ground-water groundwater quality. Allowable
1240 screen types include wire wrap, louvered, bridge slot, and factory slotted and shall be labeled as

1241 conforming to NSF/ANSI/CAN 61-2021 (Drinking Water System Components – Health Effects)
1242 and NSF/ANSI/CAN 372-2020 (Drinking Water System Components – Lead Content).

1243 D. Joints. Joints shall be watertight and mechanically sound. Welded joints shall have smooth
1244 interior surfaces and shall be welded in accordance with acceptable welding practice. E. Grout.
1245 The grouting material used shall meet the appropriate specification listed in this subsection.

1246 1. Neat cement grout shall consist of cement and water with not more than six gallons of
1247 water per bag (94 pounds) of cement.

1248 2. Bentonite clay may be used in conjunction with neat Portland cement to form a grouting
1249 mixture. The bentonite used must be specifically recommended by the manufacturer as
1250 being suitable for use as a well grout material and cannot exceed 6.0% by weight of the
1251 mixture.

1252 3. Bentonite clay used for grouting shall be sodium bentonite with a minimum of 20% clay
1253 solids by weight of water. The bentonite clay shall be specifically recommended by the
1254 manufacturer for use as a grouting material.

1255 An exception exists (i) when exceptional conditions require the use of a less fluid grout, to
1256 bridge voids, a mixture of cement, sand and water in the proportion of not more than two
1257 parts by weight of sand to one part of cement with not more than six gallons of clean water
1258 per bag of cement may be used if approved by the district or local health department, or
1259 (ii) for bored wells only, a concrete (1-part sand, 1-part cement, 2-parts pea gravel mix with
1260 all aggregates passing a ½-inch sieve) grout with not more than six gallons of clean water
1261 per bag of cement may be used provided a minimum three-inch annular space is available.

1262 4. Other grouting materials may be approved by the division on a case-by-case basis.
1263 Review and approval shall be based on whether the proposed material can consistently
1264 be expected to meet the intent of grouting expressed in 12VAC5-630-410 F 2. The
1265 proposed material must be an industry acceptable material used for the purpose of
1266 grouting water wells. Controlled low strength material (flowable fill) or other product
1267 incorporating fly ash, other coal combustion byproducts, or other wastes shall not be
1268 approved for use as grout.

1269 E. Gravel. F. Gravel and sand utilized for gravel filter packed wells shall be uniformly graded,
1270 cleaned, washed, disinfected and of a suitable size, well rounded, acid resistant, and have a high
1271 silica content.

1272 G. Water used during well construction shall be obtained from a suitable source or the well
1273 being constructed. A suitable source means a pure water source, or, when a pure water source
1274 is not locally available, water taken from another source then disinfected using compounds
1275 labeled as meeting NSF/ANSI/CAN Standard 60-2020 environmental specifications.

1276 H. Compounds used in the disinfection of completed wells shall be labeled as meeting
1277 NSF/ANSI/CAN Standard 60-2020 environmental specifications.

1278 **Statutory Authority**

1279 §§ 32.1-12 and 32.1-176.4 of the Code of Virginia.

1280 **Historical Notes**

1281 Derived from VR355-34-100 § 3.6, eff. April 1, 1992.

1282 **12VAC5-630-410. Construction; general.**

1283 A. Private wells shall be constructed using the criteria described in this section. The water well
1284 system provider shall provide advance notification regarding the initiation of well construction to
1285 the district or local health department to allow department personnel the opportunity to observe
1286 well construction. The water well systems provider may construct the well as conditions warrant

1287 and shall be under no obligation to delay construction activities pending arrival of district or local
1288 health department personnel.

1289 B. Well bore.

1290 1. The method of advancement of the well bore in which the private well is constructed
1291 shall be determined by the water well systems provider relative to local geologic and
1292 aquifer conditions.

1293 2. When the construction permit designates a well site, the well bore shall be placed at
1294 the well site. When the construction permit designates a well area, the well bore may be
1295 placed anywhere within the well area. If a well bore advanced within a well area must be
1296 discontinued for any reason, the well bore shall be abandoned in accordance with
1297 12VAC5-630-450 and a new well bore may be undertaken within the well area.

1298 3. Other land disturbance associated with well construction, such as grading and mud pit
1299 construction, is not limited to the well area.

1300 4. With the exception of driven wells, the well bore shall be large enough to accommodate
1301 the well casing and screen with sufficient annular space on all sides of the casing in the
1302 interval to be grouted to freely accommodate a tremie pipe or sounding tube.

1303 5. Drilling fluids used to stabilize the well bore shall be maintained within limits that will
1304 allow their complete removal from the water produced from the well, and shall not damage
1305 the capacity, efficiency, and quality of the well.

1306 6. Representative samples of formation materials shall be collected during well bore
1307 advancement with sufficient frequency to allow for preparation of the driller's log (uniform
1308 water well completion report) of the type of rock, sediment, or soil encountered.

1309 C. Casing.

1310 1. The casing shall maintain the well bore by preventing its walls from collapsing, provide
1311 a channel for the conveyance of water, and protect the quality of the water withdrawn from
1312 the well. The thickness of the casing shall be sufficient to resist the force imposed during
1313 installation and which can be anticipated after installation.

1314 ~~1- 2.~~ 2. Class IIIA and IVA wells shall be cased to a depth of at least 100 feet.

1315 ~~2- 3.~~ 3. Class IIIB and IVB wells shall be cased to a depth of at least 50 feet.

1316 ~~3- 4.~~ 4. Except as provided in subdivisions a through e below, all Class IIIC and IV IVC wells
1317 shall be cased to a minimum depth of 20 feet or terminated not less than one foot in
1318 bedrock when bedrock is encountered at a depth less than 20 feet.

1319 a. When in collapsing material, the casing shall terminate in the aquifer but in no
1320 instance be less than 20 feet.

1321 b. Where an aquifer is encountered at less than 20 feet, Class IV IVC wells may be
1322 cased to within one foot of the water bearing strata. In the instance of Class IV wells
1323 the intent of this chapter is to protect ~~ground water~~ groundwater quality, and not to
1324 ensure a potable water supply.

1325 Exception: Class IV wells placed closer than 50 feet from a building foundation treated
1326 with a chemical termiticide or other pesticide shall comply with the minimum casing
1327 depth requirements of 12VAC5-630-380 F 2.

1328 c. Alternate casing depths may be accepted for bored wells when the only aquifer lies
1329 between 11 and 20 feet provided the casing is placed within one foot of the aquifer
1330 and must not be less than 10 feet in depth from the ground surface.

1331 d. Class III-C IIIC driven wells shall be cased to the water bearing strata; however, in
1332 no case less than 10 feet. No minimum casing requirements apply to Class IV IVC
1333 driven wells except that in order to protect ~~ground water~~ groundwater they shall be

1334 capable of meeting the minimum grouting requirements as described in subdivision [
1335 ~~C-5-e~~ F.5.e] of this section.

1336 e. Closed-loop ground-source heat pump wells do not have to be cased.

1337 4. All private 5. When PVC casing is terminated in bedrock, the well casing shall be sealed
1338 using a mechanical seal or packer.

1339 6. Extension of casing above ground surface. Private well casings shall be extended at
1340 least 12 inches above ground or at least 12 inches above a concrete floor in a well house
1341 with a gravity flow drain. The following wells are exempted from this requirement; however,
1342 their location shall be permanently marked for easy location in the future:

1343 a. Drilled shallow well suction pump systems that will not operate unless a vacuum is
1344 maintained. The casings for these wells are also the suction lines through which water
1345 is drawn.

1346 b. Deep well ejector pump systems that utilize a casing adaptor and must maintain a
1347 vacuum to operate.

1348 c. Closed-loop ground-source heat pump wells.

1349 d. Heat pump return wells that are completely sealed.

1350 ~~5. All steel casings shall meet or exceed the material specifications found in 12VAC5-630-~~
1351 ~~480.~~

1352 ~~6. No plastic well casing shall be installed which will exceed 80% of its RHCP (resistance~~
1353 ~~to hydraulic collapse pressure). When experience has shown, in the division's opinion,~~
1354 ~~that the prevailing geologic conditions are subject to collapse or shifting, or where heavy~~
1355 ~~clay or unstable backfill materials occur, plastic well casings may not exceed 50% of the~~
1356 ~~RHCP rating. It shall be the responsibility of the well driller to submit calculations to the~~
1357 ~~division demonstrating that individual well casings do not exceed these ratings.~~

1358 7. The casing shall be centered in the well bore the entire depth of the well in order to
1359 provide for even distribution of filter pack and grout in the annular space.

1360 8. Joints shall be compatible with the casing material, specific to the task, and be watertight
1361 under normal operating conditions, with watertight joints above the screened interval.

1362 9. Casing straightness and alignment:

1363 a. Casing in all private wells shall be sufficiently straight that it will not interfere with
1364 the installation and operation of a pump suitable for the intended purpose of the well.

1365 b. For casing intended to accommodate a line shaft turbine pump, the maximum
1366 allowable horizontal deviation of the well from the vertical shall not exceed 2/3 times
1367 the smallest inside diameter per 100 feet of that part of the well being tested to the
1368 depth of the anticipated pump installation.

1369 ~~B.~~ D. Screens.

1370 1. The screen shall allow passage of water from the aquifer and provide sufficient tensile,
1371 collapse, and compression strength to withstand the physical loading it will be exposed to
1372 during installation, completion, development, and operational conditions. When used for
1373 the prevention of entry of foreign materials, screens shall be free of rough edges,
1374 irregularities, or other defects. A positive watertight seal between the screen and the
1375 casing shall be provided when appropriate.

1376 ~~C.~~ 2. Screen length, diameter, and slot size shall be determined based on field
1377 examination of representative samples of formation material collected during
1378 advancement of the well bore, and may be supplemented by sieve analysis of materials
1379 in the water bearing zone or geophysical logging of the well bore.

1380 3. Joints between (i) casing and screen and (ii) screen and screen shall meet the
1381 requirements of subdivision C 8 of this section.

1382 4. The bottom of the screen, or of the deepest screen in the case of multiple screens, shall
1383 be configured to reduce the possibility of native formation or well construction material
1384 heaving up into the screened interval. A closed bottom may not be required for screens
1385 installed in some formation materials.

1386 5. The screen shall be centered in the well bore.

1387 E. Filter pack.

1388 1. When a filter pack is required, the filter pack material used shall be determined based
1389 on field examination of representative samples of the water bearing formation in the
1390 withdrawal interval, and may be supplemented by sieve analysis. The filter pack shall be
1391 placed in the annular space by a method that prevents bridging and creates uniform
1392 distribution.

1393 2. The filter pack shall extend above the top of the screened interval to a thickness
1394 sufficient to compensate for settling that may occur during development and operation of
1395 the well.

1396 3. Filter pack material may be used with a screen as a formation stabilizer when water is
1397 withdrawn from a poorly consolidated rock subject to disintegration and caving when the
1398 well is pumped. Formation stabilizer shall be at least as coarse as the formation native
1399 material.

1400 F. Grouting.

1401 1. General. All private Private wells shall be grouted. It is preferred that no openings are
1402 made in the side of the well casing.

1403 2. Purpose. The annular space between the casing and well bore is one of the principal
1404 avenues through which undesirable water and contaminants may gain access to a well.
1405 The goal of grouting a well is to preclude the entrance of undesirable water and
1406 contaminants. Therefore, the annular space shall be filled with a neat cement grout, a
1407 mixture of bentonite and neat cement or bentonite clay grout specifically approved by the
1408 manufacturer for use as a grouting material.

1409 3. Specifications. The grouting material used shall meet the appropriate specification listed
1410 below:

1411 a. Neat cement grout shall consist of cement and water with not more than six gallons
1412 of water per bag (94 pounds) of cement.

1413 b. Bentonite clay may be used in conjunction with neat Portland cement to form a
1414 grouting mixture. The bentonite used must be specifically recommended by the
1415 manufacturer as being suitable for use as a well grout material and cannot exceed
1416 6.0% by weight of the mixture.

1417 c. Bentonite clay used for grouting shall be sodium bentonite with a minimum of 20%
1418 clay solids by weight of water. The bentonite clay shall be specifically recommended
1419 by the manufacturer for use as a grouting material.

1420 Exception: (i) When exceptional conditions require the use of a less fluid grout, to
1421 bridge voids, a mixture of cement, sand and water in the proportion of not more than
1422 two parts by weight of sand to one part of cement with not more than six gallons of
1423 clean water per bag of cement may be used if approved by the district or local health
1424 department, or (ii) for bored wells only, a concrete (1-1-2 mix with all aggregates
1425 passing a 1/2-inch sieve) grout with not more than six gallons of clean water per bag

1426 of cement may be used provided a minimum three-inch annular space is available and
1427 its use approved by the district or local health department.

1428 In cases where an open borehole has been drilled below the depth to which the casing
1429 is to be grouted, the lower part of the hole must be backfilled, or a packer must be set
1430 in the hole, to retain the slurry at the desired depth. Backfilling the hole with gravel and
1431 capping with sand is an acceptable practice. Material ordinarily sold as plaster or
1432 mortar sand is usually satisfactory; more than half the sand should be of grain sizes
1433 between 0.012 inches and 0.024 inches.

1434 3. Based on the well casing material and native geology, grout material shall be selected
1435 to minimize potential for spidering, cracking, or separation of grout from the well casing.

