

The Board of Health will hold its next quarterly meeting on December 10 in a hybrid meeting. Physical attendees will assemble at the Perimeter Center located at 9960 Mayland Drive in Richmond. The virtual participants should register through the electronic process described in the following pages. The meeting will begin at 9:00 a.m.

Due to social distancing requirements, and the level of transmission in the Richmond and Henrico health districts, all physical attendees will need to comply with the following:

- Wearing a mask in the Perimeter Center. If you are not able to wear a mask, you are strongly encouraged to attend virtually instead.
- Social distancing. To aide in this, seats will be spaced out in the meeting room. This spacing will allow for approximately 10 members of the public to sit in the room. All others will need to participate virtually.

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

There will be a public comment signup sheet in the room at the Perimeter Center. For those who are attending virtually, there is a registration question if you would like to offer public comment. The list of public speakers will be generated by pulling the physical and virtual sign up lists for public comment will be pulled at 10:00am on the morning of the meeting. The public comment period is limited to 20 minutes maximum, but may be extended by the Board.

To Register for the Board of Health Meeting on December 10, 2021

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

The purpose of these instructions is to help any member of the public who wishes to observe or participate in the Board of Health meeting virtually on December 10 to understand how to do so.

1) Open the link the online meeting registration:


<https://covaconf.webex.com/covaconf/onstage/g.php?MTID=ec744b7fe6adb7cb5e0771751d0306e04>.

The screenshot shows a Webex event registration page. At the top, the Cisco Webex logo is visible. The event title is "Event Information: Board of Health Meeting - 9am". Below the title, it states "Registration is required to join this event. If you have not registered, please do so now." The event status is "Not started" with a "Register" link. The date and time are "Thursday, June 4, 2020 8:00 am Eastern Daylight Time (New York, GMT-04:00)" with a "Change time zone" link. The duration is "7 hours". There is a "Description:" field which is currently empty. Below the event details, there is a "By joining this event, you are accepting the Cisco Webex Terms of Service and Privacy Statement." link. On the right side, there is a "Join Event Now" button. Below the button, it says "You cannot join the event now because it has not started." There are input fields for "First name:", "Last name:", "Email address:", and "Event password:". At the bottom of the page, there is a "Register" button. A modal window is open over the "Join Event Now" section, displaying a message about the new Webex web app. The modal window has a close button (X) in the top right corner. The message reads: "Try the new Webex web app! Nothing to install, Simple and intuitive, Ideal for participants who do not need to present. Learn more".

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

Event Information: Board of Health Meeting - 9am

Registration is required to join this event. If you have not registered, please do so now.

Event status: Not started ([Register](#)) 

Date and time: Thursday, June 4, 2020 8:00 am
Eastern Daylight Time (New York, GMT-04:00)
[Change time zone](#)

Duration: 7 hours

Description:

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



Register for Board of Health Meeting - 9am

Please complete this form to register for the event. An asterisk (*) indicates required information.

English

Please answer the following questions.

* First name:	<input type="text"/>	* Last name:	<input type="text"/>
* Email address:	<input type="text"/>	* Phone number:	<input type="text"/>
* Confirm email address:	<input type="text"/>		

Are you a member of the media?:
 Yes
 No

If yes, what media outlet are you with?:


If you would like to sign up to speak during the public comment period please place a check next to the topic you would like to speak about::

- Regulations for Licensure of Nursing Homes 12VAC5-371
- Regulations Governing Newborn Screening Services 12VAC5-71
- Regulations for the Licensure of Hospitals 12VAC5-410
- State EMS Plan
- Other

If you chose Other for the public comment period, please list the topic::

Submit

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



Register for Board of Health Meeting - 9am

Please complete this form to register for the event. An asterisk (*) indicates required information. [English](#)

Please answer the following questions.

* First name:	<input type="text" value="Bob"/>	* Last name:	<input type="text" value="Smith"/>
* Email address:	<input type="text" value="bob.smith@google.com"/>	* Phone number:	<input type="text" value="1"/> <input type="text" value="804-867-5309"/>
* Confirm email address:	<input type="text" value="bob.smith@google.com"/>		


Are you a member of the media?:
 Yes
 No

If yes, what media outlet are you with?:


If you would like to sign up to speak during the public comment period please place a check next to the topic you would like to speak about::

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- State EMS Plan
- Other

If you chose Other for the public comment period, please list the topic::



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



Registration Confirmed

Thank you for registering.

You are now registered for the event: **Board of Health Meeting - 9am**

You will receive a confirmation email message that contains detailed information about joining the event.

The event will start at 8:00 am New York Time on June 4, 2020.
Please join the event on time.

Invite a Friend

To invite a friend to this event, enter your friend's email address.

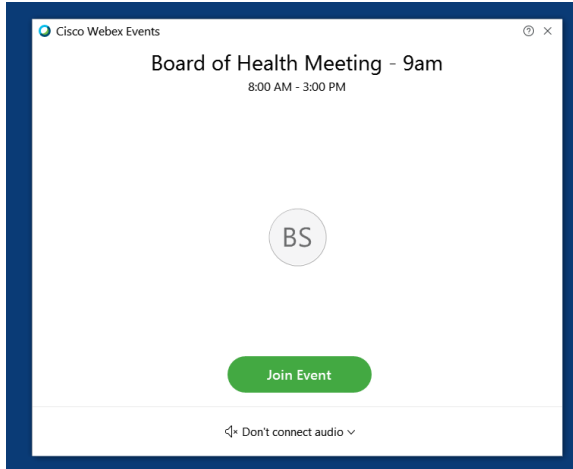
Set Up Webex Events

To participate in fully interactive events, please click [here](#) for setting up Webex Events on this computer.

The playback of UCF (Universal Communications Format) rich media files requires appropriate players. To view this type of rich media files in the event, please check whether you have the players installed on your computer by going to [Verify Rich Media Players](#).

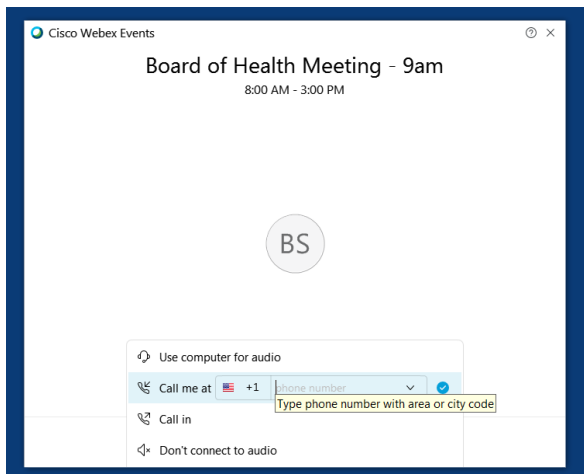
To view system requirements, go to www.webex.com.

JOINING THE MEETING



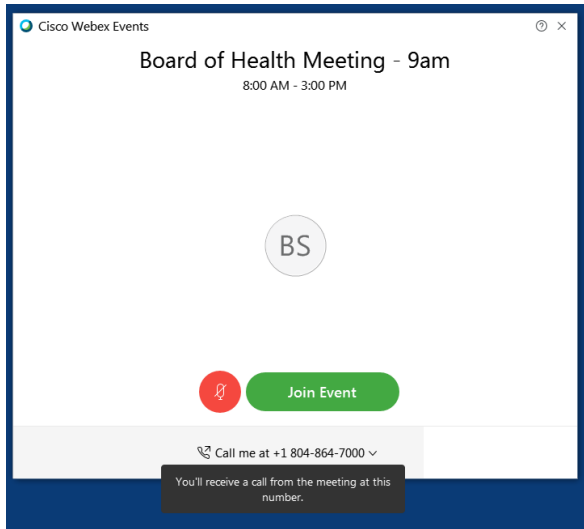
On the day of the meeting, you will click in the email to join the meeting.

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



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

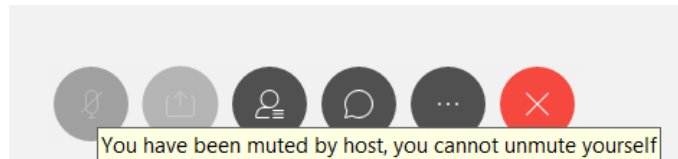
Enter your 10 digit phone number and click the blue check mark.



Click Join Event.

You will receive a phone call from the meeting platform.

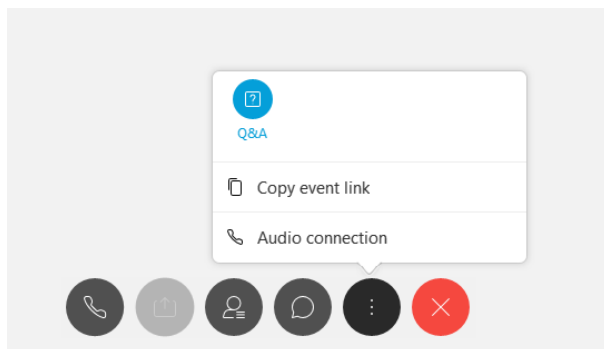
You will be prompted to press 1 when you answer the phone to connect.



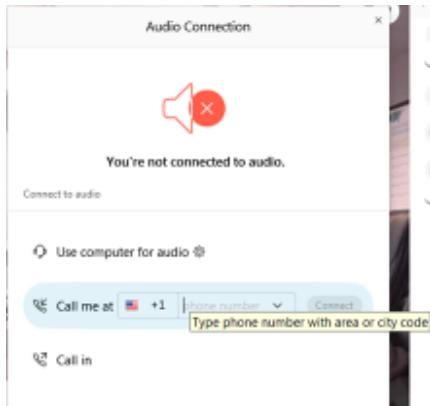
Note that you will be automatically muted when you join the meeting. You cannot unmute yourself to be heard during the meeting until the host unmutes you. This will occur during the public comment period for those who have signed up to do so.

Audio settings:

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



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



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

State of Board of Health
Agenda
December 10, 2021 – 9:00 a.m.
Hybrid Meeting
Perimeter Center – Boardroom 2 & WebEx

Call to Order and Welcome	Faye Prichard, Chair
Introductions	Ms. Prichard
Review of Agenda	Alexandra Jansson, MPP Senior Policy Analyst
Approval of September 2, 2021 Minutes	Ms. Prichard
Commissioner’s Report	M. Norman Oliver, MD, MA State Health Commissioner
Regulatory Action Update	Ms. Jansson
Break	
<u>Special Lunch Presentation</u> Behavioral Health Update	Alexis Aplasca, MD, FAAP, FAPA Chief Clinical Officer Department of Behavioral Health and Developmental Services
Public Comment Period	
<u>Regulatory Action Items</u> Home Care Organization Regulations 12VAC5-381 (Proposed Amendments)	Rebekah E. Allen, JD Senior Policy Analyst Office of Licensure and Certification
Disease Reporting and Control Regulations 12VAC5-90 (Proposed Amendments)	Lilian Peake, MD, MPH Director Office of Epidemiology
Sewage Handling and Disposal Regulations 12VAC5-610 (Fast Track Amendments)	Marcia J. Degen, PhD., PE Environmental Technical Services Manager Office of Environmental Health Services
Regulations Governing Virginia Newborn Screening Services 12VAC5-71	Heather Board Acting Director Office of Family Health Services

(Final Amendments)

Break

Non-Regulatory Action Items

Board of Health Annual Report/
Plan for Well-Being Update

Heather Board
Acting Director
Office of Family Health Services

Presentations

Legislative Update
2022 Proposals

Joe Hilbert
Deputy Commissioner for Governmental &
Regulatory Affairs

Other Business

Adjourn

**State Board of Health
September 2, 2021 - 9:00am
Hybrid Meeting**

Perimeter Center, Boardroom 2, 9960 Mayland Drive, Henrico VA 23233 and via WebEx

Members Present: Faye Prichard, Chair; Gary Critzer; Jim Edmondson; Elizabeth Harrison; Linda Hines, RN; Anna Jeng, ScD; Patricia Kinser, PhD; Wendy Klein, MD, Vice Chair; Benita Miller, DDS; Holly Puritz, MD; Jim Shuler, DVM; Stacey Swartz, PharmD; Katherine Waddell; and Mary Margaret Whipple.

*The following members attended virtually due to public health concerns for physical distancing and transmission levels for COVID-19: Gary Critzer; Elizabeth Harrison; Linda Hines, RN; Anna Jeng, ScD; Patricia Kinser, PhD; Wendy Klein, MD, Vice Chair; Stacey Swartz, PharmD; Katherine Waddell; and Mary Margaret Whipple.

Members Absent: Tommy East.

VDH Staff Present: Rebekah E. Allen, JD, Senior Policy Analyst, Office of Licensure and Certification; Dr. Danny Avula, Vaccine Coordinator and Director, Richmond and Henrico Health Districts; Dr. Laurie Forlano, Deputy Director, Office of Epidemiology; Stephanie Gilliam, Deputy Director for Budget, Office of Financial Management; William Gormley, MD, PhD, Chief Medical Examiner, Office of the Chief Medical Examiner; Bob Hicks, Deputy Commissioner for Public Health and Preparedness; Joe Hilbert, Deputy Commissioner for Governmental and Regulatory Affairs; Dr. Parham Jaber, Chief Deputy Commissioner for Community Health Services; Alexandra Jansson, Senior Policy Analyst; Bob Mauskopf, Director of Office of Emergency Preparedness; Dr. M. Norman Oliver, State Health Commissioner; Tim Powell, Director, Center for Public Health Informatics; John Ringer, Director for Public Health Planning and Evaluation; Michael Sarkissian, Director, Data and Quality, Office of Information Management; Tammie Smith, Public Relations Coordinator.

Other Staff Present: Robin Kurz, JD, Senior Assistant Attorney General; Allyson Tysinger, Senior Assistant Attorney General/Section Chief; Pamela Kestner, Chief Deputy, Department of Housing and Community Development

Call to Order

Ms. Prichard called the meeting to order at 9:04am.

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 virtual binder.

Approval of June 10, 2021 Minutes

Dr. Shuler made the motion to approve the minutes from the June 10, 2021 meeting with Mr. Edmondson seconding the motion. The minutes were approved unanimously by roll call vote.

Commissioner's Report

Dr. Oliver provided the Commissioner's Report to the Board. They discussed the novel coronavirus (COVID-19) situation and response with respect to:

- Disease Burden and Transmission
- Testing
- Containment
- Community Mitigation
- Communications
- Vaccination

There was discussion around school participation in the Virginia School Screening Testing for Assurance program, racial and ethnic ratios for vaccinations and cases, utilization of primary care physicians in vaccinations and boosters, and the need for additional communication campaigns to respond to and address myths about COVID-19, especially for pregnant women and school boards. There was also discussion around burnout among healthcare workers and public health workforce, updates on the booster vaccine rollout and vaccine wastage, and incentives for vaccines.