1436 4. Other materials. Other grouting materials may be approved by the division on a case
1437 by case basis. Review and approval shall be based on whether the proposed material can
1438 consistently be expected to meet the intent of grouting expressed in 12VAC5-630-410-G
1439 2. The proposed material must be an industry acceptable material used for the purpose of
1440 grouting water wells. When an open well bore has been drilled below the depth to which
1441 the casing is to be grouted, the lower part of the hole must be backfilled, or a packer must
1442 be set in the hole to retain the slurry at the desired depth. Backfilling the hole with gravel
1443 and capping with sand is an acceptable practice. Material ordinarily sold as plaster or
1444 mortar sand is satisfactory; more than half the sand should be of grain sizes between
1445 0.012 inches and 0.024 inches.

1446 5. Depth.

1447 a. All Class IIIA and Class IVA wells shall be grouted to a minimum depth of 20 feet.

1448 b. All Class IIIB and Class IVB wells shall be grouted to a minimum depth of 50 feet.

1449 c. All Class IIIC and Class IV IVC wells shall be grouted to a minimum depth of 20 feet
1450 when the casing depth is equal to or greater than 20 feet. When the casing depth is
1451 less than 20 feet, the casing shall be grouted in accordance with this subsection, from
1452 the lower terminus of the casing to the surface.

1453 Exception: Class IV wells placed closer than 50 feet from a building foundation treated
1454 with a chemical termiticide or other pesticide shall comply with the minimum grouting
1455 depth requirements of 12VAC5-630-380-F-2.

1456 d. Alternate grouting depths may be accepted for bored wells when the only aquifer
1457 suitable for a private well lies between 11 and 20 feet provided the grouting shall
1458 terminate at least one foot above the aquifer but must not be less than 10 feet in depth
1459 from the ground surface.

1460 e. Driven wells shall be grouted to a minimum depth of five feet by excavating an
1461 oversize hole at least four inches in diameter larger than the casing and pouring
1462 placing an approved grout mixture into the annular space.

1463 6. Installation. Grout shall be installed by means of one of the following methods.

1464 a. Placement using a grout pump or tremie pipe from the bottom of the annular space
1465 upward in one operation until the annular space is filled, ~~whenever the grouting depth~~
1466 ~~exceeds 20 feet. Pouring of grout is acceptable for drilled wells whenever grouting~~
1467 ~~depth does not exceed 20 feet.~~

1468 b. Pouring of grout is acceptable for bored wells whenever when the grouting depth
1469 does not exceed 30 20 feet provided there is a minimum of a 3-inch annular space [
1470 and the annular space is free of standing water.] Grouting shall be brought to the
1471 ground surface and flared to provide a one foot radius around the casing at least six
1472 inches thick. However, whenever pitless adapters are used, the grout shall terminate
1473 at the base of the pitless adapter. When an outer casing is necessary to construct a

1474 ~~new well, where possible, the outer casing shall be pulled simultaneously with the~~
1475 ~~grouting operation.~~

1476 c. Bentonite chips or pellets are acceptable for bored wells when the grouting depth
1477 does not exceed 20 feet provided the annular space is at least four inches greater than
1478 the outside diameter of the casing or coupling and the casing [and the annular space
1479 is free of standing water] . Bentonite chips or pellets shall be placed via a tremie pipe
1480 having an interior diameter at least four times the size of the pellet or chip.

1481 d. Placement of bentonite chips by free fall shall only occur within five feet of the
1482 ground surface.

1483 ~~7. Annular space. The clear annular space around the outside of the casing and the well~~
1484 ~~bore shall be at least 1.5 inches on all sides except for bored wells which shall have at~~
1485 ~~least a 3-inch annular space~~ Surface completion of grout. Grout shall be brought to the
1486 ground surface and flared to provide a one-foot radius around the casing at least six inches
1487 thick. However, whenever pitless adapters are used, the grout shall terminate at the base
1488 of the pitless adapter. When an outer casing is necessary to construct a new well, where
1489 possible, the outer casing shall be pulled simultaneously with the grouting operation.

1490 ~~D.~~ G. Additional casing and grouting. When a well is to be constructed within 100 feet of a
1491 subsurface sewage disposal system, which has been or is proposed to be installed at a depth
1492 greater than five feet below the ground surface, the casing and grouting of the water well shall be
1493 increased to maintain at least a 15-foot vertical separation between the trench bottom and the
1494 lower terminus of the casing and grouting.

1495 ~~E.~~ H. Well head.

1496 1. General. No open wells or well heads or unprotected openings into the interior of the
1497 well shall be permitted. Prior to the ~~driller~~ water well systems provider leaving the well
1498 construction site, the owner shall have the ~~driller~~ water well systems provider protect the
1499 well bore hole by installing a cover adequate to prevent accidental contamination.

1500 2. Mechanical well seals. Mechanical well seals (either sanitary well seals or pitless
1501 adapters) shall be used on all Class III and Class IV wells and shall be water and air tight
1502 except as provided in 12VAC5-630-410 ~~F~~ L4.

1503 3. Other. Wells greater than eight inches in diameter shall be provided with a watertight
1504 overlapping (shoebox) type cover, constructed of reinforced concrete or steel.

1505 ~~F.~~ L. Appurtenances passing through casing.

1506 1. General. ~~All openings~~ Openings through well casings shall be provided with a positive
1507 water stop.

1508 2. Pitless well adapters. ~~Pitless well adapters shall be subject to approval by the division.~~
1509 ~~All pitless adapters shall be installed according to the manufacturers recommendations.~~
1510 When used, pitless units and pitless adaptors shall be attached to the casing in a manner
1511 that will make the connection watertight. If an access port is installed, it shall be watertight.

1512 3. Sanitary well seals. ~~Sanitary well seals shall be subject to approval by the division. All~~
1513 When used, sanitary well seals, shall be installed according to the ~~manufacturers~~
1514 manufacturer's recommendations. A one piece top plate shall be used on a well that
1515 terminates outdoors.

1516 4. Venting. ~~Venting, where necessary as determined by the district health department,~~
1517 ~~shall be provided in such a manner as to allow for the passage of air, but not water, insects,~~
1518 ~~or foreign materials, into the well.~~

1519 J. Well development.

1520 1. "Well development" means the act of repairing damage to the geologic formation from
1521 drilling procedures and increasing the porosity and permeability of the materials
1522 surrounding the intake portion of the well. It is accomplished by application of mechanical
1523 energy, chemicals, or both to (i) remove drilling fluids and formation damage caused by
1524 the well bore drilling and well completion processes; (ii) remove formation fines near the
1525 well bore to increase hydraulic conductivity and create a filter medium; (iii) establish
1526 optimal hydraulic contact between the well and the geologic formation (aquifer) supplying
1527 water; (iv) provide for an acceptable level of sand and turbidity; and (v) provide for an
1528 appropriate level of drawdown at the production pumping rate.

1529 2. Private wells shall be developed. Disinfection required by 12VAC5-630-430 and water
1530 quality testing required by 12VAC5-630-431 shall not be conducted on a well prior to well
1531 development.

1532 K. Well maintenance and repair.

1533 1. Equipment and water or other materials used during hydraulic fracturing of bedrock
1534 wells shall comply with 12VAC5-630-400.

1535 2. Private wells shall be disinfected per 12VAC5-630-430 following maintenance,
1536 redevelopment, or other activity requiring access to the interior of the casing of a
1537 completed well.

1538 **Statutory Authority**

1539 §§ 32.1-12 and 32.1-176.4 of the Code of Virginia.

1540 **Historical Notes**

1541 Derived from VR355-34-100 § 3.7, eff. April 1, 1992.

1542 **12VAC5-630-420. Observation, monitoring, and remediation wells.**

1543 A. Except as provided in subsections B and C of this section, observation and monitoring,
1544 and remediation wells are exempted from this chapter. The exemption shall not apply to test and
1545 exploration wells constructed for the purpose of evaluating groundwater quality or available
1546 quantity related to a proposed beneficial use such as water supply for a subdivision, office park,
1547 or proposed commercial or industrial application.

1548 B. Observation and monitoring, and remediation wells shall be constructed in accordance with
1549 the requirements for private wells if they are to remain in service after the completion of the ground
1550 water groundwater study.

1551 C. Observation and monitoring, and remediation wells shall be properly permanently
1552 abandoned in accordance with 12VAC5-630-450 within 90 days of cessation of use. Unless
1553 specifically allowed under terms of a permit issued by DEQ, temporary abandonment of
1554 observation, monitoring, and remediation wells shall not occur.

1555 **Statutory Authority**

1556 §§ 32.1-12 and 32.1-176.4 of the Code of Virginia.

1557 **Historical Notes**

1558 Derived from VR355-34-100 § 3.8, eff. April 1, 1992.

1559 **12VAC5-630-430. Disinfection.**

1560 All Class III private A. Private wells shall be disinfected before placing the well(s) well in
1561 service.

1562 B. Methodology. Disinfection shall be accomplished by maintaining one of the following
1563 methods:

1564 1. Maintaining a 100 mg/l solution of chlorine in the well for 24 hours utilizing the dosage
1565 rates set forth in 12VAC5-630-470.

1566 2. Applying a quantity of water/chlorine solution to ensure a minimum of 100 mg/L of
1567 available chlorine throughout the well and immediate formation materials. Disinfection
1568 contact time shall be established on the basis of contact units, which are calculated as
1569 mg/L chlorine multiplied by hours of exposure. Contact time shall equate to a minimum of
1570 1,000 contact units (50 mg/L chlorine x 20 hours = 1,000 contact units; 200 mg/L chlorine
1571 x 5 hours = 1,000 contact units; etc.).

1572 **Statutory Authority**

1573 §§ 32.1-12 and 32.1-176.4 of the Code of Virginia.

1574 **Historical Notes**

1575 Derived from VR355-34-100 § 3.9, eff. April 1, 1992.

1576 **12VAC5-630-431. Water quality.**

1577 A. Class IV wells exempt. The water quality requirements contained in this section apply to
1578 Class III private wells. Class IV private wells (wells not constructed as a source of water for human
1579 consumption) are not subject to water quality requirements.

1580 B. Sample tap. A sample tap shall be provided at or near the water entry point into the system
1581 so that samples may be taken directly from the source; this requirement may be met by utilizing
1582 the first tap on a line near where the plumbing enters the house (may be a hose bib), provided
1583 the tap precedes any water treatment devices.

1584 C. Disinfection. The entire water system including the well shall be disinfected prior to use
1585 pursuant to 12VAC5-630-430.

1586 D. Sampling. After operating the well to remove any remaining disinfectant, a sample of the
1587 water from the well shall be collected for bacteriological examination. The sample may be
1588 collected by the owner, water well systems provider, or other person in accordance with
1589 procedures established by the department and provided the sample is submitted to a private
1590 laboratory accredited by the Department of General Services, Division of Consolidated Laboratory
1591 Services, for analysis.

1592 E. Test interpretation. A Class III private well shall be considered satisfactory if the water
1593 sample tests negative for coliform organisms as described in subdivision 1 or 2 of this subsection.
1594 Sources with positive counts shall be tested as described in subdivision 3 of this subsection to
1595 determine if the water supply is amenable to continuous disinfection. Samples that exhibit
1596 confluent growth shall be considered inconclusive and another sample shall be collected.

1597 1. When a private well has no unsatisfactory water sample within the previous 12 months,
1598 one water sample which tests negative for coliform bacteria shall be considered
1599 satisfactory for coliform organisms.

1600 2. When a private well has had one or more positive water samples within the past 12
1601 months for coliform bacteria, at least two consecutive samples must be collected and
1602 found negative for coliform organisms before the supply may be considered satisfactory
1603 for coliform organisms. The samples must be collected at least 24 hours apart and the
1604 well may not be disinfected between samples.

1605 3. When a private well does not test satisfactory for coliform organisms continuous
1606 disinfection may be recommended to the homeowner if the water supply is found to be
1607 suitable for continuous disinfection. A minimum of 10 independent samples shall be
1608 collected and tested for total coliform using an MPN methodology. To be independent,
1609 samples shall be collected no less frequently than one sample per day. The geometric
1610 mean of the samples shall be calculated and if the result is less than 100 organisms per
1611 100 ml, the supply shall be considered satisfactory for continuous disinfection.

1612 F. Water treatment. If tests indicate that the water samples test positive for coliform organisms
1613 and do not meet the standards described in this section and no other approved source is available,
1614 adequate methods of water treatment shall be applied. The treatment device shall be
1615 demonstrated to be effective pursuant to subdivision E 3 of this section prior to the issuance of
1616 an inspection statement. The district or local health department shall be consulted when treatment
1617 is necessary.

1618 G. Conversion of Class IV well to Class III potable well. In order to convert an existing Class
1619 IV to a Class III well, the owner shall provide the following information to the local health
1620 department.

1621 1. A complete application indicating the intent to convert the well classification.

1622 2. A copy of the existing uniform water well completion report documenting that the well
1623 meets Class IIIA, Class IIIB, or Class IIIC construction standards in accordance with this
1624 chapter.

1625 3. Confirmation that the well meets separation distance criteria for Class III wells listed on
1626 Table 1.

1627 4. A negative bacteria water sample in accordance with subsections D, E, and F of this
1628 section.

1629 **Statutory Authority**

1630 §§ 32.1-12 and 32.1-176.4 of the Code of Virginia.

1631 **~~12VAC5-630-440. Information to be reported~~ Repealed.**

1632 ~~[A copy of a Uniform Water Well Completion Report (see 12VAC5-630-490) shall be provided~~
1633 ~~to the district or local health department within 30 days of the completion of the well or completion~~
1634 ~~of alterations thereto.]~~

1635 **Statutory Authority**

1636 ~~§§ 32.1-12 and 32.1-176 of the Code of Virginia.~~

1637 **Historical Notes**

1638 Derived from VR355-34-100 § 3.10, eff. April 1, 1992.

1639 **12VAC5-630-450. Well abandonment.**

1640 ~~A. Well abandonment is governed jointly by the Department of Environmental Quality and the~~
1641 ~~Department of Health pursuant to § 62.1-44.92(6) of the Ground Water Act of 1973 (Repealed).~~
1642 ~~In addition, the The abandonment of any a private well governed by this chapter, or any a private~~
1643 ~~well abandoned as a condition of a permit issued under this chapter, shall be administered by the~~
1644 ~~Department of Health in conformance with this section. The owner or owner's agent shall provide~~
1645 ~~advance notification regarding the initiation of well abandonment to the district or local health~~
1646 ~~department to allow department personnel the opportunity to observe well abandonment. The~~
1647 ~~owner or owner's agent shall be under no obligation to delay abandonment activities pending~~
1648 ~~arrival of department personnel.~~

1649 B. Prohibited materials. The following materials, even if classifiable as clean fill or beneficial
1650 use byproducts in other applications, shall not be used as clean fill or grout in any well
1651 abandonment procedure.

1652 1. Contaminated media.

1653 2. Non-manufactured gravel, brick, broken concrete, crushed glass, porcelain, or road
1654 pavement, except as these materials are present as incidental constituents of undisturbed
1655 soil or natural earth materials.

1656 3. Controlled low strength material (flowable fill) or other product incorporating fly ash,
1657 other coal combustion byproduct, or other waste.

1658 C. Temporary abandonment. A temporarily abandoned well shall be sealed with a water-tight
1659 cap or well head seal. Such a well shall be maintained so that it will not be a source or channel
1660 for contamination to ~~ground-water~~ groundwater during temporary abandonment.

1661 ~~C.~~ D. Permanent abandonment. The object of proper permanent abandonment is to prevent
1662 contamination from reaching ~~ground-water~~ groundwater resources via a component of the well,
1663 including casing, annular space, and well cap. Permanently abandoned wells, with the exception
1664 of bored wells abandoned per the methods identified in subdivisions 5 a and 5 b (3) of this
1665 subsection shall no longer be classified as wells. A permanently abandoned well shall be
1666 abandoned in the following manner:

1667 1. ~~All casing~~ Casing material may be salvaged.
1668 2. Before the well is ~~plugged~~ abandoned, it shall be checked from land surface to the entire
1669 depth of the well to ascertain freedom from obstructions that may interfere with ~~plugging~~
1670 ~~(sealing)~~ abandonment operations.

1671 3. The well shall be thoroughly chlorinated using the dosage rates in 12VAC5-630-430
1672 prior to ~~plugging (sealing)~~ abandonment.

1673 4. Grout used in well abandonment shall conform to 12VAC5-630-400 E.

1674 5. Bored wells, rock or brick-lined, and uncased wells shall be abandoned using one of
1675 the following methods:

1676 a. Clean fill method. Bored, rock or brick-lined, and uncased wells abandoned by this
1677 method shall remain designated as wells with respect to the siting of onsite sewage
1678 treatment system components per the requirements of 12VAC5-610 and 12VAC5-613.
1679 The well shall be backfilled with clean fill to the water level. A two-foot-thick bentonite
1680 plug shall be placed immediately above the water level. Clean fill shall be placed on
1681 top of the bentonite plug and brought up to at least five feet from the ground surface.
1682 The top five feet of the well casing, if present, shall be removed from the bore hole. If
1683 an open annular space is present around the well casing, the annular space shall be
1684 filled with grout to the maximum depth possible, but not less than or equal to 20 feet.
1685 A one-foot-thick cement or bentonite grout plug that completely fills the bore void
1686 space shall be placed a minimum of five feet from the ground surface. The remaining
1687 space shall be filled with clean fill which is mounded a minimum of one foot above the
1688 surrounding ground surface. ~~Bored wells or uncased wells abandoned in this manner~~
1689 ~~shall be treated as wells with respect to determining the minimum separation distance~~
1690 ~~to sources of contamination listed in Table 3.1. When the well is fewer than 25 feet~~
1691 ~~deep, this procedure shall be followed to the greatest extent possible, including~~
1692 ~~removing at a minimum the top five feet of casing below ground and grouting the open~~
1693 ~~annular space as described in this subdivision.~~ The location of these wells shall be
1694 permanently marked for future ~~location~~ reference.

1695 5. Wells b. Grout abandonment method. Bored, rock or brick-lined, and uncased wells
1696 abandoned by this method shall no longer be designated as wells, with the exception
1697 of subdivision 5 b (3) of this subsection. At a minimum, the top five feet of well casing
1698 below ground, if present, shall be removed from the well bore.

1699 (1) When a continuous annular space is present around the well casing, the annular
1700 space shall be filled with grout, placed via a tremie pipe, to the maximum depth
1701 possible, but not less than 20 feet.

1702 (2) When an annular space is present but not continuous, materials shall be completely
1703 removed from the annular space to the maximum depth possible, but not less than 20
1704 feet, and the annular space shall be filled with grout placed via a tremie pipe.

1705 (3) When an annular space is present but not continuous, and cannot be cleared
1706 sufficiently for the annular space to be filled with grout to a depth not less than 20 feet,
1707 then accessible annular space will be filled with grout placed via a tremie pipe. Wells
1708 in which the annular space cannot be filled with grout to depth of at least 20 feet shall
1709 be treated as a well with respect to the siting of onsite sewage treatment components
1710 per the requirements of 12VAC5-610 and 12VAC5-613.

1711 (4) If existing well documentation (uniform water well completion report) indicates that
1712 the annular space is filled with grout to a minimum depth of 20 feet, the condition of
1713 the grout shall be confirmed by visual observation of the top of the grout following the
1714 removal of the top five feet of well casing below ground. If the grout appears intact, no
1715 further confirmation of grout condition shall be required and abandonment shall
1716 proceed. If the grout condition appears compromised based on visual examination,
1717 then the requirements of subdivision 5 b (2) or 5 b (3) of this subsection shall apply.

1718 (5) Once the annular space is addressed the well shall be pumped dry and completely
1719 filled with grout poured from the surface. If the well is not pumped dry, grout shall be
1720 placed by introduction through a tremie pipe. The placement of grout in the well bore
1721 shall completely fill the bore void space to within a minimum of five feet from the ground
1722 surface. The well shall be capped with clean fill which is mounded a minimum of one
1723 foot above the surrounding ground surface. When the well is fewer than 25 feet deep,
1724 this procedure shall be followed to the greatest extent possible, including removing at
1725 a minimum the top five feet of casing below ground and cleaning or grouting the open
1726 annular space as described in this subdivision.

1727 6. Drilled wells, including observation, monitoring, and remediation wells constructed in
1728 collapsing material shall be completely filled with grout ~~or clay slurry~~ by introduction
1729 through ~~placed via a tremie pipe~~ initially extending to the bottom of the well. Such pipe
1730 shall be raised, but remain submerged in grout, as the well is filled.

1731 6. Wells The well shall be capped with clean fill mounded to a minimum of one foot above
1732 the surrounding ground surface and graded to provide positive drainage away from the
1733 well.

1734 7. Drilled wells, including observation, monitoring, and remediation wells, constructed in
1735 consolidated rock formations or which penetrate zones of consolidated rock shall be
1736 completely filled with grout placed via a tremie pipe. At the discretion of the water well
1737 service provider, the well may be filled with sand or gravel opposite the zones of
1738 consolidated rock. The top of the sand or gravel fill shall be at least five feet below the top
1739 of the consolidated rock and at least 20 feet below the land surface. The remainder of the
1740 well shall be filled with grout ~~or clay slurry~~ placed via a tremie pipe. The well shall be
1741 capped with clean fill mounded to a minimum of one foot above the surrounding ground
1742 surface and graded to provide positive drainage away from the well.

1743 7. 8. Other abandonment procedures may be approved by the division on a case by case
1744 basis.

1745 8. Test and exploration wells shall be abandoned in such a manner to prevent the well
1746 from being a channel for the vertical movement of water or a source of contamination to
1747 ground water.

1748 9. When bored wells are bored advanced and a water source is not found, and the casing
1749 has not been placed in the bore hole, the well bore hole ~~may~~ shall be abandoned by
1750 backfilling with the bore spoils cuttings or clean fill or both to at least five feet below the
1751 ground surface. A two-foot-thick ~~bentonite grout~~ plug of grout shall be placed at a minimum
1752 of five feet from the ground surface. The remainder of the bore hole shall be filled with the
1753 bore spoils cuttings or clean fill or both.

1754 **Statutory Authority**

1755 §§ 32.1-12 and 32.1-176.4 of the Code of Virginia.

1756 **Historical Notes**

1757 Derived from VR355-34-100 § 3.11, eff. April 1, 1992.

1758 **12VAC5-630-460. Water system yields for residential use wells.**

1759 A. ~~All drinking~~ Drinking water systems that utilize one or more Class III wells shall be capable
1760 of supplying water in adequate quantity for the intended usage. ~~All such systems, with~~ Systems
1761 with a capacity ~~less than~~ under three gallons per minute, shall have a capacity ability to produce
1762 and store 150 gallons per bedroom per day and be capable of delivering a sustained flow of five
1763 gallons per minute per connection for 10 minutes for ordinary residential use. Systems with a
1764 capacity of three gallons per minute or more do not require additional storage.

1765 B. The certified water well systems provider shall certify the storage capacity and the yield of
1766 the well on the Uniform Water Well Completion Report.

1767 **Statutory Authority**

1768 §§ 32.1-12 and 32.1-176.4 of the Code of Virginia.

1769 **Historical Notes**

1770 Derived from Virginia Register Volume 28, Issue 22, eff. August 16, 2012.

1771 **12VAC5-630-470. Chlorination dosage rates. (Repealed.)**

Casing Diameter (Inches)	Volume per 100 Feet (Gallons)	70% Sodium Hypochlorite (Oz. Dry Wt.)	5% Sodium Hypochlorite (Liquid Meas.)
2	16	0.5	4 oz. -
4	65	2	18 oz. -
6	147	4	40 oz. -
8	261	6	4.25 pts. -
10	408	8	7 pts. -
12	588	12	10 pts. -
16	1045	20	2 gal. -
20	1632	32	3.3 gal. -
24	2350	48	4.67 gal. -
30	3672	70	7.3 gal. -
36	5288	104	10.5 gal. -

1772 **Statutory Authority**

1773 ~~§§ 32.1-12 and 32.1-176 of the Code of Virginia.~~

1774 **Historical Notes**

1775 Derived from VR355-34-100, Appendix II; eff. April 1, 1992.

1776 ~~12VAC5-630-480. Well casing specifications. (Repealed.)~~

Steel Casings				
Nom. Size (inches)	Weight (lbs./ft.)	Thickness (inches)	External Diameter	Internal Diameter
4	10.79	.188	4.5	4.026
6	13.00	.188	6.625	6.25
8	24.70	.277	8.625	8.074
10	31.20	.279	10.75	10.192

1777 ~~Statutory Authority~~

1778 ~~Statutory Authority §§ 32.1-12 and 32.1-176 of the Code of Virginia.~~

1779 ~~Historical Notes~~

1780 ~~Derived from VR355-34-100, Appendix III; effective April 1, 1992.~~

1781 FORMS (12VAC5-630)

1782 [Application for: Sewage System - Water Supply, AOSE Form D \(rev. 7/2007\);](#)

1783 [Application for Express Class IV Well Construction Permit;](#)

1784 [Record of Inspection - Private Water Supply System.](#)

1785 [Uniform Water Well Completion Report.](#)

1786 [Uniform Water Well Completion Form, GW-2 \(eff. 8/2016\)](#)

1787 [Registration Statement for Express Geothermal Well Permit \(eff. 6/2012\)](#)

1788 [Documents Incorporated by Reference \(12VAC5-630\)](#)

1789 [NSF International, P.O. Box 130140, 789 N. Dixboro Road, Ann Arbor, MI 48105](#)

1790 [\(http://www.nsf.org/\)](http://www.nsf.org/)

1791 [NSF/ANSI/CAN Standard 60-2020 Drinking Water Treatment Chemicals - Health Effects, 2020](#)

1793 [NSF/ANSI/CAN Standard 61-2021 Drinking Water System Components - Health Effects, 2021](#)

1795 [NSF/ANSI/CAN Standard 372-2020 Drinking Water System Components - Lead Content, 2020](#)

1797 [NSF/ANSI/CAN Standard 600-2021 Health Effects Evaluation and Criteria for Chemicals in Drinking Water, 2021](#)

1799 [NSF/ANSI/CAN Standard 600-2021 Addendum, Health Effects Evaluation and Criteria for Chemicals in Drinking Water, 2021](#)

1800 [Chemicals in Drinking Water, 2021](#)



COMMONWEALTH of VIRGINIA

Department of Health
P O BOX 2448
RICHMOND, VA 23218

Colin M. Greene, MD, MPH
State Health Commissioner

TTY 7-1-1 OR
1-800-828-1120

MEMORANDUM

DATE: August 8, 2022

TO: State Board of Health

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

SUBJECT: Fast Track – Regulations for the Licensure of Home Care Organizations – Changes to the Term of the License and Fee Schedule

Enclosed for your review are fast track amendments to the Regulations for the Licensure of Home Care Organizations.

Chapter 172 (2022 Acts of Assembly) amended Code of Virginia § 32.1-162.9 to change home care organization licenses from an annual license to a three-year license. This act also mandated that the fee for renewal of a home care organization license shall be \$1,500 until such time as the Board of Health may amend or repeal regulations for the licensure of home care organizations. This regulatory action updates the fee amounts for both initial and renewal of home care organization licenses, updates the term of the license, and updates the method by which existing home care organizations communicate either changes to their licenses or their request for an exemption. By updating the fee schedule so that both initial and renewed HCO licenses are \$1,500, it will preserve current fee revenue and the current yearly cost of an HCO license, in light of the increase in term length from one year to three years.