There was also a presentation by Deloitte, who are consulting with VDH. They provided an overview of the VDH 2025 Transformation initiative, including a discussion of the Steering Committee and Leadership Labs, as well as the path forward.

There was discussion around having the Board of Health be more involved in the process, and data interoperability.

Center for Public Health Informatics

Mr. Powell provided an overview of the newly created Center for Public Health Informatics (Center). This presentation background on informatics, the mission of the Center, and several ongoing data initiatives surrounding data systems and modernization.

There was discussion about data initiatives and how to move forward with adding staff and resources such as American Rescue Plan Act funds.

Regulatory Action Update

Ms. Jansson reviewed the summary of all pending VDH regulatory actions. Since the June 2021 meeting the Commissioner has approved the two following non-regulatory actions on behalf of the Board while the Board was not in session:

- Public Health Order of Emergency - Masks in K-12 Schools
- Electronic Participating in Meetings Policy

Ms. Jansson advised the Board that there are 19 periodic reviews in progress:

- 12 VAC 5-66 Regulations Governing Durable Do Not Resuscitate Orders

DRAFT – NOT APPROVED

- 12 VAC 5-80 Virginia Hearing Impairment Identification and Monitoring System
- 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 5-216 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 5-421 Food Regulations
- 12 VAC 5-440 Regulations for Summer Camps
- 12 VAC 5-450 Rules and Regulations Governing Campgrounds
- 12 VAC 5-460 Regulations Governing Tourist Establishment Swimming Pools and Other Public Pools
- 12 VAC 5-462 Swimming Pool Regulations Governing the Posting of Water Quality Results
- 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

There was discussion regarding the number of regulatory chapters VDH is responsible for and also a brief update on the progress of the doula regulations from the June 10 meeting.

Lunch Presentation: Health and Housing

Ms. Kestner presented an overview of activities ongoing in Virginia related to the connection between housing and health. Topics included:

- Workgroups
- State agency activities
- Overview of the Department of Housing and Community Development and programs

The Board expressed thanks to Ms. Kestner for the informative presentation and the ongoing work. There was discussion around how citizens are connected to programs, how funding is distributed, and what happens to undistributed funds.

Public Comment Period

Three persons were signed up for the public comment period. Brent Rawlings from the Virginia Hospital and Healthcare Association spoke in favor of the Emergency Amendments/NOIRA to the Patient Level Data Reporting Regulations. Kristin Parde with the Pharmaceutical Manufacturers of America spoke in favor of the Emergency Regulations/NOIRA for Drug Price Transparency, although she did request some revisions. She also told the Board that she would

be submitting written comments. Heidi Dix with the Department of Behavioral Health and Developmental Services spoke in favor of the Emergency Regulations/NOIRA to the Patient Level Data Reporting Regulations.

Emergency Regulations/NOIRA for Prescription Drug Price Transparency

Ms. Allen presented Emergency Regulations/Notice of Intended Regulatory Action (NOIRA) for the Prescription Drug Price Transparency. These regulations are intended to address the enactment of Chapter 304 of the 2021 Acts of Assembly, Special Session I. The General Assembly required VDH to adopt regulations standards for prescription drug price transparency and reporting. In order to ensure that such regulations protect the health, safety, and welfare of citizens, it is necessary to assess relevant available information about prescription drug prices to determine what should be included or incorporated into the regulatory text. VDH may also address other issues that arise as a result of this NOIRA.

These regulations must include 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.

Dr. Shuler moved to adopt the Emergency Regulations/NOIRA and Dr. Miller seconded the motion. There was a brief discussion about the public comment from Kristin Parde and how to submit those comments when the regulations moved forward. The motion was passed unanimously.

Emergency Amendments/NOIRA to the Regulations of the Patient Level Data System

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

The goal of the regulatory change is to conform the provisions of 12VAC5-217-20 to the requirements in Chapter 552 Item 307(D1) of the 2021 Acts of Assembly Special Session I. This chapter requires inpatient hospitals to report the admission source of any individuals meeting the criteria for voluntary or involuntary psychiatric commitment as outlined in § 16.1-338, 16.1-339, 16.1-340.1, 16.1-345, 37.2-805, 37.2-809, or 37.2-904, Code of Virginia, to the Board of Health (“the Board”). The Board shall collect and share any and all data regarding the admission source of individuals admitted to inpatient hospitals as a psychiatric patient, pursuant to Virginia Code § 32.1-276.6, with the Department of Behavioral Health and Developmental Services (DBHDS) through the addition of a new legal status field. The new field will be included in the patient-level data that DBHDS receives from Virginia Health Information (VHI). The existing list of

information from that Code section does not include criteria for voluntary or involuntary psychiatric commitment, accordingly the creation of a new legal status field is required.

Dr. Shuler moved to adopt the emergency amendments/NOIRA, and the motion was seconded by Dr. Puritz. The motion passed unanimously.

Proposed Amendments to the Disease Reporting and Control Regulations...

Dr. Forlano presented the proposed amendments to the Disease Reporting and Control Regulations. The Regulations for Disease Reporting and Control provide information about the process and procedures for reporting diseases to VDH, including what diseases must be reported, who must report them and other details related to reporting and disease control. VDH is proposing amendments to the regulations to ensure all health providers report necessary public health information. This regulatory action requires COVID-19 case and laboratory report forms be submitted electronically; clarifies that the category “laboratory directors” includes any entity that holds CLIA Certificates of Waiver; adds ethnicity to the fields required to be reported by all parties related to COVID-19; and adds “coronavirus, severe” to the list of infectious disease that shall be reported to persons practicing funeral services.

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.

Ms. Hines moved to adopt the amendments and Dr. Puritz seconded the motion. There was some discussion to clarify what had changed since the emergency amendments had been adopted. The motion passed unanimously.

*Dr. Shuler left the meeting following the vote and there was no quorum of the Board members physically assembled in a single location, resulting in no further votes being able to be taken.

Cremation Fee Increase

Dr. Gormley presented to the Board a request that the cremation fee currently set at \$50 be increased to \$100. The fee had not been increased since 1974, and this increase adjusts to an appropriate level for the cost and number of cremation examinations that have increased each year.

Budget Update: Special Session II

Ms. Gilliam presented an update on the budget outcomes for VDH from the Special Session II in August 2021. She described the allocations to VDH from the American Rescue Plan Act across multiple service areas and projects. There was discussion about how the projects would be monitored and reported. There was also discussion around the cost of consultant firms in assisting with monitoring and executing the projects.

Legislative Update - Development of 2022 Proposals

Mr. Hilbert presented an update to the Board regarding the development of agency proposals for the 2022 regular General Assembly session. Mr. Hilbert reviewed the legislative development process and reviewed the nine legislative proposals that were submitted to the Administration for consideration.

There was discussion around allocation of further resources and how Board members may act in support of VDH during the regular General Assembly session.

Meeting Dates for 2022

The meeting dates for the 2022 calendar year were reviewed briefly.

Other Business

Members who had reports were asked to submit them to Ms. Prichard by September 3, 2021. Mr. Edmondson briefly discussed women’s health issues and requested information from the Office of the Attorney General on the Supreme Court. Ms. Hines asked that there be an update on the mental health crisis from recent closure of facilities. There was no other business discussed.

Adjourn

Meeting adjourned at 2:50pm.



COMMONWEALTH of VIRGINIA

Department of Health

P O BOX 2448

RICHMOND, VA 23218

M. NORMAN OLIVER, MD, MA
STATE HEALTH COMMISSIONER

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

MEMORANDUM

DATE: November 23, 2021

TO: State Board of Health

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

SUBJECT: Proposed Stage – Regulations for the Licensure of Home Care Organizations –
Amending Regulation after Assessment and Receipt of Public Comment

Enclosed for your review are proposed amendments to the Regulations for the Licensure of Home Care Organizations (12VAC5-381-10 *et seq.*).

This chapter has not undergone a completed standard rulemaking since its original promulgation in 2006 and the chapter needs a thorough review and update. The previously published Notice of Intended Regulatory Action for this action also served as a periodic review of this chapter, as required by Executive Order 14 (amended July 16, 2018). VDH reviewed and analyzed three comments received from one commenter submitted during the 30-day public comment period following publication of the NOIRA as well as additional comments received after the public comment period. These comments along with the recommendations of VDH staff based on their experience licensing and inspection home care organizations has resulted in the proposed amendments.

The proposed amendments to 12VAC5-381-10 *et seq.*: make extensive changes to reduce or eliminate ambiguity, including revising, removing, and adding definitions; create a new license reinstatement process; address what constitutes a material change to a license and how it is separate from the license renewal process; update the fee schedule, which has not been modified in at least 15 years; clarify the process to open a branch office and what an HCO may denote as its total geographic area for the provision of services; introduce more stringent infection prevention requirements; explain in greater detail the licensure, inspection, plan of correction, renewal, and variance processes; consolidate relevant regulatory sections; and make minor technical changes.

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	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-381-10 <i>et seq.</i>
VAC Chapter title(s)	Regulations for the Licensure of Home Care Organizations
Action title	Amend the Regulation after Assessment and Receipt of Public Comment
Date this document prepared	November 23, 2021

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

Brief Summary

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

This regulation governs the licensure of home care organizations. This regulatory action seeks to assess all current regulation content and determine whether it should be amended or retained in its current form. Regulatory language was reviewed and clarified if the content was unclear, inconsistent, or outdated, and was revised to conform to the *Form, Style and Procedure Manual for Publication of Virginia Regulations*. Language was also revised to more accurately reflect on whom the regulatory requirements were placed.

The various types of policies and procedures required were consolidated into the section entitled "Policies and procedures." Other sections were also consolidated, including home visits and on-site inspections. Sections have been added to more clearly explain the different licensure processes, including creating a new reinstatement licensure process. Language was added to clarify points of ambiguity that have caused confusion and inconsistency for regulants, such as the issue of branch offices and changes to existing licenses.

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.

“Agency” means the Virginia Department of Health.

“APA” means the Virginia Administrative Process Act, § 2.2-4000 *et seq.* of the Code of Virginia.

“Board” means Virginia Board of Health.

“HCO” means home care organizations.

“OLC” means the Office of Licensure and Certification.

Mandate and Impetus

Identify the mandate for this regulatory change and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, or board decision). For purposes of executive branch review, “mandate” has the same meaning as defined in Executive Order 14 (as amended, July 16, 2018), “a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part.”

Section 32.1-162.12 of the Code of Virginia requires the Board to adopt regulations for HCOs as may be necessary to protect the public health, safety, and welfare. Chapter 105 (2018 Acts of Assembly) also introduced statutory provisions regarding branch offices, which are not currently addressed in the regulations for HCOs.

The periodic review of this regulation is mandated by Executive Order 14 (as amended July 16, 2018).

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 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. Section 32.1-162.12 of the Code of Virginia 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’s intended to solve.

The rationale or justification for this regulatory change is that regulations should be clearly written, up to date, conform to the law, and should be the least burdensome means of protecting the health, safety, and welfare of citizens. The regulatory change is essential to protect the health, safety, and welfare of citizens because unclear regulations hamper regulators' ability to comply, out of date regulations may make reference to standards and practices that are not current, and reducing regulatory burden on home care organizations allows these regulators to redirect resources to client and patient care. The goals of this regulatory change are to bring the regulatory text into alignment with the *Form, Style and Procedure Manual for Publication of Virginia Regulations*, statutes, and legal decisions; resolve ambiguities that have been identified by agency staff that hinder oversight of HCOs; and update the regulations to reflect current best practices.

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 is renamed "Home Care Organization Licensure Regulation."

Section 10 Definitions

Added new definitions for business day, client, home health services, independent contractor, inspector, legal representative, owner, parent HCO, patient, pharmaceutical services, plan of care, and skilled services director. Revised definitions for activities of daily living, administer, administrator, barrier crimes, blanket fidelity bond, branch office, clinical record (formerly client record), contract services, drop site, employee, functional limitations, governing body, HCO/organization (formerly home care organization/HCO), home health agency, infusion therapy, instrumental activities of daily living, licensed practical nurse, licensee, medical plan of care, nursing services, OLC, personal care services, physician (formerly primary care physician), quality improvement, registered nurse residence (formerly client's residence), skilled services, sworn disclosure (formerly sworn disclosure statement), and third-party crime insurance. Removed definitions for available at all times during operating hours, chore services, companion services, discharge or termination summary, homemaker services, operator, organization, person, and service area.

Section 20 License

Revised to clarify when the commissioner may issue an HCO license and what disclosures are needed for a parent HCO to add a branch office to its license. Revised text to more closely align with Section 10's definitions.

Section 30 Exemption from licensure

Revised to clarify who may be exempted from licensure, how to request an exemption, and the obligation to inform the agency if the exemption eligibility is lost. Revised text to more closely align with Section 10's definitions.

Section 35 Total geographic area and office location

A new section addressing what constitutes total geographic service area, the requirement that HCO offices and drop sites be in a business or commercial zoned building, and that existing HCOs will have one year to come into compliance upon the effective date of the regulations. Revised text to more closely align with Section 10's definitions.

Section 40 License application; initial and renewal

Renamed "Request for initial license issuance." Language regarding licensure renewal was moved to a new section (see Section 45 below). Added language to more clearly identify an applicant's responsibilities when applying for initial licensure, the initial licensure process, when the commissioner may deny licensure, and an applicant's ability to reapply if denied licensure. Revised text to more closely align with Section 10's definitions.

Section 45 License expiration and renewal

A new section. Language regarding licensure renewal was moved here from Section 40 and modified to more clearly identify a licensee's responsibilities when applying for renewal of licensure, the renewal licensure process, the agency's notification to the Department of Medical Assistance Services, and an HCO's options if it failed to timely renew. Revised text to more closely align with Section 10's definitions.

Section 50 Compliance appropriate for all types of HCOs

Repealed as duplicative.

Section 60 Changes to or reissue of a license

Renamed "Surrender of license; material change of license." Revised to clarify what is a material change to a license and to clarify an HCO's obligations and the process to obtain a changed license. Revised text to more closely align with Section 10's definitions.

Section 65 License reinstatement

A new section. Creates a new reinstatement licensure process by which an HCO that failed to timely renew its license prior to expiration can apply for reinstatement of license rather than obtaining a new one. Section addresses an HCO's responsibilities when applying for reinstatement licensure, the reinstatement licensure process, when the commissioner may deny licensure, and an HCO's ability to reapply if denied licensure.