The State Board of Health is requested to approve the Fast Track Action. Should the State Board of Health approve the Fast Track Action, the amendments 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 proposed regulatory text will be published in the Virginia Register of Regulations and on the Virginia Regulatory Town Hall website. A 30-day public comment period will begin. Fifteen days after the close of the public comment period, the regulation will become effective.



townhall.virginia.gov

Fast-Track Regulation Agency Background Document

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-381
VAC Chapter title(s)	Regulations for the Licensure of Home Care Organizations
Action title	Fee Change for Home Care Organizations after Enactment of Chapter 172 (2022 Acts of Assembly)
Date this document prepared	August 8, 2022

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

Brief Summary

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

Chapter 172 (2022 Acts of Assembly) amended Code of Virginia § 32.1-162.9 to change home care organization licenses from an annual license to a three-year license. This act also mandated that the fee for renewal of a home care organization license shall be \$1,500 until such time as the Board of Health may amend or repeal regulations for the licensure of home care organizations. This regulatory action updates the fee amounts for both initial and renewal of home care organization licenses, updates the term of the license, and updates the method by which existing home care organizations communicate either changes to their licenses or their request for an exemption.

Acronyms and Definitions

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

“Board” means the State Board of Health.

“HCO” means home care organization.

“VDH” means the Virginia Department of Health.

Statement of Final Agency Action

Provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

Mandate and Impetus

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

Consistent with Virginia Code § 2.2-4012.1, also explain why this rulemaking is expected to be noncontroversial and therefore appropriate for the fast-track rulemaking process.

Chapter 172 (2022 Acts of Assembly) amended Code of Virginia § 32.1-162.9 to change home care organization licenses from an annual license to a three-year license. This act also mandated that the fee for renewal of a home care organization license shall be \$1,500 until such time as the Board of Health may amend or repeal regulations for the licensure of home care organizations.

It is anticipated that this action will be noncontroversial and therefore appropriate for the fast-track process because the fee amount for the new three-year HCO licenses is the same amount on a per-year basis as what the regulations mandate for a one-year license (i.e., \$500 for the prior one-year license, now \$1,500 for a three-year license) and the vast majority of HCOs are already utilizing the forms created by VDH to communicate changes to their licenses or requests for an exemption.

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.

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 Title 32.1 of the Code of Virginia. Code of Virginia § 32.1-162.12 requires the Board to adopt regulations governing the activities and services provided by home care organizations.

Purpose

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

The rationale or justification for the regulatory change is that VDH should maintain its revenue to support the HCO licensure program, the regulations should be consistent with statutes, and HCO licensees should provide consistent, complete information to VDH so VDH can efficiently and accurately process changes to licensing records. The regulatory change is essential to protect the health, safety, or welfare of citizens because VDH cannot provide adequate inspection and oversight for HCOs if it is losing funding equal to roughly three full-time HCO inspectors. The goal of the regulatory change is to preserve VDH's current fee revenue and to eliminate inconsistencies in receiving and processing license changes and exemption requests.

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.

12VAC5-381-40. License application; initial and renewal.
Amended to make HCO license terms to be three years instead of one.

12VAC5-381-70. Fees.
Amended to increase the fees for HCO license to \$1,500; amended to specify the written request for an exemption or license change needs to be on the relevant application.

FORMS (12VAC5-381).
Amended to include the exemption request application.

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 is that the regulations will be consistent with the statutes and HCO licensees will have received clarification on written requests for a license change or exemption. The primary advantages to VDH or the Commonwealth is that VDH will not be losing approximately \$300,000 in revenue annually and the data received from HCO licensees about license changes or request for an exemption will be consistent and more likely to be complete. There are no primary disadvantages to the public, VDH, or the Commonwealth.

Requirements More Restrictive than Federal

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

There are not applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

Consistent with § 2.2-4007.04 of the Code of Virginia, identify any other state agencies, localities, or other entities particularly affected by the regulatory change. Other entities could include local partners such as tribal governments, school boards, community services boards, and similar regional organizations. "Particularly affected" are those that are likely to bear any identified disproportionate material impact which would not be experienced by other agencies, localities, or entities. "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulation or regulatory change are most likely to occur. If no agency, locality, or entity is particularly affected, include a specific statement to that effect.

Other State Agencies Particularly Affected

None

Localities Particularly Affected

None

Other Entities Particularly Affected

Other entities particularly affected are current and prospective HCO licensees.

Economic Impact

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

Impact on State Agencies

<p><i>For your agency:</i> projected costs, savings, fees or revenues resulting from the regulatory change, including:</p> <ul style="list-style-type: none"> 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 	<p>There are no project costs, savings, fees, or revenue increase resulting from the regulatory change. The fee amounts prescribed in this regulatory action would preserve the current yearly value of the license (\$500). While revenue may go up or down on an annual basis, depending on how many three-year licenses were due for renewal or new applications were received, the revenue received over the life of an HCO license remains unchanged.</p> <p>Without this regulatory change, VDH is projecting it will lose \$300,000 annually, since currently the</p>
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	regulations prescribed a \$500 fee for an initial HCO license. Since that license's terms is now three years, VDH would be losing \$1,000 per license. Since approximately 300 new HCO applications are received every year, that totals \$300,000 annually.
<i>For other state agencies:</i> projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.	There are no projected costs, savings, fees, or revenues resulting from the regulatory change.
<i>For all agencies:</i> Benefits the regulatory change is designed to produce.	This regulatory action is designed to promote and ensure the health and safety of clients and patients who receive personal care services and skilled services from HCOS by ensuring VDH has adequate fee revenue to support sufficient staff to perform inspections and other oversight functions of HCOs and by ensuring consistent processes are followed by HCOs and VDH's staff to ensure integrity of licensing data.

Impact on Localities

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

Projected costs, savings, fees or revenues resulting from the regulatory change.	There are no projected costs, savings, fees or revenues resulting from the regulatory change for localities.
Benefits the regulatory change is designed to produce.	This regulatory action is designed to promote and ensure the health and safety of clients and patients who receive personal care services and skilled services from HCOS by ensuring VDH has adequate fee revenue to support sufficient staff to perform inspections and other oversight functions of HCOs and by ensuring consistent processes are followed by HCOs and VDH's staff to ensure integrity of licensing data.

Impact on Other Entities

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

Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect.	The individuals, businesses, or other entities likely to be affected by the regulatory change include persons seeking services from an HCO; licensed HCOs; and persons or entities seeking licensure to operate an HCO.
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;	As of July 1, 2022, there are approximately 1,580 licensed HCOs in Virginia, the vast majority of which are believed to be small businesses. VDH does not collect, nor has any HCO voluntarily supplied, data about whether an HCO is independently owned and operated or whether an HCO employs fewer than 500 employees.

<p>b) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.</p>	
<p>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.</p>	<p>All persons or entities seeking licensure to operate an HCO would incur a fee of \$1,500 per application for an initial license whose term is three years; VDH anticipates that for nearly all applicants, this would be a one-time cost.</p> <p>All licensed HCOs would incur a cost of at least a \$1,500 fee per application for a renewed HCO license whose term is three years in length</p> <p>VDH believes that any administrative costs for reporting changes to an HCO and requesting an exemption by using the prescribed form would be incidental to their existing administrative costs, as the regulations already prescribe these to be communicated in writing. VDH anticipates that the time and HCO takes to write a freeform communication to VDH is equal to the time that an HCO would take to complete a written form.</p> <p>VDH does not predict any projected costs for purchases of equipment or services resulting from the regulatory change for licensed HCOs and persons or entities seeking licensure to operate an HCO.</p> <p>VDH does not anticipate any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change.</p>
<p>Benefits the regulatory change is designed to produce.</p>	<p>This regulatory action is designed to promote and ensure the health and safety of clients and patients who receive personal care services and skilled services from HCOS by ensuring VDH has adequate fee revenue to support sufficient staff to perform inspections and other oversight functions of HCOs and by ensuring consistent processes are followed by HCOs and VDH's staff to ensure integrity of licensing data.</p>

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 required the Board to adopt regulations governing the licensure of home care organizations and amending the regulation is the least burdensome method to accomplish the purpose of this action. The requirements proposed in this action are not more burdensome ore more costly than what the regulations already require.

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

Regulatory Flexibility Analysis

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

In developing the proposed regulations, the Board considered that the affected industry consists primarily of small businesses. Providing a small business exemption would result in the overwhelming number of HCOs being exempt from the requirements, just as establishing performance standards or less stringent requirements specific to small business would have the effect of lowered standards and requirements in nearly every case. Consequently, there are no other alternative regulatory methods to minimizing the adverse impact on small businesses that the Board could utilize without being inconsistent with health, safety, environmental and economic welfare in accomplishing the objectives of the General Assembly mandates.

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

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.

Consistent with § 2.2-4011 of the Code of Virginia, if an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

If you are objecting to the use of the fast-track process as the means of promulgating this regulation, please clearly indicate your objection in your comment. Please also indicate the nature of, and reason for, your objection to using this process.

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

Detail of Changes

List all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Use all tables that apply, but delete inapplicable tables.

Table 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
381-40	N/A	<p>12VAC5-381-40. License application; initial and renewal.</p> <p>A. The OLC provides prelicensure consultation and technical assistance regarding the licensure process. The purpose of such consultation is to explain the regulation and the survey process. Prelicensure consultations are arranged after a completed initial application is on file with the OLC.</p> <p>B. Licensure applications are obtained from the OLC. The OLC shall consider an application complete when all requested information and the appropriate fee, stated in 12VAC5-381-70, is submitted. If the OLC finds the application incomplete, the applicant will be notified in writing.</p> <p>C. The activities and services of each applicant and licensee shall be subject to an inspection by the OLC to determine if the organization is in compliance with the provisions of this chapter and state law.</p>	<p>CHANGE: The Board is proposing the following change:</p> <p>12VAC5-381-40. License application; initial and renewal.</p> <p>A. The OLC provides prelicensure consultation and technical assistance regarding the licensure process. The purpose of such consultation is to explain the regulation and the survey process. Prelicensure consultations are arranged after a completed initial application is on file with the OLC.</p> <p>B. Licensure applications are obtained from the OLC. The OLC shall consider an application complete when all requested information and the appropriate fee, stated in 12VAC5-381-70, is submitted. If the OLC finds the application incomplete, the applicant will be notified in writing.</p> <p>C. The activities and services of each applicant and licensee shall be subject to an inspection by the OLC to determine if the organization is in compliance with the provisions of this chapter and state law.</p> <p>D. A completed application for initial licensure must be submitted at least 60 days prior to the organization's planned opening date to allow the OLC time to process the application. An incomplete application shall become inactive six months after it is received by the OLC. Applicants must then reapply for licensure</p>

		<p>D. A completed application for initial licensure must be submitted at least 60 days prior to the organization's planned opening date to allow the OLC time to process the application. An incomplete application shall become inactive six months after it is received by the OLC. Applicants must then reapply for licensure with a completed application and application fee. An application for a license may be withdrawn at any time.</p> <p>E. Licenses are renewed annually. The OLC shall make renewal applications available at least 60 days prior to the expiration date of the current license.</p> <p>F. It is the home care organization's responsibility to complete and return a renewal application to assure timely processing. Should a current license expire before a new license is issued, the current license shall remain in effect provided a complete and accurate application was filed on time.</p>	<p>with a completed application and application fee. An application for a license may be withdrawn at any time.</p> <p>E. Licenses are renewed annually <u>triennially</u>. The OLC shall make renewal applications available at least 60 days prior to the expiration date of the current license.</p> <p>F. It is the home care organization's responsibility to complete and return a renewal application to assure timely processing. Should a current license expire before a new license is issued, the current license shall remain in effect provided a complete and accurate application was filed on time.</p> <p>INTENT: The intent of this regulatory change is to mirror the language of Chapter 172 (2022 Acts of Assembly).</p> <p>RATIONALE: The rationale for this regulatory change is that the regulations should be consistent with the statutes.</p> <p>LIKELY IMPACT: The likely impact of this regulatory change will be reduced confusion for current and prospective HCO licensees, as the language in the statutes and regulations will be consistent with one another.</p>
381-70	N/A	<p>12VAC5-381-70. Fees.</p> <p>A. The OLC shall collect a fee of \$500 for each initial and renewal license application. Fees shall accompany the licensure application and are not refundable.</p> <p>B. An additional late fee of \$50 shall be collected for an organization's failure to file a renewal application by the date specified.</p> <p>C. A processing fee of \$250 shall be collected for each reissuance or replacement of a license and shall accompany the written</p>	<p>CHANGE: The Board is proposing the following change:</p> <p>12VAC5-381-70. Fees.</p> <p>A. The OLC shall collect a fee of \$500 <u>\$1,500</u> for each initial and renewal license application. Fees shall accompany the licensure application and are not refundable.</p> <p>B. An additional late fee of \$50 shall be collected for an organization's failure to file a renewal application by the date specified.</p> <p>C. A processing fee of \$250 shall be collected for each reissuance or replacement of a license and shall</p>