Section 70 Fees

Revises fees to reflect increases in operating costs since last revision at least 15 years ago, including the additional burden of inspecting branch offices, which were introduced in 2018. Clarifies that fees are nonrefundable. Revised text to more closely align with Section 10's definitions.

Section 80 On-site inspections

Revised to more clearly explain the on-site inspection process and an HCO's obligations during and after the inspection; decreases inspection frequency from biennial to triennial. Revised text to more closely align with Section 10's definitions.

Section 90 Home visits

Repealed; consolidated with Section 80.

Section 100 Complaint investigations conducted by the OLC

Renamed "Complaint investigations." Revised to give agency discretion to determine if an on-site inspection is necessary for a complaint investigation, subject to the criteria identified, and to specify an HCO's obligation to cooperate in this determination. Revised text to more closely align with Section 10's definitions.

Section 105 Plan of correction

A new section; consolidates the plan of correction language found in Sections 80 and 100 to ensure the plan of correction is consistent across all occurrences. Revisions include clarification that an HCO or an applicant for licensure does not have unlimited opportunities to revise unacceptable plans of correction.

Section 110 Criminal records checks

Revised to reflect statutorily language about mandated criminal records check, including language on how HCOs can satisfy this requirement when utilizing staff from temporary staffing agencies or independent contractors. Revised text to more closely align with Section 10's definitions.

Section 120 Variances

Renamed "Allowable variances." Revised text to reflect the commissioner grants variances, to clarify the variance request process, and to more closely align with Section 10's definitions.

Section 130 Revocation or suspension of a license

Renamed "Violation of this chapter or applicable law; denial, revocation, or suspension of a license." Revised text to match statutory provisions and to more closely align with Section 10's definitions.

Section 140 Return of a license

Repealed; consolidated with Section 60.

Section 150 Management and administration

Revised text to more closely align with Section 10's definitions and removed duplicative subsections. Added language that HCOs have to document in writing who can act as their agent in transactions with the agency.

Section 160 Governing body

Revised text to more closely align with Section 10's definitions. Added language to require the governing body have a written organizational plan and bylaws, including minimum requirements for the bylaws.

Section 170 Administrator

Revised text to more closely align with Section 10's definitions and for clarity.

Section 180 Written policies and procedures

Renamed "Policies and procedures." Revised text to more closely align with Section 10's definitions. Revised text to consolidate requirements for policies and procedures into a single section and to increase review interval from one year to two years. Revised text to clarify ambiguities, incorporate relevant statutory and regulatory references, and to add more specificity to the infection prevention policies and procedures.

Section 190 Financial controls

Revised text to more closely align with Section 10's definitions. Revised text so that HCOs obtain a review by an independent certified public accountant rather than an audit and that HCOs are required to notify the agency if they are the subject of a Medicaid Fraud investigation.

Section 200 Personnel practices

Renamed "Employee practices." Revised text to more closely align with Section 10's definitions and to clarify that job description requirements apply to all workers, whether compensated or not, whether employed or contracted. Revised text to require orientation include fraud, abuse, and neglect training.

Section 210 Indemnity coverage

Revised text to more closely align with Section 10's definitions and to reference professional liability insurance instead of malpractice insurance. Revised text to remove statutory reference and replaced with coverage minimums that increase annually.

Section 220 Contract services

Revised text to more closely align with Section 10's definitions.

Section 230 Client rights

Renamed "Client and patient rights." Revised text to more closely align with Section 10's definitions and to more closely align with the rights language for home health agency patients.

Section 240 Handling complaints received from clients

Renamed "Complaint handling procedures." Revised text to more closely align with Section 10's definitions. Revised text to expand complaint record retention from 3 to 5 years.

Section 250 Quality improvement

Revised text to more closely align with Section 10's definitions and for improved clarity.

Section 260 Infection control

Revised text to more closely align with Section 10's definitions and to add requirement for an employee health program. Remove infection control activities that are now found in Section 180.

Section 270 Drop sites

Revised text to more closely align with Section 10's definitions and for improved clarity.

Section 280 Client record system

Renamed "Clinical record system." Revised text to more closely align with Section 10's definitions and for improved clarity. Revised to what the medical plan of care or plan of care should include.

Section 290 Home attendants

Revised text to more closely align with Section 10's definitions and to remove reference to obsolete training curriculum, which has been replaced with a training program that an HCO may offer its home attendants and volunteers instead.

Section 300 Skilled services

Revised text to more closely align with Section 10's definitions, for improved clarity, and to specify that pharmaceutical services are a type of skilled services.

Section 310 Nursing services

Revised text to more closely align with Section 10's definitions, to correct a regulatory reference, and to specify that supervision should be at least every 60 calendar days.

Section 320 Therapy services

Revised text to more closely align with Section 10's definitions, for improved clarity, and to specify that supervision should in alignment with the therapy licensing board's standards.

Section 330 Home attendants assisting with skilled services

Revised text to more closely align with Section 10's definitions, for improved clarity, to correct a statutory reference, and to specify that home attendants should be supervised in-person at least once every 60 calendar days.

Section 340 Medical social services

Revised text to more closely align with Section 10's definitions, for improved clarity, and to reduce the minimum experience needed for the licensed clinical social worker or the individual who has master's degree in social work.

Section 350 Pharmacy services

Renamed "Pharmaceutical services." Revised text to more closely align with Section 10's definitions and to remove policies and procedures that are now found in Section 180.

DOCUMENTS INCORPORATED BY REFERENCE (12VAC5-381)

Repealed; no documents are incorporated by reference in the proposed regulatory text.

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 is removal of language that was unclear, inconsistent, or outdated while still ensuring adequate protections for health and safety. There are no primary disadvantages to the public. The primary advantages to the agency or the Commonwealth is that clearly articulated licensure processes and standards should result in reduced confusion for regulants and subsequently more agency time being devoted to oversight activities in the field. There are no primary disadvantages to the agency or the Commonwealth.

The other pertinent matter of interest to the regulated community, government officials and the public is that the Board is not proposing changes to Section 360 in this regulatory action. A separate regulatory action has been initiated to amend Section 360, as a new legislative mandate was created--after the Notice for Intended Regulatory Action in this action was published—that directly impacts Section 360. To ensure that the regulated community, government officials and the public are provided adequate notice of the changes contemplated for Section 360, all amendments for that section will be addressed in that separate regulatory action and not in the present one.

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 is no requirement of the regulatory change that is more restrictive than applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

Identify any other state agencies, localities, or other entities particularly affected by the regulatory change. "Particularly affected" are those that are likely to bear any identified disproportionate material impact which would not be experienced by other agencies, localities, or entities. "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulation or regulatory change are most likely to occur. If no agency, locality, or entity is particularly affected, include a specific statement to that effect.

There are no other state agencies or localities particularly affected. The entities that are particularly affected are current regulants and prospective regulants.

Economic Impact

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

Impact on State Agencies

<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 costs, savings, or revenue loss resulting from the regulatory change.</p> <p>The agency estimates that the proposed fees in Section 70 would result in a minimum annual fee revenue of \$2,684,750. This assumes that licensee numbers (1,547), branch office numbers (102), and applicant numbers (approximately 350 annually) remain relatively stable. The number of licensees requesting a material change to their</p>
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	<p>license is highly variable and difficult to predict, making fee revenue projections from that fee equally difficult to predict. Since the agency is proposing to introduce a new reinstatement process that currently has no analog in its other licensure programs, it is difficult to predict what fee revenue may result from HCOs utilizing that process. As explained in the two paragraphs below, this increase in fee revenue is aimed at supporting adequate staff to perform inspections and other oversight functions.</p> <p>The HCO program currently has a team of four FTEs and one wage employee serving as inspectors, in addition to one FTE supervisor and one FTE administrative support. Each FTE inspector can perform an annual average of 65 HCO inspections, which includes biennial licensure inspections, initial licensure inspections, and complaint inspections. Assuming the number of regulants remains relatively stable, if the agency can move forward with the proposed change to a triennial interval for licensure inspections, there would be approximately 906 inspections due every year. This would require a total staff of 14 FTE inspectors, two FTE supervisors, and two FTE administrative supports. Based on current salaries and fringe benefit calculations for these positions, the agency would have a total staffing cost of \$1,951,588.</p> <p>After accounting for the staffing cost, the remaining fee revenue (a minimum of \$733,162) would be utilized to cover the travel expenses of the FTE inspectors. The annual cost of leasing 14 state vehicles is estimated to be \$55,650 (\$331.25 per month per car). Using average fuel costs incurred by FTE inspectors during SFY2019 and adjusting for increased fuel prices since SFY2019, annual cost of fuel is estimated to be \$8,400. Per diem costs (using a blend of \$59/\$69/\$79 per diem to reflect the differing costs of statewide travel) and lodging costs (using a blend of hotel rates and taxes from the DC metro area to represent the high end and hotel rates and taxes from Highland County to represent the low end) consumes the remaining \$669,112 of the minimum fee revenue.</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>There are no projected costs, savings, fees, or revenues resulting from the regulatory change for other state agencies.</p>
<p><i>For all agencies:</i> Benefits the regulatory change is designed to produce.</p>	<p>This regulatory action is designed to promote and</p>

	ensure the health and safety of clients and patients who receive personal care services and skilled services from HCOs, including ensuring the agency has sufficient fee revenue to support adequate staff to perform inspections and other oversight functions.
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Impact on Localities

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, including ensuring the agency has sufficient fee revenue to support adequate staff to perform inspections and other oversight functions.

Impact on Other Entities

Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect.	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; b) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.	As of November 23, 2021, there are 1,547 licensed HCOs in Virginia and 102 branch offices, the vast majority of which are believed to be small businesses.
All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Be specific and include all costs including, but not limited to: a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change; c) fees; d) purchases of equipment or services; and e) time required to comply with the requirements.	All persons or entities seeking licensure to operate an HCO would incur a fee of \$2,000 per initial licensure application; the agency anticipates that for most applicants, this would be a one-time cost. All licensed HCOs would incur a cost of at least a \$1,250 fee per license renewal application, with a small minority of HCOs incurring an additional annual cost of \$500 for each branch office they operate. A minority of licensed HCOs may incur a cost of \$500 for late filing of their license renewal application. Because the proposed reinstatement process is new, the agency predicts a small minority of licensed HCOs would incur a cost of at least a \$2,500 fee per license reinstatement application, with an even tinier minority of HCOs incurring an

	<p>additional annual cost of \$750 for each branch office they operate.</p> <p>The agency believes that any administrative costs for reporting and recordkeeping required for compliance by small businesses would be incidental to their existing administrative costs. The agency also notes that by requiring a review instead of an audit, licensed HCOs should recognize some cost savings as reviews are typically less expensive than audits.</p> <p>The agency 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>The agency 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; however, the agency does note that a new requirement mandates that HCO offices (including drop sites and branch offices) be in buildings zoned for business or commercial use, so some HCOs may face a cost to secure a compliant operating space, though the agency does not have sufficient information at this time to predict how many HCOs would be affected. Affected HCOs would have one year from the effective date of the regulatory change to come into compliance.</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, including ensuring the agency has sufficient fee revenue to support adequate staff to perform inspections and other oversight functions.</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.

Regulatory Flexibility Analysis

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

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.

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

If you are using this form to report the result of a periodic review/small business impact review that is being conducted as part of this regulatory action, and was announced during the NOIRA stage, indicate whether the regulatory change meets the criteria set out in Executive Order 14 (as amended, July 16, 2018), e.g., is necessary for the protection of public health, safety, and welfare; minimizes the economic impact on small businesses consistent with the stated objectives of applicable law; and is clearly written and easily understandable.

In addition, as required by § 2.2-4007.1 E and F of the Code of Virginia, discuss the agency’s consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation; (3) the complexity of the regulation; (4) the extent to which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation. Also, discuss why the agency’s decision, consistent with applicable law, will minimize the economic impact of regulations on small businesses.

This regulation is necessary for the protection of public health, safety, and welfare. This regulation also minimizes the economic impact on small businesses consistent with the stated objectives of applicable law. There is room for improvement on the clarity and understandability of the regulation.

There is a continued need for this regulation because the mandate to regulate home care organizations still exists in the Code of Virginia. Public comments were received from a single commenter during the 30-day public comment period following publication of the Notice of Intended Regulatory Action. These comments offered specific recommendations for the regulations, with a general aim of requesting less restrictive regulations. The complexity of the regulation is on par with the complexity of other medical care facility regulations that the Board has promulgated. The regulation does not overlap, duplicate, or conflict with federal or state law or regulation. It has been 6 years since the regulation has been evaluated.

Public Comment

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

Commenter	Comment	Agency response
<p>Marcia A. Tetterton, Virginia Association for Home Care and Hospice</p>	<p>Part I. Definitions and General Information</p> <p>12VAC5-381-10. Definitions. "Branch office" means a geographically separate office of the home care organization that performs all or part of the primary functions of the home care organization on a smaller scale.</p> <p>12VAC5-381-120. Variances. A. The OLC <u>Commissioner</u> can authorize variances only to its own licensing regulations, not to regulations of another agency or to any requirements in federal, state, or local laws.</p> <p>12VAC5-381-160. Governing Body. A. The organization shall have a governing body that is legally responsible for the management, operation and fiscal affairs of the organization. The governing body of a hospital that operates a home care organization shall include in its internal organization structure an identified unit of home care services. B. The governing body shall: 1. Determine which services are to be provided by the organization; 2. Ensure that the organization is staffed and adequately equipped to provide the services it offers to clients, whether provided directly by the organization or through contract; 3. Comply with federal and state laws, regulations and local ordinances governing operations of the organization; and 4. Establish a quality improvement committee. C. The governing body shall review annually and approve the written policies and procedures of the organization.</p>	<p>The Board has responded to each suggestion below, grouped by regulatory section:</p> <ul style="list-style-type: none"> • 12VAC5-381-10 – The Board notes this comment and will remove “on a smaller scale” but not “organization” as the branch office’s scope of function is tied to the parent HCO’s functions. • 12VAC5-381-120 – The Board has incorporated this suggestion into the proposed text. • 12VAC5-381-160 – The Board notes this comment; a quality improvement committee is standard across all OLC medical facility license types because of its critical role in ensuring quality care. • 12VAC5-381-180 – The Board notes this comment and has revised the text to more clearly indicate which drugs are reportable and to address CBD oil, THC-A oil, and drug abuse in the presence of HCO employees, volunteers, and independent contractors. • 12VAC5-381-190 – The Board notes this comment, but does not agree that the listed documents provided by the commenter are of equal value in determining whether an HCO has kept its records in accordance with GAAP and has sufficient financial controls. • 12VAC5-381-280 – The Board notes this comment, but does not believe that there is justification for allowing HCOs the equivalence of two calendar weeks to update a clinical record. • 12VAC5-381-290 – The Board agrees that subdivision A 6 needs to be revised. The Board does not agree that 20 hours is sufficient to adequately address these subject areas, as the federal requirements that this comment appears to be

	<p>D. The governing body shall review annually and approve the recommendations of the quality improvement committee, when appropriate.</p> <p>12VAC5-381-180. Written Policies and Procedures.</p> <p>C. Administrative and operational policies and procedures shall include, but are not limited to:</p> <p>10. Communicable and reportable diseases pursuant to <u>guidelines established by the Virginia Department of Health;</u></p> <p>18. <u>CBD oil and THC-A oil for medical treatment, prescription or illegal drug abuse by client in the aide's presence; and</u></p> <p>12VAC5-381-190. Financial Controls.</p> <p>D. All financial records shall be audited at least triennially by an independent certified public accountant (CPA) or audited as otherwise provided by law. A copy of most recent tax return prepared by an independent financial organization, or an audit, or a balance sheet, or a financial statement prepared by a certified public accounting firm.</p> <p>12VAC5-381-280. Client Record System.</p> <p>G. Signed and dated notes on the care or services provided by each individual delivering service shall be written on the day the service is delivered and incorporated in the client record within seven <u>ten</u> working days.</p> <p>12VAC5-381-290. Home Attendants.</p> <p>Home attendants shall be able to speak, read and write English and shall meet one of the following qualifications:</p> <p>6. Have satisfactorily completed a <u>20-hour training program and competency tested by a licensed nurse. Completion of the 20-hour training program and competency testing shall be documented in the home health aide's personnel record. Other individuals may be</u></p>	<p>derived from is for a 75-hour training program covering these topics</p> <ul style="list-style-type: none"> • 12VAC5-381-300 – The Board notes this comment and has eliminated “primary care” before each instance of physician. • 12VAC5-381-310 – The Board notes this comment, but does not agree that a minimum supervision interval should be eliminated as it may negatively incentivize regulants to under-assess a patient’s needs. • 12VAC5-381-340 – The Board agrees that subsection A of this section needs to be revised. The Board has revised this requirement in a way it believes matches the commenter’s intent, though the specific language suggested was not utilized in whole. • 12VAC5-381-360 – The Board notes this comment; however, the Board has a separate regulatory action in progress that address the provisions of this section and will not be making changes to this section in this regulatory action.
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	<p><u>used to provide instruction under the supervision of a licensed nurse. The 20-hour training program shall address each of the following subject areas:</u></p> <ul style="list-style-type: none"> <u>(i) Communications skills, including the ability to read, write and verbally report information to the person receiving services, representatives, other caregivers and supervisor.</u> <u>(ii) Observation, reporting and documentation of patient status and the care or service furnished.</u> <u>(iii) Reading and recording temperature, pulse, and respiration.</u> <u>(iv) Basic infection control procedures.</u> <u>(v) Basic elements of body functioning and changes in body function that must be reported to an aide's supervisor.</u> <u>(vi) Maintenance of a clean, safe, and healthy environment.</u> <u>(vii) Recognizing emergencies and knowledge of emergency procedures.</u> <u>(viii) The physical, emotional, and developmental needs of and ways to work with the populations served including the need for respect for the patient, his or her privacy and his or her property.</u> <u>(ix) Appropriate and safe techniques in personal hygiene and grooming that include</u> <ul style="list-style-type: none"> <u>(A) Bed bath.</u> <u>(B) Sponge, tub, or shower bath.</u> <u>(C) Hair shampoo, sink, tub, or bed.</u> <u>(D) Nail and skin care.</u> <u>(E) Oral hygiene.</u> <u>(F) Toileting and elimination.</u> <u>(x) Safe transfer techniques and ambulation.</u> <u>(xi) Normal range of motion and positioning.</u> <u>(xii) Adequate nutrition and fluid intake.</u> 	
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	<p>(xiii) <u>Recognizing and reporting changes in skin condition, including pressure ulcer.</u></p> <p>(xiv) <u>Any other task that home care organization may choose to provider as permitted under state law.</u></p> <p>using the "Personal Care Aide Training Curriculum," 2003 edition, of the Department of Medical Assistance Services. However, this training is permissible for home attendants of personal care services only.</p> <p>Part III. Skilled Services 12VAC5-381-300. Skilled Services. B. All skilled services delivered shall be prescribed in a medical plan of care that contains at least the following information: 1. Diagnosis and prognosis; 2. Functional limitations; 3. Orders for all skilled services, including: (i) specific procedures, (ii) treatment modalities, and (iii) frequency and duration of the services ordered; 4. Orders for medications, when applicable; and 5. Orders for special dietary or nutritional needs, when applicable. The medical plan of care shall be approved and signed by the client's <u>primary care ordering</u> physician. E. The medical plan of care shall be reviewed and approved, and signed by the <u>primary care ordering</u> physician at least every 60 days.</p> <p>12VAC5-381-310. Nursing Services. B. Supervision of services shall be provided as often as necessary as determined by the client's needs, the assessment by the registered nurse, and the organization's written policies not to exceed 90 days.</p> <p>12VAC5-381-340. Medical Social Services. A. Medical social services shall be provided according to the medical plan of care by or under the direction of a qualified social worker who holds, at a minimum, a bachelor's degree with major studies in social work,</p>	
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	<p>sociology, or psychology from a four-year college or university accredited by the Council on Social Work Education and has at least two years experience in case work or counseling in a health care or social services delivery system. that has master's or doctoral degree from a school of social work accredited by the Council on Social Work Education, and has 1 year of social work experience in a health care setting.</p> <p>The organization shall have one year from January 1, 2006, to ensure the designated individual meets the qualifications of this standard.</p> <p>Part V. Personal Care Services 12VAC5-381-360. Personal Care Services.</p> <p>A. An organization may provide personal care services in support of the client's health and safety in his home. The organization shall designate a registered <u>licensed</u> nurse responsible for the supervision of personal care services.</p> <p>B. The personal care services shall include:</p> <p>5. Documenting the services delivered in the client's record service plan.</p> <p>C. Such services shall be delivered based on a written plan of services developed by a licensed health care provider registered nurse, in collaboration with the client and client's family. The plan shall include at least the following:</p> <p>1. Assessment Evaluation of the client's needs;</p> <p>D. The <u>service</u> plan shall be retained in the client's record. Copies of the <u>service</u> plan shall be provided to the client receiving services and reviewed with the assigned home attendant prior to delivering services.</p> <p>E. Supervision of services <u>home attendants</u> shall be provided as often as necessary as determined by the client's needs <u>service plan by a the assessment of the registered licensed health care professional nurse</u>, and the organization's written policies not to exceed 90 <u>120</u> days.</p>	
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	<p>F. A registered nurse or licensed practical nurse shall be available during all hours that personal care services are being provided.</p>	
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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.

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 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
381-10	N/A	<p style="text-align: center;">CHAPTER 381 REGULATIONS FOR LICENSURE OF HOME CARE ORGANIZATIONS Part I Definitions and General Information 12VAC5-381-10. Definitions. The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:</p>	<p>CHANGE: The Board is proposing the following changes:</p> <p style="text-align: center;">Chapter 381 REGULATIONS FOR THE LICENSURE OF HOME CARE ORGANIZATIONS ORGANIZATION <u>LICENSURE REGULATION</u> Part I Definitions and General Information 12VAC5-381-10. Definitions. The following words and terms when used in this chapter shall have</p>