		<p>request for reissuance or replacement.</p> <p>D. A one time processing fee of \$75 for exemption from licensure shall accompany the written exemption request.</p>	<p>accompany the written request <u>application</u> for reissuance or replacement.</p> <p>D. A one time processing fee of \$75 for exemption from licensure shall accompany the written exemption request <u>application</u>.</p> <p>INTENT: The intent of this regulatory change is to preserve VDH's current fee revenue and to ensure HCOs are providing consistent information when making changes to their licenses or request an exemption.</p> <p>RATIONALE: The rationale for this regulatory change is that (i) presently an HCO license is worth \$500 a year and increasing the fee for initial and renewed HCO license to \$1,500 is consistent with that valuation, as HCO licenses have three year terms instead of one year terms; and (ii) requiring HCOs to provide the minimum necessary data to process license changes or exemption request in a form ensures that HCOs are more likely to provide all necessary information in one attempt.</p> <p>LIKELY IMPACT: The likely impact of this regulatory change will be the continued financial health of the HCO licensure program and VDH staff being able to more efficiently and accurately process licensure change notifications and exemption requests into an HCO's licensing record.</p>
FORMS	N/A	<p>FORMS (12VAC5-381)</p> <p>Application for Home Care Organization Licensure (rev. 4/2021)</p> <p>Renewal Addendum for Licenses Expiring July 31, 2021 (eff. 4/2021)</p>	<p>CHANGE: The Board is proposing the following change:</p> <p>FORMS (12VAC5-381)</p> <p>Application for Home Care Organization Licensure (rev. 4/2021)</p> <p>Renewal Addendum for Licenses Expiring July 31, 2021 (eff. 4/2021)</p> <p><u>Application for Exemption from Home Care Organization Licensure (eff. 9/2010)</u></p>

			<p>INTENT: The intent of this regulatory change is to update the FORMS section to reference all current forms.</p> <p>RATIONALE: The rationale for this regulatory change is that forms standardize the information being provided to VDH by HCO licensees.</p> <p>LIKELY IMPACT: The likely impact of the new requirements is consistency in the information and data being received by VDH.</p>
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Office of Regulatory Management
Economic Review Form

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-381
VAC Chapter title(s)	Regulations for the Licensure of Home Care Organizations
Action title	Fee Change for Home Care Organizations after Enactment of Chapter 172 (2022 Acts of Assembly)
Date this document prepared	August 11, 2022

Cost Benefit Analysis

Table 1a: Costs and Benefits of the Proposed Changes (Primary Option)

<p>(1) Direct Costs & Benefits</p>	<ul style="list-style-type: none"> Increase home care organization (HCO) licensure fees to \$1,500 per license and the term of the license to three years. <p>Direct Costs: \$1,000 increase per applicant for an initial license, which does maintain the current yearly cost of the license of \$500/yr. VDH estimates that an increase in the initial fee for HCO licenses may reduce the annual number of new applicants by 20% (240 instead of 300). Please note that the \$1,500 per applicant for a renewed license is already mandated in the second enactment clause of Chapter 172 (2022 Acts of Assembly) and is not included in the cost-benefit calculation below because the Act supersedes the regulation.</p> <p>Direct Benefits: Preserving approximately \$240,000 in fee revenue over the term of the initial three-year license that would otherwise be lost without the regulatory change. VDH estimates that this increase in the initial fee for HCO licenses may reduce the annual number of new applicants by 20% (240 instead of 300).</p> <ul style="list-style-type: none"> Require HCO licensees to submit their written requests for a license change or exemption on a prescribed form. <p>Direct Costs: \$0 per HCO licensee.</p> <p>Direct Benefits: \$60,204 benefit for VDH by saving approximately 4 hours of staff time (\$17.30/hr) for approximately 870 license change and exemption requests received annually.</p>	
<p>(2) Quantitative Factors</p>	<p>Estimated Dollar Amount</p>	<p>Present Value</p>

Direct Costs	(a) \$2,400,000	(c) \$2,108,666
Direct Benefits	(b) \$3,002,040	(d) \$2,637,625
(3) Benefits-Costs Ratio	1.25	(4) Net Benefit \$528,959
(5) Indirect Costs & Benefits	VDH is not aware of any quantifiable indirect costs or indirect benefits at this time.	
(6) Information Sources	VDH historical financial records; current number of and historical trends in HCO licensee and applicant population.	
(7) Optional	<p>VDH has numerous challenges and constraints that limit a cost benefit analysis, including limited data availability, limited statutory discretion, and insufficient analytical models.</p> <p>The qualitative benefits of the proposed regulatory change are ensuring VDH has adequate fee revenue to support sufficient staff to perform inspections and other oversight functions of HCOs to promote and ensure the health and safety of clients and patients who receive personal care services and skilled services from HCOs and ensuring consistent processes are followed by HCOs and VDH's staff to improve efficiency in VDH operations and integrity of licensing data.</p>	

Table 1b: Costs and Benefits under the Status Quo (No change to the regulation)

(1) Direct Costs & Benefits	<ul style="list-style-type: none"> HCO licensure fees is \$500 for an initial license. <p>Direct Costs: \$300,000 cost to VDH in lost fee revenue over the term of the initial three-year license; VDH estimates that the annual number of new applicants would remain steady at 300.</p> <p>Direct Benefits: Initial HCO licensees would save \$1000 over the term of the initial three-year license</p> <ul style="list-style-type: none"> Require HCO licensees to submit their written requests for a license change or exemption without prescribing the form to use. <p>Direct Costs: \$0 per HCO licensee. \$60,204 cost for VDH of 4 hours of staff time (\$17.30/hr) for approximately 870 license change and exemption requests received annually.</p>
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	Direct Benefits: VDH is not aware of any quantifiable direct benefits at this time.		
(2) Quantitative Factors	Estimated Dollar Amount	Present Value	
Direct Costs	(a) \$3,602,040	(c) \$3,164,792	
Direct Benefits	(b) \$3,000,000	(d) \$2,635,833	
(3) Benefits-Costs Ratio	0.832861379	(4) Net Benefit	-\$528,959
(5) Indirect Costs & Benefits	VDH is not aware of any quantifiable indirect costs or indirect benefits at this time.		
(6) Information Sources	VDH historical financial records; current number of and historical trends in HCO licensee and applicant population.		
(7) Optional	<p>VDH has numerous challenges and constraints that limit a cost benefit analysis, including limited data availability, limited statutory discretion, and insufficient analytical models.</p> <p>The qualitative benefits of the proposed regulatory change are ensuring VDH has adequate fee revenue to support sufficient staff to perform inspections and other oversight functions of HCOs to promote and ensure the health and safety of clients and patients who receive personal care services and skilled services from HCOs and ensuring consistent processes are followed by HCOs and VDH's staff to improve efficiency in VDH operations and integrity of licensing data.</p>		

Table 1c: Costs and Benefits under an Alternative Approach

(1) Direct Costs & Benefits	<ul style="list-style-type: none"> HCO licensure fees is \$1000 for an initial license. <p>Direct Costs: \$255,000 cost to VDH in lost fee revenue over the term of the initial three-year license; VDH estimates that this increase in the initial fee for HCO licenses may reduce the annual number of new applicants by 15% (255 instead of 300).</p> <p>Direct Benefits: Initial HCO licensees would save \$500 over the term of the initial three-year license</p> <ul style="list-style-type: none"> Require HCO licensees to submit their written requests for a license change or exemption without prescribing the form to use.
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	<p>Direct Costs: \$0 per HCO licensee. \$60,204 cost for VDH of 4 hours of staff time (\$17.30/hr) for approximately 870 license change and exemption requests received annually.</p> <p>Direct Benefits: VDH is not aware of any quantifiable direct benefits at this time.</p>		
(2) Quantitative Factors	Estimated Dollar Amount	Present Value	
Direct Costs	(a) \$1,877,040	(c) \$1,649,188	
Direct Benefits	(b) \$1,275,000	(d) \$1,120,229	
(3) Benefits-Costs Ratio	0.68	(4) Net Benefit	-\$528,959
(5) Indirect Costs & Benefits	VDH is not aware of any quantifiable indirect costs or indirect benefits at this time.		
(6) Information Sources	VDH historical financial records; current number of and historical trends in HCO licensee and applicant population.		
(7) Optional	<p>VDH has numerous challenges and constraints that limit a cost benefit analysis, including limited data availability, limited statutory discretion, and insufficient analytical models.</p> <p>The qualitative benefits of the proposed regulatory change are ensuring VDH has adequate fee revenue to support sufficient staff to perform inspections and other oversight functions of HCOs to promote and ensure the health and safety of clients and patients who receive personal care services and skilled services from HCOs and ensuring consistent processes are followed by HCOs and VDH's staff to improve efficiency in VDH operations and integrity of licensing data.</p>		

Impact on Local Partners

Table 2: Impact on Local Partners

(1) Direct Costs & Benefits	Local partners will not incur any direct costs or benefits of the regulatory change as they are not subject to the mandates contained in 12VAC5-381.
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(2) Quantitative Factors	Estimated Dollar Amount
Direct Costs	(a) \$0
Direct Benefits	(b) \$0
(3) Indirect Costs & Benefits	VDH is not aware of any quantifiable indirect costs or benefits for local partners.
(4) Information Sources	See response to (1) of this Table.
(5) Assistance	N/A
(6) Optional	VDH has numerous challenges and constraints that limit a cost benefit analysis, including limited data availability, limited statutory discretion, and insufficient analytical models.

Economic Impacts on Families

Table 3: Impact on Families

(1) Direct Costs & Benefits	Families will not incur any direct costs or benefits of the regulatory change as they are not subject to the mandates contained in 12VAC5-381.
(2) Quantitative Factors	Estimated Dollar Amount
Direct Costs	(a) \$0
Direct Benefits	(b) \$0
(3) Indirect Costs & Benefits	VDH is not aware of any quantifiable indirect costs or benefits for families.
(4) Information Sources	See response to (1) of this Table.

(5) Optional	VDH has numerous challenges and constraints that limit a cost benefit analysis, including limited data availability, limited statutory discretion, and insufficient analytical models.
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Impacts on Small Businesses

Table 4: Impact on Small Businesses

(1) Direct Costs & Benefits	<ul style="list-style-type: none"> • Increase home care organization (HCO) licensure fees to \$1,500 per license and the term of the license to three years. <p>Direct Costs: \$1,000 increase per applicant for an initial license, which does maintain the current yearly cost of the license of \$500/yr. VDH estimates that an increase in the initial fee for HCO licenses may reduce the annual number of new applicants by 20% (240 instead of 300). VDH speculates that the vast majority (at least 90%) are small businesses, though applicants are not required to disclose nor have any volunteered whether they qualify as “small businesses” within the meaning of Code of Virginia § 2.2-4007.1, so this estimate is based on anecdotal evidence. VDH estimates a cost of \$240,000 over the term of the initial three-year license from lost fee revenue; assuming 90% of applicants are small business, 90% of the \$240,000 is attributable to small businesses or \$216,000.</p> <p>Direct Benefits: Preserving approximately \$240,000 (of which 90% is \$216,000) in fee revenue over the term of the initial three-year license that would otherwise be lost without the regulatory change. VDH estimates that an increase in the initial fee for HCO licenses may reduce the annual number of new applicants by 20% (240 instead of 300).</p> <ul style="list-style-type: none"> • Require HCO licensees to submit their written requests for a license change or exemption on a prescribed form. <p>Direct Costs: \$0 per HCO licensee.</p> <p>Direct Benefits: \$60,204 benefit for VDH by saving approximately 4 hours of staff time (\$17.30/hr) for approximately 870 license change and exemption requests received annually. Apportioning for the speculated small business population, 90% of \$60,204 is \$54,184.</p>
(2) Quantitative Factors	Estimated Dollar Amount

Direct Costs	(a) \$2,160,000
Direct Benefits	(b) \$2,701,836
(3) Indirect Costs & Benefits	VDH is not aware of any quantifiable indirect cost or indirect benefits.
(4) Alternatives	<p>In developing the proposed regulations, the State Board of Health (Board) considered that the affected industry consists primarily of small businesses. Providing a small business exemption would result in the overwhelming number of applicants and HCO licensees being exempt from the proposed regulatory change, just as establishing performance standards or less stringent requirements specific to small business would have the effect of lowered standards and requirements in nearly every case. Consequently, there are no other alternative regulatory methods to minimizing the adverse impact on small businesses that the Board could utilize without being inconsistent with health, safety, environmental, and economic welfare in accomplishing the objectives of the General Assembly mandates.</p> <p>However, there is some flexibility built into the regulation for all regulants (not just small businesses) in that individual regulants may ask for a variance that would allow for an individualized alternative to enable compliance with the purpose of a specific regulatory standard, if compliance would otherwise be economically burdensome and be an impractical hardship unique to the regulant.</p>
(5) Information Sources	VDH historical financial records; current number of and historical trends in HCO licensee and applicant population.
(6) Optional	<p>VDH has numerous challenges and constraints that limit a cost benefit analysis, including limited data availability, limited statutory discretion, and insufficient analytical models.</p> <p>The qualitative benefits of the proposed regulatory change are ensuring VDH has adequate fee revenue to support sufficient staff to perform inspections and other oversight functions of HCOs to promote and ensure the health and safety of clients and patients who receive personal care services and skilled services from HCOs and ensuring consistent processes are followed by HCOs and VDH's staff to improve efficiency in VDH operations and integrity of licensing data.</p>

Changes to Number of Regulatory Requirements

Table 5: Total Number of Requirements

	Number of Requirements			
Chapter number	Initial Count	Additions	Subtractions	Net Change
381	218	4	4	0

1 **Project 6371 - Fast-Track**

2 **Department of Health**

3 **Fee Change for Home Care Organizations after Enactment of Chapter 172 (2022 Acts of**
4 **Assembly)**

5 **12VAC5-381-40. License application; initial and renewal.**

6 A. The OLC provides precicensure consultation and technical assistance regarding the
7 licensure process. The purpose of such consultation is to explain the regulation and the survey
8 process. Precicensure consultations are arranged after a completed initial application is on file
9 with the OLC.

10 B. Licensure applications are obtained from the OLC. The OLC shall consider an application
11 complete when all requested information and the appropriate fee, stated in 12VAC5-381-70, is
12 submitted. If the OLC finds the application incomplete, the applicant will be notified in writing.