	<p>"Activities of daily living" or "ADLs" means bathing, dressing, toileting, transferring, bowel control, bladder control and eating/feeding. A person's degree of independence in performing these activities is part of determining the appropriate level of care and services. A need for assistance exists when the client is unable to complete an activity due to cognitive impairment, functional disability, physical health problems, or safety. The client's functional level is based on the client's need for assistance most or all of the time to perform personal care tasks in order to live independently.</p> <p>"Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion or any other means, to the body of a client by (i) a practitioner or by his authorized agent and under his direction or (ii) the client at the direction and in the presence of the practitioner as defined in § 54.1-3401 of the Code of Virginia.</p> <p>"Administrator" means a person designated in writing by the governing body as having the necessary authority for the day-to-day management of the organization. The administrator must be an employee of the organization. The administrator, the director of nursing, or other clinical director may be the same individual if that individual is dually qualified.</p> <p>"Available at all times during operating hours" means an individual is readily available on the premises or by telecommunications.</p> <p>"Barrier crimes" means certain offenses, specified in § 32.1-162.9:1 of the Code of Virginia, that automatically bar an</p>	<p>the following meanings unless the context clearly indicates otherwise:</p> <p>"Activities of daily living" or "ADLs" means bathing, dressing, toileting, transferring, bowel control, bladder control and eating/feeding. A person's <u>An individual's</u> degree of independence in performing these activities is part of determining the appropriate level of care and services. A need for assistance exists when the client <u>or patient</u> is unable to complete an activity due to cognitive impairment, functional disability, physical health problems, or safety. The client's <u>or patient's</u> functional level is based on the client's <u>his</u> need for assistance most or all of the time to perform personal care tasks in order to live independently.</p> <p>"Administer" means the direct application of a controlled substance prescription drug as defined in § 54.1-3401 of the Code of Virginia or a <u>nonprescription drug</u>, whether by injection, inhalation, ingestion or any other means, to the body of a client <u>or patient</u> by (i) a practitioner or by his authorized agent and under his direction or (ii) the client <u>or patient</u> at the direction and in the presence of the practitioner as defined in § 54.1-3401 of the Code of Virginia.</p> <p>"Administrator" means a person <u>an individual</u> designated in writing by the governing body as having the <u>responsibility and</u> necessary authority for the day-to-day <u>daily</u> management of the organization <u>an HCO or a branch office of an HCO</u>. The administrator must be an employee of the organization <u>HCO</u>. The administrator, the <u>skilled services</u> director of nursing, or other clinical director may be the same individual if that individual is dually qualified.</p> <p>"Available at all times during operating hours" means an individual is <u>readily available on the premises or by telecommunications.</u></p> <p>"Barrier crimes" <u>"Barrier crime"</u> means certain offenses <u>any offense set forth in clause (i) of the definition of barrier crime in § 19.2-392.02, specified in § 32.1-162.9:1 of the Code of Virginia, that automatically bar an individual convicted of those offenses</u></p>
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	<p>individual convicted of those offenses from employment with a home care organization.</p> <p>"Blanket fidelity bond" means a bond that provides coverage that protects an organization's losses as a result of employee theft or fraud.</p> <p>"Branch office" means a geographically separate office of the home care organization that performs all or part of the primary functions of the home care organization on a smaller scale.</p> <p>"Chore services" means assistance with nonroutine, heavy home maintenance for persons unable to perform such tasks. Chore services include minor repair work on furniture and appliances; carrying coal, wood and water; chopping wood; removing snow; yard maintenance; and painting.</p> <p>"Client record" means the centralized location for documenting information about the client and the care and services provided to the client by the organization. A client record is a continuous and accurate account of care or services, whether hard copy or electronic, provided to a client, including information that has been dated and signed by the individuals who prescribed or delivered the care or service.</p> <p>"Client's residence" means the place where the individual or client makes his home such as his own apartment or house, a relative's home or an assisted living facility, but does not include a hospital, nursing facility or other extended care facility.</p> <p>"Commissioner" means the State Health Commissioner.</p>	<p>from employment with a home care organization.</p> <p>"Blanket fidelity bond" means a bond that provides coverage that protects an organization's <u>HCO's</u> losses as a result of employee theft or fraud.</p> <p>"Branch office" means a geographically separate office of the home care organization <u>an HCO</u> that performs all or part of the primary functions of the home care organization <u>parent HCO on a smaller scale.</u></p> <p>"Chore services" means assistance with nonroutine, heavy home maintenance for persons unable to perform such tasks. Chore services include minor repair work on furniture and appliances; carrying coal, wood and water; chopping wood; removing snow; yard maintenance; and painting.</p> <p><u>"Business day" means any day that is not a Saturday, Sunday, legal holiday, or day on which the department is closed. For the purposes of this chapter, any day on which the Governor authorizes the closing of the state government shall be considered a legal holiday.</u></p> <p><u>"Client" means an individual who only receives personal care services from an HCO.</u></p> <p>"Client record" <u>"Clinical record"</u> means the centralized location for documenting information about the client <u>or patient</u> and the care and services provided to the client <u>him</u> by the organization <u>an HCO</u>. A <u>client clinical</u> record is a continuous and accurate account of care or services, whether hard copy or electronic, provided to a client <u>or patient</u>, including information that has been dated and signed by the individuals who prescribed or delivered the care or service.</p> <p>"Client's residence" means the place where the individual or client makes his home such as his own apartment or house, a relative's home or an assisted living facility, but does not include a hospital, nursing facility or other extended care facility.</p> <p>"Commissioner" means the State Health Commissioner.</p>
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	<p>"Companion services" means assisting persons unable to care for themselves without assistance. Companion services include transportation, meal preparation, shopping, light housekeeping, companionship, and household management.</p> <p>"Contract services" means services provided through agreement with another agency, organization, or individual on behalf of the organization. The agreement specifies the services or personnel to be provided on behalf of the organization and the fees to provide these services or personnel.</p> <p>"Criminal record report" means the statement issued by the Central Criminal Record Exchange, Virginia Department of State Police.</p> <p>"Department" means the Virginia Department of Health.</p> <p>"Discharge or termination summary" means a final written summary filed in a closed client record of the service delivered, goals achieved and final disposition at the time of client's discharge or termination from service.</p> <p>"Dispense" means to deliver a drug to an ultimate user by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling or compounding necessary to prepare the substance for that delivery.</p> <p>"Drop site" means a location that HCO staff use in the performance of daily tasks such as obtaining supplies, using fax and copy machines, charting notes on care or services provided, and storing client records. These locations may also be called charting</p>	<p>"Companion services" means assisting persons unable to care for themselves without assistance. Companion services include transportation, meal preparation, shopping, light housekeeping, companionship, and household management.</p> <p>"Contract services" means services provided through agreement with another agency, organization, or individual on behalf of the organization <u>an HCO</u>. The agreement specifies the services or personnel <u>employees</u> to be provided on behalf of the organization <u>an HCO</u> and the fees to provide these services or personnel <u>employees</u>.</p> <p>"Criminal record report" means the statement issued by the Central Criminal Record Exchange, Virginia Department of State Police.</p> <p>"Department" means the Virginia Department of Health.</p> <p>"Discharge or termination summary" means a final written summary filed in a closed client record of the service delivered, goals achieved and final disposition at the time of client's discharge or termination from service.</p> <p>"Dispense" means to deliver a drug to an ultimate user by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling or compounding necessary to prepare the substance for that delivery.</p> <p>"Drop site" means a location that HCO staff <u>employees</u> use in the performance of daily tasks such as obtaining supplies, using fax and copy machines, charting notes on care or services provided, and storing client <u>clinical</u> records. These locations may also be called charting stations, workstations, or convenience sites.</p> <p>"Employee" means an individual who has the status of an employee as defined by the U.S. Internal Revenue Service <u>an individual in the service of an HCO under any contract of hire, express or implied, oral or written, where the HCO has the power or right to control and direct the employee in the material details of how the work is to be performed. This excludes</u></p>
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	<p>stations, workstations, or convenience sites.</p> <p>"Employee" means an individual who has the status of an employee as defined by the U.S. Internal Revenue Service.</p> <p>"Functional limitations" means the level of a client's need for assistance based on an assessment conducted by the supervising nurse. There are three criteria to assessing functional status: (i) the client's impairment level and need for personal assistance, (ii) the client's lack of capacity, and (iii) how the client usually performed the activity over a period of time. If a person is mentally and physically free of impairment, there is not a safety risk to the individual, or the person chooses not to complete an activity due to personal preference or choice, then that person does not need assistance.</p> <p>"Governing body" means the individual, group or governmental agency that has legal responsibility and authority over the operation of the home care organization.</p> <p>"Home attendant" means a nonlicensed individual performing skilled, pharmaceutical and personal care services, under the supervision of the appropriate health professional, to a client in the client's residence. Home attendants are also known as certified nurse aides or CNAs, home care aides, home health aides, or personal care aides.</p> <p>"Home care organization" or "HCO" means a public or private entity providing an organized program of home health, pharmaceutical or personal care services, according to § 32.1-162.1 of the Code of Virginia in the residence of a client or</p>	<p><u>individuals who receives a 1099-NEC from the HCO.</u></p> <p><u>"Functional limitations" means the level of a client's or patient's need for assistance based on an assessment conducted by the supervising nurse who shall be a registered nurse holding an active license issued by the Virginia Department of Health Professions or an active multistate licensure privilege to practice nursing in Virginia as a registered nurse. There are three criteria to assessing functional status: (i) the client's impairment level and need for personal assistance, (ii) the client's lack of capacity, and (iii) how the client usually performed the activity over a period of time. If a person is mentally and physically free of impairment, there is not a safety risk to the individual, or the person chooses not to complete an activity due to personal preference or choice, then that person does not need assistance.</u></p> <p><u>"Governing body" means the individual, group, entity, or governmental agency that has been designated in writing by the owner and who has legal responsibility and authority over for the overall management and operation of the home care organization an HCO.</u></p> <p><u>"HCO" or "organization" means a home care organization, which is public or private entity providing an organized program of home health, skilled, pharmaceutical, or personal care services in the residence of a client or patient to maintain his health and safety in his residence. An HCO does not include any family members, relatives or friends providing caregiving services to individuals who need assistance to remain independent and in their own residences.</u></p> <p><u>"Home attendant" means a nonlicensed an individual without an active health care practitioner license or an active multistate licensure privilege to practice who performing performs skilled, pharmaceutical and personal care services, under the supervision of the appropriate actively licensed health professional care practitioner, to a client or patient in the client's his residence. Home attendants</u></p>
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	<p>individual to maintain the client's health and safety in his home. A home care organization does not include any family members, relatives or friends providing caregiving services to persons who need assistance to remain independent and in their own homes.</p> <p>"Home health agency" means a public or private agency or organization, or part of an agency or organization, that meets the requirements for participation in Medicare under 42 CFR 440.70 (d), by providing skilled nursing services and at least one other therapeutic service, for example, physical, speech, or occupational therapy; medical social services; or home health aide services, and also meets the capitalization requirements under 42 CFR 489.28.</p> <p>"Homemaker services" means assistance to persons with the inability to perform one or more instrumental activities of daily living. Homemaker services may also include assistance with bathing areas the client cannot reach, fastening client's clothing, combing hair, brushing dentures, shaving with an electric razor, and providing stabilization to a client while walking. Homemaker services do not include feeding, bed baths, transferring, lifting, putting on braces or other supports, cutting nails or shaving with a blade.</p> <p>"Infusion therapy" means the procedures or processes that involve the administration of injectable medications to clients via the intravenous, subcutaneous, epidural, or intrathecal routes. Infusion therapy does not include oral, enteral, or topical medications.</p> <p>"Instrumental activities of daily living" means meal preparation,</p>	<p>are also known as certified nurse aides or CNAs, home care aides, home health aides, or personal care aides, or nursing assistants.</p> <p>"Home care organization" or "HCO" means a public or private entity providing an organized program of home health, pharmaceutical, or personal care services, according to § 32.1-162.1 of the Code of Virginia in the residence of a client or individual to maintain the client's health and safety in his home. A home care organization does not include any family members, relatives or friends providing caregiving services to persons who need assistance to remain independent and in their own homes.</p> <p>"Home health agency" means a public or private agency or organization, or part of an agency or organization, that meets the requirements for participation in Medicare under <u>has the same meaning ascribed to the term in 42 CFR 440.70 (d), by providing skilled nursing services and at least one other therapeutic service, for example, physical, speech, or occupational therapy; medical social services; or home health aide services, and also meets the capitalization requirements under 42 CFR 489.28.</u></p> <p>"Homemaker services" means assistance to persons with the inability to perform one or more instrumental activities of daily living. Homemaker services may also include assistance with bathing areas the client cannot reach, fastening client's clothing, combing hair, brushing dentures, shaving with an electric razor, and providing stabilization to a client while walking. Homemaker services do not include feeding, bed baths, transferring, lifting, putting on braces or other supports, cutting nails or shaving with a blade.</p> <p><u>"Home health services" means services provided by or under the direct supervision of any health care professional under a medical plan of care in a patient's residence on a visit or hourly basis to patients who have or are at risk of injury, illness, or a</u></p>
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	<p>housekeeping/light housework, shopping for personal items, laundry, or using the telephone. A client's degree of independence in performing these activities is part of determining the appropriate level of care and services.</p> <p>"Licensed practical nurse" means a person who holds a current license issued by the Virginia Board of Nursing or a current multistate licensure privilege to practice nursing in Virginia as a licensed practical nurse.</p> <p>"Licensee" means a licensed home care provider.</p> <p>"Medical plan of care" means a written plan of services, and items needed to treat a client's medical condition, that is prescribed, signed and periodically reviewed by the client's primary care physician.</p> <p>"Nursing services" means client care services, including, but not limited to, the curative, restorative, or preventive aspects of nursing that are performed or supervised by a registered nurse according to a medical plan of care.</p> <p>"OLC" means the Office of Licensure and Certification of the Virginia Department of Health.</p> <p>"Operator" means any individual, partnership, association, trust, corporation, municipality, county, local government agency or any other legal or commercial entity that is responsible for the day-to-day administrative management and operation of the organization.</p> <p>"Organization" means a home care organization.</p> <p>"Person" means any individual, partnership, association, trust, corporation, municipality, county, local government agency or any</p>	<p><u>disabling condition and require short- or long-term interventions.</u></p> <p><u>"Independent contractor" means an individual in the service of an HCO under any contract of hire, express or implied, oral or written, where the HCO has the power or right to control and direct the employee in the material details of how the work is to be performed and who receives a 1099-NEC from the HCO.</u></p> <p>"Infusion therapy" means the procedures or processes that involve the administration of injectable medications to clients <u>the patient</u> via the intravenous, subcutaneous, epidural, or intrathecal routes. Infusion therapy does not include oral, enteral, or topical medications.</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>"Instrumental activities of daily living" means meal preparation, housekeeping/light <u>housekeeping or light</u> housework, shopping for personal items, laundry, or using the telephone. A client's <u>or patient's</u> degree of independence in performing these activities is part of determining the appropriate level of care and services.</p> <p><u>"Legal representative" means a person legally responsible for representing or standing in the place of the client or patient for the conduct of his affairs. This may include a guardian, conservator, attorney-in-fact under durable power of attorney, trustee, or other person expressly named by a court of competent jurisdiction or by the client or patient as his agency in a legal document that specifies the scope of the representative's authority to act. A legal representative may only represent or stand in the place of a client or patient for the function or functions for which he has legal authority to act.</u></p> <p>"Licensed practical nurse" means a person <u>an individual</u> who holds a current <u>an active</u> license issued by the Virginia Board of Nursing or a current <u>an active</u> multistate licensure privilege to practice nursing in Virginia as a licensed practical nurse.</p>
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		<p>other legal or commercial entity that operates a home care organization.</p> <p>"Personal care services" means the provision of nonskilled services, including assistance in the activities of daily living, and may include instrumental activities of daily living, related to the needs of the client, who has or is at risk of an illness, injury or disabling condition. A need for assistance exists when the client is unable to complete an activity due to cognitive impairment, functional disability, physical health problems, or safety. The client's functional level is based on the client's need for assistance most or all of the time to perform the tasks of daily living in order to live independently.</p> <p>"Primary care physician" means a physician licensed in Virginia, according to Chapter 29 (§ 54.1-2900 et seq.) of Title 54.1 of the Code of Virginia, or licensed in an adjacent state and identified by the client as having the primary responsibility in determining the delivery of the client's medical care. The responsibility of physicians contained in this chapter may be implemented by nurse practitioners or physician assistants as assigned by the supervising physician and within the parameters of professional licensing.</p> <p>"Qualified" means meeting current legal requirements of licensure, registration or certification in Virginia or having appropriate training, including competency testing, and experience commensurate with assigned responsibilities.</p> <p>"Quality improvement" means ongoing activities designed to objectively and systematically evaluate the quality of client care and services, pursue</p>	<p>"Licensee" means a licensed home care provider an HCO that has received and maintains an active license under the provisions of Article 7.1 (§ 32.1-162.7 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia and this chapter.</p> <p>"Medical plan of care" means a written plan of <u>skilled services, personal care services,</u> and items needed to treat a <u>client's patient's</u> medical condition, that is prescribed, signed and periodically reviewed by the <u>client's patient's primary care</u> physician.</p> <p>"Nursing services" means <u>client patient</u> care services, including, but not limited to, the curative, restorative, or preventive aspects of nursing that are performed or supervised by a registered nurse according to a medical plan of care.</p> <p>"OLC" means the Office of Licensure and Certification of the Virginia Department of Health department.</p> <p>"Operator" means any individual, partnership, association, trust, corporation, municipality, county, local government agency or any other legal or commercial entity that is responsible for the day-to-day administrative management and operation of the organization.</p> <p>"Organization" means a home care organization.</p> <p><u>"Owner" means the person who has ultimate legal responsibility and authority to own, operate, manage, or otherwise control the conduct of an HCO.</u></p> <p>"Person" means any individual, partnership, association, trust, corporation, municipality, county, local government agency or any other legal or commercial entity that operates a home care organization.</p> <p><u>"Parent HCO" means the HCO that develops and maintains administrative controls of branch offices, and is ultimately responsible for the implementation of the plan of care or medical plan of care and for services furnished to patients and clients.</u></p> <p><u>"Patient" means an individual who receives skilled services and may</u></p>
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	<p>opportunities to improve client care and services, and resolve identified problems. Quality improvement is an approach to the ongoing study and improvement of the processes of providing health care services to meet the needs of clients and others.</p> <p>"Registered nurse" means a person who holds a current license issued by the Virginia Board of Nursing or a current multistate licensure privilege to practice nursing in Virginia as a registered nurse.</p> <p>"Service area" means a clearly delineated geographic area in which the organization arranges for the provision of home care services, personal care services, or pharmaceutical services to be available and readily accessible to persons.</p> <p>"Skilled services" means the provision of the home health services listed in 12VAC5-381-300.</p> <p>"Supervision" means the ongoing process of monitoring the skills, competencies and performance of the individual supervised and providing regular, documented, face-to-face guidance and instruction.</p> <p>"Sworn disclosure statement" means a document disclosing an applicant's criminal convictions and pending criminal charges occurring in Virginia or any other state.</p> <p>"Third-party crime insurance" means insurance coverage that protects an organization's losses as a result of employee theft or fraud.</p> <p>Statutory Authority</p>	<p><u>receive personal care services from an HCO.</u></p> <p>"Personal care services" means the provision of nonskilled services, including assistance in the activities of daily living, and may include instrumental activities of daily living, related to the needs of the client <u>or patient</u>, who has or is at risk of an illness, injury or disabling condition. A need for assistance exists when the client <u>or patient</u> is unable to complete an activity due to cognitive impairment, functional disability, physical health problems, or safety. The client's <u>or patient's</u> functional level is based on the client's <u>his</u> need for assistance most or all of the time to perform the tasks of daily living in order to live independently.</p> <p><u>"Pharmaceutical services" means dispensing and administration of a drug or drugs, parenteral nutritional support, and associated patient instruction.</u></p> <p>"Primary care physician" <u>"Physician"</u> means a physician <u>actively licensed in Virginia, according pursuant to Chapter 29 (§ 54.1-2900 et seq.) of Title 54.1 of the Code of Virginia, or actively licensed in an adjacent state and identified by the client or patient as having the primary responsibility in determining the delivery of the client's or patient's medical care.</u> The responsibility of physicians contained in this chapter may be implemented by nurse practitioners or physician assistants as assigned by the supervising physician and within the parameters of professional licensing.</p> <p><u>"Plan of care" means a written plan of personal care services to provide direction on the type of care to be provided that address the client's care needs and that is developed, signed, and periodically reviewed by a registered nurse employed or contracted by an HCO.</u></p> <p>"Qualified" means meeting current legal requirements of licensure, registration or certification in Virginia or having appropriate training, including competency testing, and experience commensurate with assigned responsibilities.</p>
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		<p>§§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p>	<p>"Quality improvement" means ongoing activities designed to objectively and systematically evaluate the quality of client <u>and patient</u> care and services, pursue opportunities to improve client <u>and patient</u> care and services, and resolve identified problems. Quality improvement is an approach to the ongoing study and improvement of the processes of providing health care services to meet the needs of clients, <u>patients</u>, and others.</p> <p>"Registered nurse" means a person <u>an individual</u> who holds a current <u>an active</u> license issued by the Virginia Board of Nursing or a current <u>an active</u> multistate licensure privilege to practice nursing in Virginia as a registered nurse.</p> <p>"Residence" means the <u>place where the client or patient makes his home such as his own apartment or house, a relative's home or an assisted living facility, but does not include a general hospital, nursing home, certified nursing facility, or other extended care facility.</u></p> <p>"Service area" means a clearly delineated geographic area in which the organization arranges for the provision of home care services, personal care services, or pharmaceutical services to be available and readily accessible to persons.</p> <p>"Skilled services" means the provision of the home health services listed <u>subsection A</u> in <u>of</u> 12VAC5-381-300.</p> <p><u>"Skilled services director" means an actively licensed health care practitioner who is an employee of an HCO and is responsible for the daily direction and management of skilled services. The administrator and the skilled services director may be the same individual if that individual is dually qualified.</u></p> <p>"Supervision" means the ongoing process of monitoring the skills, competencies and performance of the individual supervised and providing regular, documented, face-to-face guidance and instruction.</p> <p>"Sworn disclosure statement" <u>"Sworn disclosure" means a document</u></p>
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			<p><u>written statement or affirmation disclosing an applicant's any criminal convictions and or any pending criminal charges, whether occurring in within or outside Virginia the Commonwealth or any other state, by an applicant for compensated employment with an HCO.</u></p> <p>"Third-party crime insurance" means insurance coverage that protects an organization's HCO's losses as a result of employee theft or fraud.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p> <p>INTENT: The intent of these proposed changes is to:</p> <ul style="list-style-type: none"> (i) clarify the difference in authority and responsibility between the administrator, owner, and the governing body; (ii) add missing definitions for terms that have been the source of confusion for regulants; (iii) eliminate defined terms that do not appear in the regulation; (iv) clarify what constitutes a business day; (v) add definitions so that subsequent regulatory sections are less complex and verbose, such as inspector, employee, independent contractor, and legal representative; and (vi) ensure terms derived from statute cross-reference the appropriate statutory provision. <p>RATIONALE: The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> (i) eliminate confusion about which parts of an HCO's operations are the responsibility of or under the purview of the administrator, owner, and the governing body; (ii) previously undefined terms that have caused confusion clearly indicate a need for a definition; (iii) there is no justification to define terms that do not appear in the regulation; (iv) eliminate confusion about what constitutes a business day since the operating hours and days of
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			<p>an HCO can vary widely from regulant to regulant;</p> <p>(v) increase readability of later sections by defining terms rather than trying to define complex subjects within a regulatory requirement; and</p> <p>(vi) eliminate any conflicts between terms defined in statute and terms defined in this chapter.</p> <p>LIKELY IMPACT: The likely impact of these proposed changes is clarity about the meaning of terms and improved readability of later regulatory sections.</p>
381-20	N/A	<p>12VAC5-381-20. License.</p> <p>A. A license to operate a home care organization is issued to a person. However, no license shall be issued to a person who has been sanctioned pursuant to 42 USC § 1320a-7b. Persons planning to seek federal certification or national accreditation pursuant to § 32.1-162.8 of the Code of Virginia must first obtain state licensure.</p> <p>B. The commissioner shall issue or renew a license to establish or operate a home care organization if the commissioner finds that the home care organization is in compliance with the law and this regulation.</p> <p>C. The commissioner may issue a license to a home care organization authorizing the licensee to provide services at one or more branch offices serving portions of the total geographic area served by the licensee, provided each branch office operates under the supervision and administrative control of the licensee. The address of each branch office at which services are provided by the licensee shall be included on any license issued to the licensee.</p> <p>D. Every home care organization shall be designated by an appropriate name. The name shall not be changed without first notifying the OLC.</p>	<p>CHANGE: The Board is proposing the following changes:</p> <p>12VAC5-381-20. License.</p> <p>A. A license to operate a home care organization is issued to a person. The commissioner may issue a license to establish an HCO if:</p> <ol style="list-style-type: none"> <u>1. The applicant and the applicant's proposed HCO are in compliance this chapter;</u> <u>2. The application fee prescribed by subsection A of 12VAC5-381-70 has been received by the OLC; and</u> <u>3. The applicant and any person having ownership interest in the proposed HCO</u> However, no license shall be issued to a person who has have not been sanctioned pursuant to 42 USC § 1320a-7b. Persons planning to seek federal certification or national accreditation pursuant to § 32.1-162.8 of the Code of Virginia must first obtain state licensure. <p>B. The commissioner shall issue or renew a license to establish or operate a home care organization if the commissioner finds that the home care organization is in compliance with the law and this regulation.</p> <p><u>B. A person may not establish, conduct, maintain, or operate in this</u></p>