13 C. The activities and services of each applicant and licensee shall be subject to an inspection
14 by the OLC to determine if the organization is in compliance with the provisions of this chapter
15 and state law.

16 D. A completed application for initial licensure must be submitted at least 60 days prior to the
17 organization's planned opening date to allow the OLC time to process the application. An
18 incomplete application shall become inactive six months after it is received by the OLC. Applicants
19 must then reapply for licensure with a completed application and application fee. An application
20 for a license may be withdrawn at any time.

21 E. Licenses are renewed ~~annually~~ triennially. The OLC shall make renewal applications
22 available at least 60 days prior to the expiration date of the current license.

23 F. It is the home care organization's responsibility to complete and return a renewal application
24 to assure timely processing. Should a current license expire before a new license is issued, the
25 current license shall remain in effect provided a complete and accurate application was filed on
26 time.

27 **Statutory Authority**

28 §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.

29 **Historical Notes**

30 Derived from Virginia Register Volume 22, Issue 3, eff. January 1, 2006; amended, Virginia
31 Register Volume 24, Issue 11, eff. March 5, 2008.

32 **12VAC5-381-70. Fees.**

33 A. The OLC shall collect a fee of ~~\$500~~ \$1,500 for each initial and renewal license application.
34 Fees shall accompany the licensure application and are not refundable.

35 B. An additional late fee of \$50 shall be collected for an organization's failure to file a renewal
36 application by the date specified.

37 C. A processing fee of \$250 shall be collected for each reissuance or replacement of a license
38 and shall accompany the ~~written request~~ application for reissuance or replacement.

39 D. A one time processing fee of \$75 for exemption from licensure shall accompany the ~~written~~
40 exemption ~~request~~ application.

41 **Statutory Authority**

42 §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.

43 **Historical Notes**

44 Derived from Virginia Register Volume 22, Issue 3, eff. January 1, 2006; amended, Virginia
45 Register Volume 24, Issue 11, eff. March 5, 2008.

46 FORMS (12VAC5-381)

47 [Application for Home Care Organization Licensure \(rev. 4/2021\)](#)

48 [Renewal Addendum for Licenses Expiring July 31, 2021 \(eff. 4/2021\)](#)

49 [Application for Exemption from Home Care Organization Licensure \(eff. 9/2010\)](#)



COMMONWEALTH of VIRGINIA

Department of Health

P O BOX 2448
RICHMOND, VA 23218

COLIN M. GREENE, MD, MPH
STATE HEALTH COMMISSIONER

TTY 7-1-1 OR
1-800-828-1120

MEMORANDUM

DATE: August 4, 2022

TO: Virginia State Board of Health

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

SUBJECT: Final Stage for Regulations Governing COVID-19 Reporting

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 Final Stage to make some of those emergency amendments permanent.

VDH brought the Proposed Stage action to the Board of Health during the September 2021 meeting. That action was submitted to Town Hall for Executive Branch Review and was published in The Virginia Register on January 31, 2022. The Public Comment Period for the action concluded on April 1, 2022 and resulted in a total of 3 comments. All of the comments received expressed concern over the need to continue reporting demographic information related to COVID-19 cases.

The data fields, including demographic information, required by previous stages of this action continue to be required in this action. These fields remain critical to our ability to investigate and contain the virus. With the exception of email address and hospitalization status, all other fields continue to be required by federal law (the Coronavirus Aid, Relief, and Economic Security Act).

Also consistent with the previous action, this Final Stage action requires that case and laboratory reports be submitted electronically; clarifies that the category "laboratory directors" includes any entity that holds CLIA Certificates of Waiver; and adds "coronavirus, severe" to the list of infectious diseases that shall be reported to persons practicing funeral services.

This Final Stage action contains two major distinctions from the previously approved action. The first is that this action clarifies that Coronavirus disease 2019 (COVID-19) is a separate reportable disease from Coronavirus infection, severe and clarifies that COVID-19 is no longer

rapidly reportable. Further, this action eliminates the requirement to report negative COVID-19 test results. Greater detail on changes in this action can be found in the Agency background document found in the Regulatory Action Packet.

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. At the conclusion of that review process, the regulation will become effective 30 days after publication in the Virginia Register unless the action is suspended by the Governor, the General Assembly, or by a request from 25 or more persons, pursuant to §§ [2.2-4013 \(D\)](#), [2.2-4014\(B\)](#), and [2.2-4007 \(J\)](#) of the Code of Virginia.



townhall.virginia.gov

Final 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	COVID-19 Emergency Update
Date this document prepared	August 3, 2022

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

Brief Summary

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

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 separates COVID-19 from the category "coronavirus, severe" on the reportable disease list; removes the requirement for COVID-19 to be rapidly reportable; 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 and hospitalization status (if applicable) to the fields required to be reported by all parties related to COVID-19; and adds "coronavirus, severe" to the list of infectious diseases 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.

Statement of Final Agency Action

Provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

This Final action was prepared on August 3, 2022 by the Virginia Department of Health to amend the Disease Reporting and Control Regulations.

Mandate and Impetus

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

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. The Governor’s Office approved the use of emergency regulatory authority for these regulation changes.

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 is 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:
 - Separate “Coronavirus disease 2019 (SARS-CoV-2)” from “coronavirus infection, severe (e.g. SARS-CoV, MERS-CoV)” on the reportable disease list and conditions reportable by directors of laboratories list.
 - 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 the requirement that hospitalization status, if applicable, be included in the list of fields that are reported by physicians 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. By no longer receiving negative reports, the agency will not be able to report percent positivity. This could be a perceived disadvantage to the members of the public who were interested in that data element; however, the Centers for Disease Control and Prevention also no longer collect or report on that element.

The primary advantage to the agency is that the proposed amendments 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.

The proposed amendments will ultimately reduce the burden on physicians, laboratory directors, and directors of medical facilities as it removes the requirement to report negative COVID-19 test results, which is the current regulatory requirement in the Emergency Regulation in effect until January 1, 2023 or until amended.

Requirements More Restrictive than Federal

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

The Coronavirus Aid, Relief, and Economic Security (CARES) Act is the applicable federal law related to COVID-19 reporting. The only requirements more restrictive than the federal law at this time are the requirements to report an email address and hospitalization status. Throughout the COVID-19 response, VDH has learned how critical it is to collect as many forms of contact information that we can in order to have the greatest chance of success in contacting that individual. This requirement was included in the Emergency and Proposed stages and received no comments. With regard to hospitalization status, it is critical for VDH to collect this information, when applicable, so that we can continue to track the severity of the illness.

Agencies, Localities, and Other Entities Particularly Affected

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

Other State Agencies Particularly Affected

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, physicians, medical facilities, and persons in charge of funeral homes are particularly affected by these amendments.

Public Comment

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

Commenter	Comment	Agency response
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<p>Robert Wade DO</p>	<p>VDH has determined that it will no longer conduct contact tracing on COVID cases. While this was being done, the collection of demographics on positive cases from point of care testing was essential in this effort. However, since this tracing is no longer being done, the demographics seem to no longer be useful.</p> <p>I understand reporting of positive cases and their demographics also stems from a requirement of the CARES Act. However, the supply of tests provided by the CARES Act are expiring or used up. Would this requirement also hold true for tests that are purchased with non CARES Act funds moving forward? In the matter of reporting influenza cases we are reporting aggregate positives to the district epidemiologist. I would like to propose that this be considered for reporting COVID case numbers.</p>	<p>The Virginia Department of Health does continue to conduct contact tracing on COVID-19 cases, particularly as it relates to outbreak situations. This information is vital to our ability to continue that effort, as well as, allowing VDH to conduct disease investigations on person, place and time. The Federal CARES Act continues to require these demographic data elements (except for email address) as it relates to COVID-19 reporting, regardless of how the tests are purchased.</p>
<p>Irene Kniss</p>	<p>Reporting all positive covid tests with demographics is an onerous task for health care providers. With the influx and wide use of at home testing, the reported positives by health care providers does not capture the full number of positive cases.</p> <p>Demographics are helpful for contact tracing but we know that contact tracing is not being done by the state department of health. If numbers are important than reporting aggregate negative and positive covid tests should be all that is necessary.</p> <p>Thanks for taking this under advisement.</p>	<p>The Virginia Department of Health does continue to conduct contact tracing on COVID-19 cases, particularly as it relates to outbreak situations. This information is vital to our ability to continue that effort, as well as, allowing VDH to conduct disease investigations on person, place and time. The Federal CARES Act continues to require these demographic data elements (except for email address) as it relates to COVID-19 reporting. These proposed amendments would no longer require disease reporters to report negative COVID-19 tests.</p>
<p>Andrew Guertler</p>	<p>It is clear that COVID-19 (SARS-CoV2) infection will be endemic. It has also become clear that contact tracing for this illness has been abandoned. There are highly effective vaccines and oral therapies have been and are being developed. The required reporting of all demographic information for people diagnosed with this disease is particularly onerous and time consuming with no obvious benefit.</p>	<p>The Virginia Department of Health does continue to conduct contact tracing on COVID-19 cases, particularly as it relates to outbreak situations. This information is vital to our ability to continue that effort, as well as, allowing VDH to conduct disease investigations on person, place and time. The Federal CARES Act continues to require these demographic data elements (except for email address) as it relates to COVID-19 reporting. These proposed amendments would no longer require disease reporters to</p>

	<p>If contact tracing is not being performed in a very timely matter (within 24 hours) the utility vanishes. While large labs likely have this process automated, smaller labs in physician offices or small clinics do not. It does not make sense to require the reporting of information that is not being utilized. Furthermore, with the availability of OTC COVID-19 tests with no reporting mechanism, these cases are never tracked or acted upon. How does it make sense to track some while knowingly missing the OTC positive cases?</p> <p>As a better option, I propose the reporting of COVID-19 cases follow the same reporting as influenza did a few years ago. Labs report bulk positives and negatives. A modification would be that COVID-19 cases requiring hospitalization be reported with all demographics while all other cases are reported as bulk numbers. Medical offices do not need to be bogged down with administrative work that is not being used in a significantly worthwhile manner.</p>	<p>report negative COVID-19 tests. At this time, reporting individual level data (rather than aggregate as suggested) for COVID-19 is still warranted at this time and required by the federal government.</p>
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Detail of Changes Made Since the Previous Stage

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

Current chapter-section number	New chapter-section number, if applicable	New requirement from previous stage	Updated new requirement since previous stage	Change, intent, rationale, and likely impact of updated requirements
12VAC5-90-80 A		<ul style="list-style-type: none"> Add "(e.g., SARS-CoV, MERS-CoV)" after "coronavirus infection, severe" in section A 		<p>Intent:</p> <ul style="list-style-type: none"> Clarify that COVID-19 is a separate reporting requirement from severe coronaviruses and that it is NOT rapidly reportable

		*Add "Coronavirus Disease 2019 (SARS-CoV-2)" to the list in section A		<p>Rationale:</p> <ul style="list-style-type: none"> The volume of cases and severity of disease no longer require that VDH be notified within 24 hours; whereas, other coronaviruses that are more severe such as SARS-CoV and MERS-CoV still warrant that response <p>Likely Impact:</p> <ul style="list-style-type: none"> Reduce the burden on disease reporters and add clarity between these disease types
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Detail of All Changes Proposed in this Regulatory Action

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

Current chapter-section number	New chapter-section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of updated requirements
12VAC5-80 A		Currently, the reportable disease list in section A only includes " <u>*coronavirus infection, severe</u> "	<p>Change:</p> <ul style="list-style-type: none"> Add "(e.g., SARS-CoV, MERS-CoV)" after "coronavirus infection, severe" in section A; <u>*Add "Coronavirus disease 2019 (SARS-CoV-2)" to the list in section A</u> <p>Intent:</p> <ul style="list-style-type: none"> Clarify that COVID-19 is a separate reporting requirement from severe coronaviruses and that it is NOT rapidly reportable <p>Rationale:</p> <ul style="list-style-type: none"> The volume of cases and severity of disease no longer

			<p>require that VDH be notified within 24 hours; whereas, other coronaviruses that are more severe such as SARS-CoV and MERS-CoV still warrant that response</p> <p>Likely Impact:</p> <ul style="list-style-type: none"> Reduce the burden on disease reporters and add clarity between these disease types
12VAC5-90-80 B		<p>Currently, the conditions reportable by laboratories list in section B only includes “*coronavirus infection, severe (e.g., SARS-CoV, MERS-CoV)”</p>	<p>Change:</p> <ul style="list-style-type: none"> Add “Coronavirus disease 2019 (SARS-CoV-2)” to the list in section B <p>Intent:</p> <ul style="list-style-type: none"> Clarify that COVID-19 is a separate reporting requirement from severe coronaviruses <p>Rationale:</p> <ul style="list-style-type: none"> Clarify the two disease categories <p>Likely Impact:</p> <ul style="list-style-type: none"> increase clarity for disease reporters
12VAC5-90-80 C		<p>Currently, the rapidly reportable disease list in section C only includes “coronavirus infection, severe”</p>	<p>Change:</p> <ul style="list-style-type: none"> Add “(e.g., SARS-CoV, MERS-CoV)” to the list in section C <p>Intent:</p> <ul style="list-style-type: none"> Increase consistency with other lists and clarify that COVID-19 is not included <p>Rationale:</p> <ul style="list-style-type: none"> The volume of cases and severity of disease no longer require that VDH be notified within 24 hours; <p>Likely Impact:</p> <ul style="list-style-type: none"> reduce the burden on disease reporters
12VAC5-90-80 I		<p>Section does not currently exist in the VAC; however, was added in the Emergency Action still in effect.</p>	<p>Change:</p> <ul style="list-style-type: none"> Add subsection I: Require all traditional data elements required for other reportable diseases plus email address, ethnicity, and hospitalization status Replace hospital chart number with medical record number 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