		<p>E. Licenses shall not be transferred or assigned.</p> <p>F. Any person establishing, conducting, maintaining, or operating a home care organization without a license shall be guilty of a Class 6 felony according to § 32.1-162.15 of the Code of Virginia.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p>	<p>Commonwealth an HCO without having obtained a license unless exempted by § 32.1-162.8 of the Code of Virginia. Persons planning to seek federal certification as a home health agency or national accreditation pursuant to § 32.1-162.8 of the Code of Virginia shall first obtain an HCO license.</p> <p>C. The commissioner may issue a license to a home care organization authorizing the licensee to provide services at <u>A licensee may establish one or more branch offices for serving portions of the total geographic area served by the licensee parent HCO; provided if:</u></p> <ol style="list-style-type: none"> <u>1. The area served by the branch office is located within the same total geographic area as the parent HCO;</u> <u>2. each Each branch office operates under the supervision and administrative control of the licensee- parent HCO;</u> <u>3. The parent HCO submits the address of each branch office at which services are provided by the licensee shall be included on any license issued to the licensee and the name of each branch office's administrator to the OLC;</u> <u>4. The parent HCO submits policies and procedures demonstrating how it will exercise supervision and administrative control over each branch office; and</u> <u>5. The parent HCO complies with 12VAC5-381-60.</u> <p><u>A parent HCO shall operate a branch office under the parent HCO's license.</u></p> <p>D. Every home care organization shall be designated by an appropriate name. The name shall not be changed without first notifying the OLC.</p> <p>E. Licenses An HCO shall may not be transferred transfer or assigned assign its license.</p>
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			<p>F. Any person establishing, conducting, maintaining, or operating a home care organization without a license shall be guilty of a Class 6 felony according to § 32.1-162.15 of the Code of Virginia.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p> <p>INTENT: The intent of these proposed changes is to:</p> <ul style="list-style-type: none"> (i) rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; (ii) match regulatory language to statutory language; and (iii) clarify the necessary information needed by the agency if an HCO wants to open a branch office. <p>RATIONALE: The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> (i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>; (ii) reducing conflicts between regulatory language and statutory language reduces confusion for readers; and (iii) explaining the process to open a branch office in greater detail should result in applicants being better prepared for the process. <p>LIKELY IMPACT: The likely impact of these proposed changes is improved readability of the section and improved clarity regarding branch offices.</p>
381-30	N/A	<p>12VAC5-381-30. Exemption from licensure.</p> <p>A. This chapter is not applicable to those individuals and home care organizations listed in § 32.1-162.8 of the Code of Virginia. Organizations planning to seek federal certification as a home health agency or national accreditation must first obtain state licensure and provide services to clients before applying for national</p>	<p>CHANGE: The Board is proposing the following changes:</p> <p>12VAC5-381-30. Exemption from licensure.</p> <p>A. This chapter is not applicable to these individuals and home care organizations listed in § 32.1-162.8 of the Code of Virginia.; Organizations planning to seek federal certification as a home health agency or national accreditation must first obtain state</p>

		<p>accreditation or federal certification.</p> <p>In addition, this chapter is not applicable to those providers of only homemaker, chore or companion services as defined in 12VAC5-381-10.</p> <p>B. A licensed organization requesting exemption must file a written request and pay the required fee stated in 12VAC5-381-70 D.</p> <p>C. The home care organization shall be notified in writing if the exemption from licensure has been granted. The basis for the exemption approval will be stated and the organization will be advised to contact the OLC to request licensure should it no longer meet the requirement for exemption.</p> <p>D. Exempted organizations are subject to complaint investigations in keeping with state law.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p>	<p>licensure and provide services to clients before applying for national accreditation or federal certification.</p> <p>In addition, this chapter is not applicable to those providers of only homemaker, chore, or companion services as defined in 12VAC5-381-10.</p> <p><u>A. This chapter may not apply to:</u></p> <ol style="list-style-type: none"> <u>1. Natural persons who provide services to a client or patient on an individual basis if such natural person is:</u> <ol style="list-style-type: none"> <u>a. Acting alone under a medical plan of care and is licensed to provide such services pursuant to Title 54.1 of the Code of Virginia; or</u> <u>b. Retained by the client, patient, or by another natural person acting on the client's or patient's behalf;</u> <u>2. Organizations providing only homemaker, chore, or companion services as defined in 12VAC5-381-10;</u> <u>3. Hospice and hospice facilities licensed pursuant to Article 7 (§ 32.1-162.1 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia; and</u> <u>4. HCOs that receive federal certification as a home health agency or are accredited by any organization recognized by the U.S. Centers for Medicare and Medicaid Services for the purposes of Medicare certification.</u> <p>B. A licensed organization A person requesting an exemption pursuant to subdivisions 1, 2, or 4 of subsection A of this section shall requesting exemption must file submit a written request for exemption with the director of the OLC and pay the required fee stated in prescribed by subsection D of 12VAC5-381-70 D. The OLC shall consider the submission date of an exemption request to be the</p>
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			<p><u>date it is postmarked or the date it is received, whichever is earlier.</u></p> <p>G. C. The OLC home care organization shall be notified <u>notify in writing the person requesting an exemption pursuant to subsection B of this section in writing</u> if the exemption from licensure has been granted. The basis for the exemption approval will be stated and the organization will be advised to contact the OLC to request licensure should it no longer meet the requirement for exemption.</p> <p>D. Exempted organizations <u>D. An HCO that has been granted an exemption pursuant to subdivisions 4 of subsection A of this section are shall:</u></p> <ol style="list-style-type: none"> <u>1. Be subject to complaint investigations in keeping with state law;; and</u> <u>2. Notify the OLC in writing no more than two business days after losing licensure exemption eligibility.</u> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p> <p>INTENT: The intent of these proposed changes is to:</p> <ol style="list-style-type: none"> (i) rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; (ii) match regulatory language to statutory language; and (iii) clarify the exemption process and the requirement to notify the agency if exemption eligibility is lost. <p>RATIONALE: The rationale behind these proposed changes is:</p> <ol style="list-style-type: none"> (i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>; (ii) reducing conflicts between regulatory language and statutory language reduces confusion for readers; and (iii) explaining the exemption process in greater detail should result in
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			<p>applicants being better prepared for the process.</p> <p>LIKELY IMPACT: The likely impact of these proposed changes is improved readability of the section and improved clarity regarding the exemption process.</p>
N/A	381-35	N/A	<p>CHANGE: The Board is proposing to add a new section as follows:</p> <p><u>12VAC5-381-35. Total geographic area and office location.</u></p> <p><u>A. On every application for licensure, an applicant or licensee shall indicate the total geographic area it intends to serve, which the applicant or licensee shall elect to be either:</u></p> <ol style="list-style-type: none"> <u>1. A single health planning region, as defined by 12VAC5-220-10; or</u> <u>2. A single planning district, as defined by 12VAC5-220-10, and any planning districts that are contiguous to the selected planning district.</u> <p><u>B. The location of the parent HCO's office and of any branch office or drop site of an HCO shall be located:</u></p> <ol style="list-style-type: none"> <u>1. In a building that is zoned for business or commercial use or if in a mixed use zoned building, in a unit zoned for business or commercial use; and</u> <u>2. In the total geographic area it serves.</u> <p><u>An HCO shall submit proof of valid occupancy, such as a lease, rental agreement, or deed, of any building serving as the location of the parent HCO's office, of any branch office, or drop site.</u></p> <p><u>C. An HCO licensed on or before the effective date of this section shall comply with the provisions of this section within one year of the effective date of this section.</u></p> <p>Statutory Authority</p>

			<p><u>§§ 32.1-162.9 and 32.1-162.12 of the Code of Virginia.</u></p> <p>INTENT: The intent of these proposed changes is to:</p> <ul style="list-style-type: none"> (i) write this section in the active voice and break paragraphs with multiple requirements into subparts; (ii) clarify what constitutes total geographic area (iii) clarify that HCO offices, branch offices, and drop sites cannot be in residential spaces; and (iv) give existing regulants time to comply. <p>RATIONALE: The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> (i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>; (ii) the agency believes that either option for total geographic area in the proposed subsection A represents large swaths of the Commonwealth in which a parent HCO could still reasonably exercise administrative control over its branch offices; (iii) allowing HCOs to conduct their businesses out of residential spaces places the agency's inspectors in potentially dangerous circumstances and is inconsistent with the other licensure programs administered by the agency; and (iv) one year should be sufficient time for an HCO to move locations, if necessary, and to determine what its new total geographic area is. <p>LIKELY IMPACT: The likely impact of these proposed changes is improved readability of the section and improved clarity about the operation of HCO offices, drop sites, and branch offices.</p>
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</p>	<p>CHANGE: The Board is proposing the following changes:</p>

	<p>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 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>Statutory Authority</p>	<p>12VAC5-381-40. License application; Request for initial license issuance 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 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>A. An applicant shall:</p>
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		<p>§§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p>	<p><u>1. Submit an application for initial licensure to the OLC;</u></p> <p><u>2. Identify the services that it intends to perform at its proposed HCO;</u></p> <p><u>3. Identify the total geographic area it intends to serve with its proposed HCO;</u></p> <p><u>4. Disclose to the OLC the ownership interest of the proposed HCO and in the case of corporations, identify by name and address all individuals or entities holding 5.0% or more of total ownership; and</u></p> <p><u>5. Shall pay the fee prescribed by 12VAC5-381-70.</u></p> <p><u>B. Each HCO and any branch office disclose upon each application filed with the OLC:</u></p> <p><u>1. Its legal business name, which shall be distinct; and</u></p> <p><u>2. Any fictitious business name that the HCO or branch office may use.</u></p> <p><u>C. The commissioner shall consider an application complete when all requested information and the nonrefundable application fee are received by the OLC. The commissioner may deny licensure to an applicant whose application has been incomplete for more than 180 calendar days.</u></p> <p><u>D. An applicant shall notify the OLC in writing that it is ready for the initial licensure inspection. The commissioner may deny licensure to an applicant who delays or attempts to delay its initial licensure inspection.</u></p> <p><u>E. The OLC shall notify the applicant of the time and date of the initial licensure inspection. The director of the OLC, at his discretion, may waive the initial licensure inspection for an applicant seeking initial licensure due to a change of ownership of an HCO that is or was licensed.</u></p>
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			<p><u>F. As part of the initial licensure inspection, an applicant shall:</u></p> <ol style="list-style-type: none"><u>1. Make available to an inspector any requested records;</u><u>2. Allow an inspector access to interview the agents, employees, independent contractors, and any person under the applicant's control, direction, or supervision; and</u><u>3. Permit an inspector to enter upon and into the property of any proposed HCO to inspect or investigate as the inspector reasonably deems necessary in order to determine the state of compliance with the provisions of this chapter and all laws administer by the board.</u> <p><u>The commissioner may deny licensure to an applicant who does not comply with this subsection.</u></p> <p><u>G. An applicant may voluntarily terminate an initial licensure inspection at any time during the inspection. The commissioner may deny licensure to any applicant who voluntarily terminates an initial licensure inspection.</u></p> <p><u>H. The OLC shall provide a written inspection report to the applicant after the initial licensure inspection. If the OLC cites one or more licensing violations in the written inspection report, the administrator shall submit a written plan of correction in accordance with the provisions of 12VAC5-381-105. The commissioner may deny licensure to an applicant who does not comply with this subsection.</u></p> <p><u>I. An applicant may:</u></p> <ol style="list-style-type: none"><u>1. Withdraw its application at any time; and</u><u>2. Reapply for licensure, provided that it pays the fee prescribed by 12VAC5-381-70, if:</u><ol style="list-style-type: none"><u>a. It withdraws its application pursuant to</u>
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			<p><u>subdivision 1 of this subsection; or</u></p> <p><u>b. The commissioner denies it initial licensure pursuant to this section, except that if the commissioner has denied an applicant licensure a total of three times, the applicant may not reapply for a license for a period of two years from the date of the third denial.</u></p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p> <p>INTENT: The intent of these proposed changes is to:</p> <ul style="list-style-type: none"> (i) write this section in the active voice and break paragraphs with multiple requirements into subparts; (ii) clarify the initial licensure process; and (iii) clarify the causes for which the State Health Commissioner may deny an initial license. <p>RATIONALE: The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> (i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>; (ii) the initial licensure process is multi-stage and explaining it in greater detail should result in applicants being better prepared for the process; and (iii) applicants should be made aware of what action or inaction of theirs may cause the State Health Commissioner to deny them an initial license. <p>LIKELY IMPACT: The likely impact of these proposed changes is improved readability of the section and improved clarity regarding the initial licensure process.</p>
N/A	381-45	N/A	<p>CHANGE: The Board is proposing to add a new section as follows:</p>

			<p><u>12VAC5-381-45. License expiration and renewal.</u></p> <p><u>A. Licenses shall expire at midnight July 31st following the date of issue and may be renewed annually, upon filing of a renewal application and payment of the nonrefundable renewal application fee prescribed by 12VAC5-381-70. The commissioner shall renew a license only after the OLC determines that the HCO is in compliance with this chapter and that the licensee and any person having an ownership interest in the licensee have not been sanctioned pursuant to 42 U.S.C. § 1320a-7b.</u></p> <p><u>B. An HCO shall submit a license renewal application to the OLC no fewer than 60 calendar days prior to the expiration date of the current license. An HCO that submits a license renewal application fewer than 60 calendar days prior to the expiration date of the current license shall pay the nonrefundable late fee prescribed by 12VAC5-381-70 in addition to the nonrefundable renewal application fee prescribed by 12VAC5-381-70. The OLC shall consider the submission date of an application to be the date it is postmarked or the date it is received, whichever is earlier.</u></p> <ol style="list-style-type: none"> <u>1. An HCO may not make any material change to its licensure record on its license renewal application.</u> <u>2. If an HCO intends to make a material change to its licensure record, the HCO shall separately file for a material change to its license, which it may file concurrently with its license renewal application, provided it pays the nonrefundable fee for material change of license prescribed by 12VAC5-381-70</u> <p><u>C. Should an active license expire before a new license is issued, the prior active license shall remain in effect provided that the licensee submitted a</u></p>
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			<p><u>complete and accurate application prior to its expiration.</u></p> <p><u>D. An HCO that fails to submit a plan of correction as required in 12VAC5-381-105 may not renew its license.</u></p> <p><u>E. An HCO whose license has expired for 30 calendar days or fewer shall comply with 12VAC5-381-65 to reinstate its license and shall pay the nonrefundable reinstatement fee prescribed by 12VAC5-381-70. An HCO whose license has expired for more than 30 calendar days shall comply with 12VAC5-381-40 to receive a new license.</u></p> <p><u>1. The OLC shall notify in writing the Department of Medical Assistance Services on September 15th of each calendar year with the names, license numbers, and locations of any HCO that failed to timely renew its license and failed to apply for reinstatement of its expired license.</u></p> <p><u>F. An HCO that ceases operation for any period of time and wishes to resume may not apply for reinstatement, but shall apply for a new license pursuant to 12VAC5-381-40.</u></p> <p>Statutory Authority <u>§§ 32.1-12 and 32.1-162.9 of the Code of Virginia.</u></p> <p>INTENT: The intent of these proposed changes is to:</p> <ul style="list-style-type: none"> (i) write this section in the active voice and break paragraphs with multiple requirements into subparts; (ii) clarify the license expiration and renewal process, and how it intersects with material changes to the license; and (iii) clarify a regulant's options if it fails to timely renew its license. <p>RATIONALE: The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> (i) the active voice and the use of subparts are the style preferred
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			<p>and recommended by <i>The Virginia Register of Regulations</i>;</p> <p>(ii) license reissuance routinely confused regulants particularly when they were trying to initiate a material change to their license at the same time they were trying to renew their license. The agency anticipates that the revised terminology and additional clarifying language will reduce confusion; and</p> <p>(iii) providing regulants notice of the consequences that result from failing to timely renew should provide sufficient incentive to timely renew.</p> <p>LIKELY IMPACT: The likely impact of these proposed changes is improved readability of the section and improved clarity regarding the license renewal and expiration process.</p>
381-50	N/A	<p>12VAC5-381-50. Compliance appropriate for all types of HCOs.</p> <p>All organizations shall be in compliance with Part I (12VAC5-381-10 et seq.) and Part II (12VAC5-381-150 et seq.) of this chapter. In addition, organizations shall be in compliance with Part III (12VAC5-381-300 et seq.), Part IV (12VAC5-381-350), or Part V (12VAC5-381-360 et seq.) of this chapter as applicable to the services provided by the organization.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p>	<p>CHANGE: The Board is proposing to repeal this section in its entirety.</p> <p>INTENT: The intent of this proposed change is to remove irrelevant information from the regulations.</p> <p>RATIONALE: The rationale behind this proposed change is that it is unnecessary to specify that requirements for a particular service are only applicable to HCOs offering that same particular service.</p> <p>LIKELY IMPACT: There is likely no impact to this repeal.</p>
381-60	N/A	<p>12VAC5-381-60. Changes to or reissue of a license.</p> <p>A. It is the responsibility of the organization's governing body to maintain a current and accurate license. Licenses that are misplaced or lost must be replaced.</p> <p>B. An organization shall give written notification 30 working days in advance of any proposed changes that may require the</p>	<p>CHANGE: The Board is proposing the following changes:</p> <p><u>12VAC5-381-60. Changes to or reissue of a Surrender of license; material change of license.</u></p> <p>A. <u>It is the responsibility of the organization's governing body to An HCO shall maintain a current an active and accurate license at all times, which shall include a listing of all branch</u></p>

		<p>reissuance of a license. Notices shall be sent to the attention of the director of the OLC.</p> <p>The following changes require the reissuance of a license and payment of a fee:</p> <ol style="list-style-type: none"> 1. Operator; 2. Organization name; or 3. Address. <p>C. The OLC will evaluate written information about any planned changes in operation that affect the terms of the license or the continuing eligibility for a license. A licensing representative may inspect the organization during the process of evaluating a proposed change.</p> <p>D. The organization will be notified in writing whether a new application is needed.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p>	<p>offices an HCO may have. Licenses that are misplaced or lost must be replaced.</p> <p>B. An organization HCO shall give written notification notify the director of the OLC in writing by submitting an application no less than 30 working calendar days in advance of any proposed changes that may require the reissuance of a license. Notices shall be sent to the attention of the director of the OLC implementing any of the following material changes-:</p> <p>The following changes require the reissuance of a license and payment of a fee:</p> <ol style="list-style-type: none"> 1. Operator Change of location of a parent HCO or any branch office; 2. Organization name Change of name of a parent HCO or any branch office; or 3. Address Change of services being provided-; 4. Change of total geographic area served; 5. Addition of any new branch office; or 6. Voluntary closure of a parent HCO or any branch office. <p>An HCO shall pay the nonrefundable fee for material change of license prescribed by 12VAC5-381-70 with each application filed. The OLC shall consider the submission date of an application to be the date it is postmarked or the date it is received, whichever is earlier.</p> <p>C. The commissioner may not consider a change of ownership of an HCO to be a material change of license. If an HCO intends to implement a change of ownership, it shall file for a new license, in accordance with 12VAC5-381-40, no less than 30 calendar days in advance of any ownership change, and shall surrender its prior license issued by the commissioner to the OLC upon receipt of the new license..</p>
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			<p><u>E. An HCO shall surrender the license issued by the commissioner to the OLC upon receipt of the changed license.</u></p> <p><u>F. If an HCO is no longer operational, it shall:</u></p> <ol style="list-style-type: none"> <u>1. Surrender its license to the OLC no more than five calendar days after the HCO ceases operations; and</u> <u>2. Notify clients, patients, and the OLC where all clinical records are be located no more than five calendar days after the HCO ceases operations.</u> <p>C. G. <u>The OLC will evaluate written information about any planned changes in operation that shall determine if any changes listed in subsection B affect the terms of the license or the continuing eligibility for a license. A licensing representative An inspector may inspect the organization HCO during the process of evaluating a proposed change.</u></p> <p>D-F. <u>The organization OLC will be notified shall notify in writing the HCO whether a new application is needed if the commissioner will issue a changed license.</u></p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p> <p>INTENT: The intent of these proposed changes is to:</p> <ol style="list-style-type: none"> (i) rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; (ii) clarify what constitutes a material change to a license and the process for material changes to the license; and (iii) remove confusing language about license reissuance. <p>RATIONALE: The rationale behind these proposed changes is:</p> <ol style="list-style-type: none"> (i) the active voice and the use of subparts are the style preferred
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			<p>and recommended by <i>The Virginia Register of Regulations</i>;</p> <p>(ii) The items identified in the proposed subsection B of this section materially affect an HCO's licensure record and in turn the agency's oversight of the HCO, and need to be timely communicated to the agency; and</p> <p>(iii) license reissuance routinely confused regulants particularly when they were trying to initiate a material change to their license at the same time they were trying to renew their license. The agency anticipates that the revised terminology will be less confusing.</p> <p>LIKELY IMPACT: The likely impact of these proposed changes is improved readability of the section and improved clarity about what changes are reportable to the agency and the process by which to report those changes.</p>
N/A	381-65	N/A	<p>CHANGE: The Board is proposing to add a new section as follows:</p> <p><u>12VAC5-381-65. License reinstatement.</u></p> <p><u>A. The commissioner shall reinstate a license only after the OLC determines that an HCO is in compliance with this chapter and that the licensee and any person having an ownership interest in the HCO have not been sanctioned pursuant to 42 U.S.C. § 1320a-7b.</u></p> <p><u>B. An HCO applying for reinstatement of its license shall:</u></p> <ol style="list-style-type: none"> <u>1. Submit an application for reinstatement of licensure to the OLC;</u> <u>2. Identify the services that it intends to perform at its HCO;</u> <u>3. Identify the total geographic area it intends to serve with its HCO;</u> <u>4. Disclose to the OLC the ownership interest of the HCO</u>