			<p>Certificates of Waiver so that all entities testing for COVID-19 are required to report to VDH;</p> <ul style="list-style-type: none"> Require all COVID-19 laboratory reports be submitted electronically to VDH; <p>Intent:</p> <ul style="list-style-type: none"> to clarify information required and methods of reporting for COVID-19 <p>Rationale:</p> <ul style="list-style-type: none"> COVID-19 requires different reporting elements and methods than other reportable diseases <p>Likely Impact:</p> <ul style="list-style-type: none"> clarify responsibilities for persons reporting COVID-19 and ensure VDH gets necessary public health data
12VAC5-90-90 C			<p>Change:</p> <ul style="list-style-type: none"> Replace hospital chart number with medical record number <p>Intent:</p> <ul style="list-style-type: none"> Update outdated references <p>Rationale:</p> <ul style="list-style-type: none"> The terminology has updated <p>Likely Impact:</p> <ul style="list-style-type: none"> Provide clarity to disease reporters
12VAC5-90-90 F			<p>Change:</p> <ul style="list-style-type: none"> Add "Coronavirus, severe (e.g., SARS-CoV, MERS-CoV) <p>Intent:</p> <ul style="list-style-type: none"> Ensure necessary precautions are in place for persons handling potentially hazardous bodies <p>Rationale:</p> <ul style="list-style-type: none"> Diseases like SARS-CoV and MERS-CoV are spread through respiratory droplets and can be extremely dangerous if the necessary precautions (PPE) are not in place <p>Likely Impact:</p> <ul style="list-style-type: none"> Increase safety for persons practicing funeral services

Office of Regulatory Management
Economic Review Form

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	COVID-19 Emergency Update
Date this document prepared	August 11, 2022

Cost Benefit Analysis

Table 1a: Costs and Benefits of the Proposed Changes (Primary Option)

(1) Direct Costs & Benefits	<ul style="list-style-type: none"> <p>• Add Coronavirus Disease 2019 (COVID-19 or SARS-CoV-2) to the disease lists in 12VAC5-90-80. Direct Costs: \$0</p> <p>Direct Benefits: Adds clarity that COVID-19 is a separate reportable disease from “coronavirus, severe” and that it is no longer rapidly reportable.</p> <p>• Remove the requirement to report negative COVID-19 test results. Direct Costs: Potentially minor costs to change electronic reporting system settings.</p> <p>Direct Benefits: Potentially significant cost savings for persons that do not have electronic laboratory reporting in place as this will greatly reduce the volume of reports that need to be submitted.</p> <p>• Include hospitalization status in the fields that are required to be reported by physicians and directors of medical facilities. Direct Costs: Potentially minor costs to change fields included in electronic reporting system settings.</p> <p>Direct Benefits: \$0</p> <p>• Clarifies that all entities with a CLIA waiver, not just pharmacies, are considered a laboratory director as it relates to this regulatory chapter. Direct Costs: \$0</p> <p>Direct Benefits: Provides clarity for regulated entities.</p>
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	<ul style="list-style-type: none"> • Clarifies the electronic methods available for laboratory reporting. Direct Costs: \$0 <p>Direct Benefits: Provides clarity for regulated entities.</p>		
(2) Quantitative Factors	Estimated Dollar Amount	Present Value	
Direct Costs	(a) \$0	(c) \$0	
Direct Benefits	(b) \$0	(d) \$0	
(3) Benefits-Costs Ratio	N/A	(4) Net Benefit	N/A
(5) Indirect Costs & Benefits	<ul style="list-style-type: none"> • VDH is no longer able to calculate percent positivity for COVID-19 Indirect Costs: \$0 <p>Indirect Benefits: \$0</p> <ul style="list-style-type: none"> • VDH receives data in a more efficient and accessible manner, which results in an improved disease response and ability to mitigate spread and inform the public Indirect Costs: \$0 <p>Indirect Benefits: \$0</p>		
(6) Information Sources	N/A		
(7) Optional			

Table 1b: Costs and Benefits under the Status Quo (No change to the regulation)

(1) Direct Costs & Benefits	<ul style="list-style-type: none"> • The lists in 12VAC5-90 currently state “coronavirus, severe” which currently includes COVID-19 and is rapidly reportable. Direct Costs: Increased burden on reporting entities to provide reports within 24 hours rather than 3 days. <p>Direct Benefits: \$0</p>
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	<ul style="list-style-type: none"> <p>All COVID-19 test results (positive and negative) are required to be reported. Direct Costs: Increased burden on reporting entities to continue to report a large volume of negative test results, which is not in compliance with current federal law (CARES Act).</p> <p>Direct Benefits: VDH continues to be able to calculate percent positivity.</p> <p>Physicians and Medical Directors are to report hospitalization status and ICU admissions through the Emergency Department Care Coordination system. Direct Costs: \$0 – however, VDH has not been able to receive the data from this program in a meaningful manner to be able to report on COVID-19 hospitalizations to indicate severity of the disease.</p> <p>Direct Benefits: \$0</p> <p>All laboratories, including pharmacies that hold Clinical Laboratory Improvement Amendments Certificates of Waiver, shall report COVID-19 results. Direct Costs: Other entities that hold CLIA waivers may not believe they have an obligation to report, even though it is a requirement of their waiver.</p> <p>Direct Benefits: \$0</p> <p>Allows laboratories to use their own form or a computer generated report. Direct Costs: VDH isn't able to receive the records in a meaningful way and has to dedicate sufficient staff to be able to work with the reporter to get the record into the format needed.</p> <p>Direct Benefits: Reporting entities who do not have electronic laboratory reporting set up or who are not sending us reports in the format needed would still be able to submit the information in the format they have it in. In assessing the past 4 months of COVID-19 laboratory data, only 3% of records received were through a method other than ELR.</p> 	
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(2) Quantitative Factors	Estimated Dollar Amount	Present Value
Direct Costs	(a) \$0	(c) 0

Direct Benefits	(b) \$0	(d) 0	
(3) Benefits-Costs Ratio	N/A	(4) Net Benefit	N/A
(5) Indirect Costs & Benefits	No indirect costs or benefits anticipated.		
(6) Information Sources	N/A		
(7) Optional			

Table 1c: Costs and Benefits under an Alternative Approach

(1) Direct Costs & Benefits	<ul style="list-style-type: none"> In light of clear statutory requirements for VDH to maintain the Disease Reporting and Control Regulations including the list of reportable diseases and the persons required to report there are no alternatives available. <p>Direct Costs: N/A</p> <p>Direct Benefits: N/A</p>		
(2) Quantitative Factors	Estimated Dollar Amount	Present Value	
Direct Costs	(a) \$0	(c) 0	
Direct Benefits	(b) \$0	(d) 0	
(3) Benefits-Costs Ratio	N/A	(4) Net Benefit	N/A
(5) Indirect Costs & Benefits	N/A		
(6) Information Sources			

(7) Optional	
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Impact on Local Partners

Table 2: Impact on Local Partners

(1) Direct Costs & Benefits	No anticipated direct impact on local partners.
(2) Quantitative Factors	Estimated Dollar Amount
Direct Costs	(a) \$0
Direct Benefits	(b) \$0
(3) Indirect Costs & Benefits	No anticipated indirect impact on local partners.
(4) Information Sources	N/A
(5) Assistance	N/A
(6) Optional	

Economic Impacts on Families

Table 3: Impact on Families

(1) Direct Costs & Benefits	No anticipated direct impacts on families.
(2) Quantitative Factors	Estimated Dollar Amount
Direct Costs	(a) \$0
Direct Benefits	(b) \$0

(3) Indirect Costs & Benefits	VDH data is more complete and readily available to inform families about COVID-19 cases in their communities.
(4) Information Sources	N/A
(5) Optional	

Impacts on Small Businesses

Table 4: Impact on Small Businesses

(1) Direct Costs & Benefits	Small laboratories or medical facilities required to report will benefit from changes related to reporting negative tests and having to report within 24 hours. These same entities might experience a slight increase in burden by no longer being able to submit their own form, but that is anticipated to be a one-time burden.
(2) Quantitative Factors	Estimated Dollar Amount
Direct Costs	(a) \$0
Direct Benefits	(b) \$0
(3) Indirect Costs & Benefits	No anticipated indirect costs or benefits to small businesses.
(4) Alternatives	No alternatives identified at this time.
(5) Information Sources	N/A
(6) Optional	

Changes to Number of Regulatory Requirements

Table 5: Total Number of Requirements

	Number of Requirements			
Chapter number	Initial Count	Additions	Subtractions	Net Change
12VAC5-90	170	1	3	-2

1 **Project 6359 - Other Action**

2 **Department of Health**

3 **COVID-19 Emergency Update**

4 **12VAC5-90-80. Lists of diseases that shall be reported.**

5 A. Reportable disease list. The board declares suspected or confirmed cases of the following
6 named diseases, toxic effects, and conditions to be reportable by the persons enumerated in
7 12VAC5-90-90. Conditions identified by an asterisk (*) require immediate communication to the
8 local health department by the most rapid means available upon suspicion or confirmation, as
9 defined in subsection C of this section. Other conditions should be reported within three days of
10 suspected or confirmed diagnosis, unless otherwise specified in this section. Neonatal Abstinence
11 Syndrome shall be reported as specified in subsection E of this section. Coronavirus disease
12 2019 (SARS-CoV-2) shall be reported as specified in subsection I of the section.

- 13 Amebiasis (*Entamoeba histolytica*)
- 14 *Anthrax (*Bacillus anthracis*)
- 15 Arboviral infections (e.g., CHIK, dengue, EEE, LAC, SLE, WNV, Zika)
- 16 Babesiosis (*Babesia* spp.)
- 17 *Botulism (*Clostridium botulinum*)
- 18 *Brucellosis (*Brucella* spp.)
- 19 Campylobacteriosis (*Campylobacter* spp.)
- 20 *Candida auris*, infection or colonization
- 21 Carbapenemase-producing organism, infection or colonization
- 22 Chancroid (*Haemophilus ducreyi*)
- 23 Chickenpox (*Varicella* virus)
- 24 Chlamydia trachomatis infection
- 25 *Cholera (*Vibrio cholerae* O1 or O139)
- 26 *Coronavirus infection, severe (e.g., SARS-CoV, MERS-CoV)
- 27 Coronavirus disease 2019 (COVID-19 or SARS-CoV-2)
- 28 Cryptosporidiosis (*Cryptosporidium* spp.)
- 29 Cyclosporiasis (*Cyclospora* spp.)
- 30 *Diphtheria (*Corynebacterium diphtheriae*)
- 31 *Disease caused by an agent that may have been used as a weapon
- 32 Ehrlichiosis/Anaplasmosis (*Ehrlichia* spp., *Anaplasma phagocytophilum*)
- 33 Giardiasis (*Giardia* spp.)
- 34 Gonorrhea (*Neisseria gonorrhoeae*)
- 35 Granuloma inguinale (*Calymmatobacterium granulomatis*)
- 36 **Haemophilus influenzae* infection, invasive
- 37 Hantavirus pulmonary syndrome
- 38 Hemolytic uremic syndrome (HUS)
- 39 *Hepatitis A
- 40 Hepatitis B (acute and chronic)
- 41 Hepatitis C (acute and chronic)

42 Hepatitis, other acute viral
43 Human immunodeficiency virus (HIV) infection
44 Influenza, confirmed
45 *Influenza-associated deaths if younger than 18 years of age
46 Lead, blood levels
47 Legionellosis (*Legionella* spp.)
48 Leprosy (Hansen's disease) (*Mycobacterium leprae*)
49 Leptospirosis (*Leptospira interrogans*)
50 Listeriosis (*Listeria monocytogenes*)
51 Lyme disease (*Borrelia* spp.)
52 Lymphogranuloma venereum (*Chlamydia trachomatis*)
53 Malaria (*Plasmodium* spp.)
54 *Measles (Rubeola)
55 *Meningococcal disease (*Neisseria meningitidis*)
56 Mumps
57 Neonatal abstinence syndrome (NAS)
58 Ophthalmia neonatorum
59 *Outbreaks, all (including foodborne, health care-associated, occupational, toxic
60 substance-related, waterborne, and any other outbreak)
61 *Pertussis (*Bordetella pertussis*)
62 *Plague (*Yersinia pestis*)
63 *Poliovirus infection, including poliomyelitis
64 *Psittacosis (*Chlamydophila psittaci*)
65 *Q fever (*Coxiella burnetii*)
66 *Rabies, human and animal
67 Rabies treatment, post-exposure
68 *Rubella, including congenital rubella syndrome
69 Salmonellosis (*Salmonella* spp.)
70 Shiga toxin-producing *Escherichia coli* infection
71 Shigellosis (*Shigella* spp.)
72 *Smallpox (*Variola* virus)
73 Spotted fever rickettsiosis (*Rickettsia* spp.)
74 Streptococcal disease, Group A, invasive or toxic shock
75 *Streptococcus pneumoniae* infection, invasive if younger than five years of age
76 Syphilis (*Treponema pallidum*) report *congenital, *primary, *secondary, and other
77 Tetanus (*Clostridium tetani*)
78 Toxic substance-related illness
79 Trichinosis (Trichinellosis) (*Trichinella spiralis*)
80 *Tuberculosis, active disease (*Mycobacterium tuberculosis* complex)
81 Tuberculosis infection
82 *Tularemia (*Francisella tularensis*)

- 83 *Typhoid/Paratyphoid infection (*Salmonella Typhi*, *Salmonella Paratyphi*)
- 84 *Unusual occurrence of disease of public health concern
- 85 *Vaccinia, disease or adverse event
- 86 Vancomycin-intermediate or vancomycin-resistant *Staphylococcus aureus* infection
- 87 *Vibriosis (*Vibrio* spp.)
- 88 *Viral hemorrhagic fever
- 89 *Yellow fever
- 90 Yersiniosis (*Yersinia* spp.)

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

- 100 Amebiasis (*Entamoeba histolytica*)
- 101 *Anthrax (*Bacillus anthracis*)
- 102 Arboviral infection, for example, CHIK, dengue, EEE, LAC, SLE, WNV, or Zika
- 103 Babesiosis (*Babesia* spp.)
- 104 *Botulism (*Clostridium botulinum*)
- 105 *Brucellosis (*Brucella* spp.)
- 106 Campylobacteriosis (*Campylobacter* spp.)
- 107 *Candida auris* - Include available antimicrobial susceptibility findings in report.
- 108 Carbapenemase-producing organism - Include available antimicrobial susceptibility
 109 findings in report.
- 110 Chancroid (*Haemophilus ducreyi*)
- 111 Chickenpox (*Varicella virus*)
- 112 Chlamydia trachomatis infection
- 113 *Cholera (*Vibrio cholerae* O1 or O139)
- 114 *Coronavirus infection, severe (e.g., SARS-CoV, MERS-CoV)
- 115 Coronavirus disease 2019 (COVID-19 or SARS-CoV-2)
- 116 Cryptosporidiosis (*Cryptosporidium* spp.)
- 117 Cyclosporiasis (*Cyclospora* spp.)
- 118 *Diphtheria (*Corynebacterium diphtheriae*)
- 119 Ehrlichiosis/Anaplasmosis (*Ehrlichia* spp., *Anaplasma phagocytophilum*)
- 120 Giardiasis (*Giardia* spp.)
- 121 Gonorrhea (*Neisseria gonorrhoeae*) - Include available antimicrobial susceptibility findings
 122 in report.
- 123 **Haemophilus influenzae* infection, invasive
- 124 Hantavirus pulmonary syndrome
- 125 *Hepatitis A

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

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

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

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

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

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

146 Legionellosis (*Legionella* spp.)

147 Leptospirosis (*Leptospira interrogans*)

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

150 Lyme disease (*Borrelia* spp.)

151 Malaria (*Plasmodium* spp.)

152 *Measles (*Rubeola*)

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

155 Mumps

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

157 1. Acid fast bacilli;

158 2. *M. tuberculosis* complex or any other mycobacteria;

159 3. Antimicrobial susceptibility results for *M. tuberculosis* complex.

160 *Pertussis (*Bordetella pertussis*)

161 *Plague (*Yersinia pestis*)

162 *Poliovirus infection

163 *Psittacosis (*Chlamydia psittaci*)

164 *Q fever (*Coxiella burnetii*)

165 *Rabies, human and animal

166 *Rubella

167 Salmonellosis (*Salmonella* spp.)

168 Shiga toxin-producing *Escherichia coli* infection

169 Shigellosis (*Shigella* spp.)

170 *Smallpox (*Variola virus*)
 171 Spotted fever rickettsiosis (*Rickettsia* spp.)
 172 Streptococcal disease, Group A, invasive or toxic shock
 173 *Streptococcus pneumoniae* infection, invasive if younger than five years of age
 174 *Syphilis (*Treponema pallidum*)
 175 Toxic substance-related illness - By blood or urine laboratory findings above the normal
 176 range, including heavy metals, pesticides, and industrial-type solvents and gases. When
 177 applicable and available, report speciation of metals when blood or urine levels are
 178 elevated in order to differentiate the chemical species (elemental, organic, or inorganic).
 179 Trichinosis (Trichinellosis) (*Trichinella spiralis*)
 180 Tuberculosis infection
 181 *Tularemia (*Francisella tularensis*)
 182 *Typhoid/Paratyphoid infection (*Salmonella Typhi*, *Salmonella Paratyphi A*, *Salmonella*
 183 *Paratyphi B*, *Salmonella Paratyphi C*)
 184 *Vaccinia, disease or adverse event
 185 Vancomycin-intermediate or vancomycin-resistant *Staphylococcus aureus* infection -
 186 Include available antimicrobial susceptibility findings in report.
 187 *Vibriosis (*Vibrio* spp., *Photobacterium damsela*, *Grimontia hollisae*), other than toxigenic
 188 *Vibrio cholera* O1 or O139, which are reportable as cholera
 189 *Viral hemorrhagic fever
 190 *Yellow fever
 191 Yersiniosis (*Yersinia* spp.)
 192 C. Reportable diseases requiring rapid communication. Certain of the diseases in the list of
 193 reportable diseases because of their extremely contagious nature, potential for greater harm, or
 194 availability of a specific intervention that must be administered in a timely manner require
 195 immediate identification and control. Reporting of persons confirmed or suspected of having these
 196 diseases, listed in this subsection, shall be made immediately by the most rapid means available,
 197 preferably by telephone to the local health department. (These same diseases are also identified
 198 by an asterisk (*) in subsections A and B, where applicable, of this section.)
 199 Anthrax (*Bacillus anthracis*)
 200 Botulism (*Clostridium botulinum*)
 201 Brucellosis (*Brucella* spp.)
 202 Cholera (*Vibrio cholerae* O1 or O139)
 203 Coronavirus infection, severe (e.g., SARS-CoV, MERS-CoV)
 204 Diphtheria (*Corynebacterium diphtheriae*)
 205 Disease caused by an agent that may have been used as a weapon
 206 *Haemophilus influenzae* infection, invasive
 207 Hepatitis A
 208 Influenza-associated deaths if younger than 18 years of age
 209 Influenza A, novel virus
 210 Measles (*Rubeola virus*)
 211 Meningococcal disease (*Neisseria meningitidis*)
 212 Outbreaks, all

- 213 Pertussis (*Bordetella pertussis*)
- 214 Plague (*Yersinia pestis*)
- 215 Poliovirus infection, including poliomyelitis
- 216 Psittacosis (*Chlamydophila psittaci*)
- 217 Q fever (*Coxiella burnetii*)
- 218 Rabies, human and animal
- 219 Rubella, including congenital rubella syndrome
- 220 Smallpox (*Variola virus*)
- 221 Syphilis, congenital, primary, and secondary (*Treponema pallidum*)
- 222 Tuberculosis, active disease (*Mycobacterium tuberculosis* complex)
- 223 Tularemia (*Francisella tularensis*)
- 224 Typhoid/Paratyphoid infection (*Salmonella Typhi*, *Salmonella Paratyphi* (all types))
- 225 Unusual occurrence of disease of public health concern
- 226 Vaccinia, disease or adverse event
- 227 Vibriosis (*Vibrio* spp., *Photobacterium damsela*, *Grimontia hollisae*), other than toxigenic
- 228 *Vibrio cholerae* O1 or O139, which are reportable as cholera
- 229 Viral hemorrhagic fever
- 230 Yellow fever

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

- 238 Anthrax (*Bacillus anthracis*)
- 239 Botulism (*Clostridium botulinum*)
- 240 Brucellosis (*Brucella* sp.)
- 241 *Candida auris*
- 242 *Candida haemulonii*
- 243 Carbapenem-resistant Enterobacteriaceae
- 244 Carbapenem-resistant *Pseudomonas aeruginosa*
- 245 Cholera (*Vibrio cholerae* O1 or O139)
- 246 Coronavirus infection, severe (e.g., SARS-CoV, MERS-CoV)
- 247 Diphtheria (*Corynebacterium diphtheriae*)
- 248 *Haemophilus influenzae* infection, invasive
- 249 Influenza, unsubtypeable
- 250 Listeriosis (*Listeria monocytogenes*)
- 251 Meningococcal disease (*Neisseria meningitidis*)
- 252 Plague (*Yersinia pestis*)
- 253 Poliovirus infection
- 254 Q fever (*Coxiella burnetii*)

255 Salmonellosis (*Salmonella* spp.)
256 Shiga toxin-producing *E. coli* infection (Laboratories that identify a Shiga toxin but do not
257 perform simultaneous culture for Shiga toxin-producing *E. coli* should forward all positive
258 stool specimens or positive enrichment broths to the Division of Consolidated Laboratory
259 Services for confirmation and further characterization.)
260 Shigellosis (*Shigella* spp.)
261 Streptococcal disease, Group A, invasive
262 Tuberculosis (A laboratory identifying *Mycobacterium tuberculosis* complex (see 12VAC5-
263 90-225) shall submit a representative and viable sample of the initial culture to the Division
264 of Consolidated Laboratory Services or other laboratory designated by the board to
265 receive such specimen.)
266 Tularemia (*Francisella tularensis*)
267 Typhoid/Paratyphoid infection (*Salmonella* Typhi, *Salmonella* Paratyphi (all types))
268 Vancomycin-intermediate or vancomycin-resistant *Staphylococcus aureus* infection
269 Vibriosis (*Vibrio* spp., *Photobacterium damsela*, *Grimontia hollisae*)
270 Yersiniosis (*Yersinia* spp.)

271 Other diseases as may be requested by the health department.

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

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

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

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

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

297 I. Coronavirus disease 2019 (SARS-CoV-2). COVID-19 shall be reported by physicians and
298 directors of medical care facilities when a person who is infected with or who is suspected of
299 having COVID-19 is treated or examined, hospitalized, or admitted into the intensive care unit.
300 Physicians and directors of medical care facilities shall report that person's name, telephone
301 number, email address, address, age, date of birth, race, ethnicity, sex, and pregnancy status;

302 name of disease diagnosed or suspected; hospitalization status (if applicable), the medical record
303 number (if applicable); the date of onset of illness; available laboratory tests and results; and the
304 name, address, and telephone number of the physician and medical facility where the
305 examination was made. Case reports shall be submitted within three days of the suspicion or
306 confirmation of disease by entering the information into the Department of Health online
307 Confidential Morbidity Report portal at <http://www.vdh.virginia.gov/clinicians> or via electronic case
308 reporting ([https://www.vdh.virginia.gov/meaningful-use/meaningful-use-submissions-of-](https://www.vdh.virginia.gov/meaningful-use/meaningful-use-submissions-of-electronic-case-reports/)
309 [electronic-case-reports/](https://www.vdh.virginia.gov/meaningful-use/meaningful-use-submissions-of-electronic-case-reports/)).

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

320 **12VAC5-90-90. Those required to report.**

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

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

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

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

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

351 within three days of identification of evidence of disease, except that those identified in 12VAC5-
352 90-80 C shall be reported immediately by the most rapid means available, preferably by
353 telephone, to the local health department serving the jurisdiction in which the laboratory is located.
354 Reports shall be made on Form Epi-1 or on the laboratory's own form if it includes the required
355 information. Computer generated reports containing the required information may be submitted.
356 Reporting may be done by means of secure electronic transmission upon agreement of the
357 laboratory director and the department. Reports of HIV genetic nucleotide sequence data
358 associated with HIV drug resistance tests must be submitted electronically. Any person making
359 such report as authorized herein shall be immune from liability as provided by § 32.1-38 of the
360 Code of Virginia.

361 A laboratory identifying evidence of any of the following conditions shall notify the local health
362 department of the positive culture or other positive test result within the timeframes specified in
363 12VAC5-90-80 and submit the initial isolate or other initial specimen to the Division of
364 Consolidated Laboratory Services within seven days of identification. All specimens must be
365 identified with the patient and physician information required in this subsection.

366 Anthrax

367 Botulism

368 Brucellosis

369 Cholera

370 Diphtheria

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

375 *Haemophilus influenzae* infection, invasive

376 Influenza A, novel virus

377 Listeriosis

378 Meningococcal disease

379 Pertussis

380 Plague

381 Poliovirus infection

382 Q fever

383 Salmonellosis

384 Shigellosis

385 Streptococcal disease, Group A, invasive

386 Tuberculosis (A laboratory identifying *Mycobacterium tuberculosis* complex (see 12VAC5-
387 90-225) shall submit a representative and viable sample of the initial culture to the Division
388 of Consolidated Laboratory Services or other laboratory designated by the board to
389 receive such specimen.)

390 Tularemia

391 Typhoid/Paratyphoid fever

392 Vancomycin-intermediate or vancomycin-resistant *Staphylococcus aureus* infection

393 *Vibrio* infection, including infections due to *Photobacterium damsela* and *Grimontia*
394 *hollisae*

395 Yersiniosis

396 Other diseases as may be requested by the health department

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

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

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

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

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

440 E. Local health directors. The local health director shall forward any report of a disease or
441 report of evidence of a disease which has been made on a resident of his jurisdiction to the Office
442 of Epidemiology within three days of receipt. This report shall be submitted immediately by the
443 most rapid means available if the disease is one requiring rapid communication, as required in
444 12VAC5-90-80 C. All such rapid reporting shall be confirmed in writing and submitted to the Office

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

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

- 458 Coronavirus, severe (e.g., SARS-CoV, MERS-CoV)
- 459 Creutzfeldt-Jakob disease
- 460 Human immunodeficiency virus infection
- 461 Hepatitis B
- 462 Hepatitis C
- 463 Rabies
- 464 Smallpox
- 465 Syphilis, infectious
- 466 Tuberculosis, active disease
- 467 Vaccinia, disease or adverse event
- 468 Viral hemorrhagic fever

469 G. Employees, conditional employees, and persons in charge of food establishments.
470 12VAC5-421-80 of the Food Regulations requires a food employee or conditional employee to
471 notify the person in charge of the food establishment when diagnosed with certain diseases that
472 are transmissible through food and requires the person in charge of the food establishment to
473 notify the regulatory authority. Refer to 12VAC5-421-80 for further guidance and clarification
474 regarding these reporting requirements.