			<p><u>and in the case of corporations, identify by name and address all individuals or entities holding 5.0% or more of total ownership; and</u></p> <p><u>5. Shall pay the fee prescribed by 12VAC5-381-70.</u></p> <p><u>The OLC shall consider the submission date of an application to be the date it is postmarked or the date it is received, whichever is earlier.</u></p> <p><u>C. The commissioner shall consider an application complete when all requested information and the nonrefundable application fee are received by the OLC. The commissioner may deny reinstatement of licensure to an HCO whose application has been incomplete for more than 60 calendar days.</u></p> <p><u>D. The OLC may conduct a reinstatement licensure inspection. As part of a reinstatement licensure inspection, an applicant shall:</u></p> <ol style="list-style-type: none"><u>1. Make available to an inspector any requested records;</u><u>2. Allow an inspector access to interview the agents, employees, independent contractors, and any person under the applicant's control, direction, or supervision; and</u><u>3. Permit an inspector to enter upon and into the property of any HCO to inspect or investigate as the inspector reasonably deems necessary in order to determine the state of compliance with the provisions of this chapter and all laws administer by the board.</u> <p><u>The commissioner may deny reinstatement of licensure to an HCO who does not comply with this subsection.</u></p> <p><u>E. An HCO may voluntarily terminate a reinstatement licensure inspection at any time during the inspection. The commissioner may</u></p>
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			<p><u>deny reinstatement of licensure to any HCO who voluntarily terminates a reinstatement licensure inspection.</u></p> <p><u>F. The OLC shall provide a written inspection report to the HCO. If the OLC cites one or more licensing violations in the written inspection report, the administrator shall submit a written plan of correction in accordance with the provisions of 12VAC5-381-105.</u></p> <p><u>G. An HCO may:</u></p> <ol style="list-style-type: none"><u>1. Withdraw its reinstatement application at any time; and</u><u>2. Reapply for licensure pursuant to 12VAC5-381-40, provided that it pays the fee prescribed by 12VAC5-381-70, if:</u><ol style="list-style-type: none"><u>a. It withdraws its application pursuant to subdivision 1 of this subsection; or</u><u>b. The commissioner denies it reinstatement of licensure pursuant to this section, except that if the commissioner has denied an HCO reinstatement of licensure three times, the applicant may not apply for a new license for a period of two years from the date of the third denial.</u> <p><u>H. If the commissioner reinstates a license pursuant to this section, the effective date of the license shall be August 1 of the calendar year in which the HCO's prior license expired.</u></p> <p>Statutory Authority <u>§§32.1-12 and 32.1-162.9 of the Code of Virginia.</u></p> <p>INTENT: The intent of these proposed changes is to:</p> <ol style="list-style-type: none">(i) write this section in the active voice and break paragraphs with multiple requirements into subparts; and(ii) create a new licensure process for those HCOs that fail to timely renew their license and wish to
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			<p>remedy the situation within 30 days of expiration.</p> <p>RATIONALE: The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> (i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>; and (ii) a licensure reinstatement process allows for some flexibility when an HCO does not timely renew, but still involves sufficient deterrents (such as the higher fee to reinstate a license) that HCOs should be remain incentivized to timely renew. <p>LIKELY IMPACT: The likely impact of these proposed changes is improved readability of the section and improved clarity about a regulant's options if it fails to timely renew its license.</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 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>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p>	<p>CHANGE: The Board is proposing the following changes:</p> <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. The department shall charge the following fees related to licensure and inspection of HCOs:</p> <table border="1" data-bbox="959 1354 1414 1833"> <tr> <td><u>Application fee for initial licensure</u></td> <td><u>\$2,000</u></td> </tr> <tr> <td><u>Re-application fee for initial licensure</u></td> <td><u>\$2,000</u></td> </tr> <tr> <td><u>Base application fee for renewal of licensure</u></td> <td><u>\$1,250</u></td> </tr> <tr> <td><u>Additional renewal fee for each branch office</u></td> <td><u>\$500</u></td> </tr> <tr> <td><u>Application fee for reinstatement of licensure</u></td> <td><u>\$2,500</u></td> </tr> <tr> <td><u>Additional reinstatement fee for each branch office</u></td> <td><u>\$750</u></td> </tr> </table>	<u>Application fee for initial licensure</u>	<u>\$2,000</u>	<u>Re-application fee for initial licensure</u>	<u>\$2,000</u>	<u>Base application fee for renewal of licensure</u>	<u>\$1,250</u>	<u>Additional renewal fee for each branch office</u>	<u>\$500</u>	<u>Application fee for reinstatement of licensure</u>	<u>\$2,500</u>	<u>Additional reinstatement fee for each branch office</u>	<u>\$750</u>
<u>Application fee for initial licensure</u>	<u>\$2,000</u>														
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<u>Base application fee for renewal of licensure</u>	<u>\$1,250</u>														
<u>Additional renewal fee for each branch office</u>	<u>\$500</u>														
<u>Application fee for reinstatement of licensure</u>	<u>\$2,500</u>														
<u>Additional reinstatement fee for each branch office</u>	<u>\$750</u>														

			<table border="1"> <tr> <td><u>Processing fee for exemption from licensure</u></td> <td><u>\$125</u></td> </tr> <tr> <td><u>Duplicate license fee</u></td> <td><u>\$25</u></td> </tr> <tr> <td><u>Fee for material change of license</u></td> <td><u>\$250</u></td> </tr> <tr> <td><u>Returned check fee</u></td> <td><u>\$50</u></td> </tr> </table> <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 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><u>B. In addition to the fees described in subsection A, the department shall charge a late fee of \$500 for any HCO that applies to renew its license fewer than 60 calendar days in advance of the license's expiration date.</u></p> <p><u>C. Unless otherwise provided, fees may not be refunded.</u></p> <p>Statutory Authority <u>§§ 32.1-12, 32.1-162.9, and 32.1-162.12 of the Code of Virginia.</u></p> <p>INTENT: The intent of these proposed changes is to:</p> <ul style="list-style-type: none"> (i) improve the readability of the fee schedule; (ii) increase fee revenue for the HCO licensure program; and (iii) clarify fees are nonrefundable. <p>RATIONALE: The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> (i) it is easier to identify the correct fees listed in a table rather than described in a narrative paragraph; (ii) the agency does not have sufficient fee revenue to support the staff needed to exercise effective oversight for HCOs and the fee structure should reflect 	<u>Processing fee for exemption from licensure</u>	<u>\$125</u>	<u>Duplicate license fee</u>	<u>\$25</u>	<u>Fee for material change of license</u>	<u>\$250</u>	<u>Returned check fee</u>	<u>\$50</u>
<u>Processing fee for exemption from licensure</u>	<u>\$125</u>										
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<u>Fee for material change of license</u>	<u>\$250</u>										
<u>Returned check fee</u>	<u>\$50</u>										

			<p>that inspection of branch offices are part of the larger HCO licensure inspection, which constitutes an additional cost to the agency beyond what an HCO without a branch office would cost to inspect; and</p> <p>(iii) removing ambiguity regarding whether fees can be refunded.</p> <p>LIKELY IMPACT: The likely impact of these proposed changes is reduced confusion for regulants on what fee is owed and sufficient fee revenue to support additional staff necessary to complete all inspections.</p>
381-80	N/A	<p>12VAC5-381-80. On-site inspections.</p> <p>A. An OLC representative shall make periodic unannounced on-site inspections of each home care organization as necessary but not less often than biennially. The organization shall be responsible for correcting any deficiencies found during any on-site inspection. Compliance with all standards will be determined by the OLC according to applicable law.</p> <p>B. The home care organization shall make available to the OLC's representative any necessary records and shall allow access to interview the agents, employees, contractors, and any person under the organization's control, direction or supervision.</p> <p>C. After the on-site inspection, the OLC's representative shall discuss the findings of the inspection with the administrator or his designee.</p> <p>D. The administrator shall submit, within 15 working days of receipt of the inspection report, an acceptable plan for correcting any deficiencies found. The plan of correction shall contain:</p> <ol style="list-style-type: none"> 1. A description of the corrective action or actions to be taken and the personnel to implement the corrective action; 	<p>CHANGE: The Board is proposing the following changes:</p> <p>12VAC5-381-80. On-site inspections.</p> <p>A. An <u>The</u> OLC representative shall make periodic unannounced on-site inspections of each home care organization <u>HCO</u> as necessary but not less often than biennially <u>triennially</u>. The organization shall be responsible for correcting any deficiencies found during any on-site inspection. Compliance with all standards will be determined by the OLC according to applicable law.</p> <p>B. The home care organization <u>HCO</u> shall make available to the OLC's representative <u>inspector</u> any necessary <u>requested</u> records and shall allow access to interview the agents, employees, <u>independent</u> contractors, and any person under the organization's <u>HCO's</u> control, direction, or supervision.</p> <ol style="list-style-type: none"> 1. <u>If an inspector arrives on the premises to conduct an inspection and a person authorized to give access to clinical records is not available on the premises, the person or the designated alternate shall be available on the premises no more than one hour after the inspector's arrival.</u> 2. <u>Upon request of the inspector and no more than</u>

		<p>2. The expected correction date;</p> <p>3. A description of the measures implemented to prevent a recurrence of the violation; and</p> <p>4. The signature of the person responsible for the validity of the report.</p> <p>E. The administrator will be notified whenever any item in the plan of correction is determined to be unacceptable.</p> <p>F. The administrator shall be responsible for assuring the plan of correction is implemented and monitored so that compliance is maintained.</p> <p>G. Completion of corrective actions shall not exceed 45 working days from the last day of the inspection.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p>	<p><u>two hours after the inspector's arrival, the HCO shall provide to the inspector a list of all of the HCO's clients and patients for the previous 12 months.</u></p> <p><u>3. If copies of records are removed from the premises, the HCO may redact names and addresses of clients or patients contained in such records prior to removal.</u></p> <p><u>4. The inspector shall inform the HCO that it may redact names and addresses of clients or patients prior to the inspector removing copies of records from the premises.</u></p> <p>C. <u>As part of any inspection, an inspector may conduct home visits with the consent of the client, patient, or his legal representative. The HCO:</u></p> <p><u>1. Shall arrange for the inspector in-home visits with the client, patient, or his legal representative, upon the inspector's request;</u></p> <p><u>2. Shall explain clearly to the client, patient, or his legal representative that a home visit is voluntary and that refusing a home visit will not affect his care;</u></p> <p><u>3. Shall obtain signed consent from the client, patient, or his legal representative;</u></p> <p><u>4. May not terminate a client or patient if he or his legal representative consents to or refuses a home visit; and</u></p> <p><u>5. May not interfere or prevent an inspector's or the department's communication with or to clients, patients, or their legal representatives, either as part of a home visit or as part of the inspection process.</u></p> <p>D. <u>After the on-site inspection, the OLC's representative OLC shall discuss the findings of the inspection with provide a written inspection report</u></p>
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			<p>to the administrator or his designee. If the OLC cites one or more licensing violations in the written inspection report, the administrator shall submit a plan of correction in accordance with 12VAC5-381-105.</p> <p>D. The administrator shall submit, within 15 working days of receipt of the inspection report, an acceptable plan for correcting any deficiencies found. The plan of correction shall contain:</p> <ol style="list-style-type: none">1. A description of the corrective action or actions to be taken and the personnel to implement the corrective action;2. The expected correction date;3. A description of the measures implemented to prevent a recurrence of the violation; and4. The signature of the person responsible for the validity of the report. <p>E. The administrator will be notified whenever any item in the plan of correction is determined to be unacceptable.</p> <p>F. The administrator shall be responsible for assuring the plan of correction is implemented and monitored so that compliance is maintained.</p> <p>G. Completion of corrective actions shall not exceed 45 working days from the last day of the inspection.</p> <p>Statutory Authority §§ 32.1-12, <u>32.1-162.9</u>, and 32.1-162.12 of the Code of Virginia.</p> <p>INTENT: The intent of these proposed changes is to:</p> <ol style="list-style-type: none">(i) rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; and(ii) consolidate relevant sections of the regulation by moving the home visit requirements to this section;
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			<p>(iii) impose time limits around the initiation of an inspection;</p> <p>(iv) affords HCOs the right to redact portions of records; and</p> <p>(v) move plans of corrections to a new section.</p> <p>RATIONALE: The rationale behind these proposed changes is:</p> <p>(i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>;</p> <p>(ii) consolidating relevant sections of the regulation allows regulants to more easily locate these requirements;</p> <p>(iii) promotes efficient and effective use of agency resources during inspections by requiring initiation of the inspection within a certain amount of time</p> <p>(iv) ensures the privacy of clients and patients; and</p> <p>(v) since plans of corrections may occur following any inspection, moving plan of correction language to a new section ensure its requirements are consistent across all occurrences end.</p> <p>LIKELY IMPACT: The likely impact of these proposed changes is improved readability of the section, improved inspection completion time, and reduced confusion for regulants.</p>
381-90	N/A	<p>12VAC5-381-90. Home visits.</p> <p>A. As part of any inspection, an OLC representative may conduct home visits.</p> <p>B. The home care organization shall be responsible for arranging in-home visits with clients, family members, and caregivers for the OLC representative.</p> <p>C. The organization shall explain clearly to the client, family or caretaker that the permission for the representative's home visit is voluntary and that consent to the home visit will not affect the client's care or other health benefits.</p>	<p>CHANGE: The Board is proposing to repeal this section in its entirety.</p> <p>INTENT: The intent of this proposed change is to consolidate relevant sections of the regulation by moving these requirements to 12VAC5-381-80.</p> <p>RATIONALE: The rationale behind this proposed change is that this repeal consolidates relevant sections of the regulation so regulants can more easily locate these requirements.</p> <p>LIKELY IMPACT: There is likely no impact as this repeal moving these requirements to 12VAC5-381-80.</p>

		<p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p>	
<p>381-100</p>	<p>N/A</p>	<p>12VAC5-381-100. Complaint investigations conducted by the OLC.</p> <p>A. The OLC has the responsibility to investigate any complaints regarding alleged violations of this chapter and applicable law.</p> <p>B. Complaints may be received in writing or orally and may be anonymous.</p> <p>C. When the investigation is complete, the licensee and the complainant, if known, will be notified of the findings of the investigation.</p> <p>D. As applicable, the administrator shall submit, within 15 working days of receipt of the complaint report, an acceptable plan of correction for any deficiencies found during a complaint investigation. The plan of correction shall contain:</p> <ol style="list-style-type: none"> 1. A description of the corrective action or actions to be taken and the personnel to implement the corrective action; 2. The expected correction date; 3. A description of the measures implemented to prevent a recurrence of the violation; and 4. The signature of the person responsible for the validity of the report. <p>E. The administrator will be notified in writing whenever any item in the plan of correction is determined to be unacceptable.</p> <p>F. The administrator shall be responsible for assuring the plan of correction is implemented and monitored so that compliance is maintained.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p>	<p>CHANGE: The Board is proposing the following changes:</p> <p>12VAC5-381-100. Complaint investigations conducted by the OLC.</p> <p>A. The OLC has the responsibility to <u>shall</u> investigate any complaints regarding alleged violations of this chapter and applicable law. <u>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 HCO's regulatory history, including the number of substantiated prior complaints;</u> <u>3. If the OLC has recently inspected the HCO, 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 clients or patients.</u> <p><u>B. The OLC may request records from an HCO to assist in making a determination pursuant to subsection A of this section. An HCO shall provide the requested records no more than two calendar days after OLC makes a request pursuant to this subsection.</u></p> <p><u>C. When the investigation is complete, the OLC shall notify the HCO and the complainant, if known, in writing of the findings of the investigation.</u></p> <p>B. Complaints may be received in writing or orally and may be anonymous.</p> <p>C. When the investigation is complete, the licensee and the</p>

			<p>complainant, if known, will be notified of the findings of the investigation.</p> <p>D. As applicable, the administrator shall submit, within 15 working days of receipt of the complaint report, an acceptable plan of correction for any deficiencies found during a complaint investigation. The plan of correction shall contain:</p> <ol style="list-style-type: none">1. A description of the corrective action or actions to be taken and the personnel to implement the corrective action;2. The expected correction date;3. A description of the measures implemented to prevent a recurrence of the violation; and4. The signature of the person responsible for the validity of the report. <p>E. The administrator will be notified in writing whenever any item in the plan of correction is determined to be unacceptable.</p> <p>F. The administrator shall be responsible for assuring the plan of correction is implemented and monitored so that compliance is maintained.</p> <p><u>D. For any licensing violation cited during a complaint investigation, the administrator shall submit a plan of correction in accordance with 12VAC5-381-105.</u></p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p> <p>INTENT: The intent of these proposed changes is to:</p> <ol style="list-style-type: none">(i) rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; and(ii) give the OLC the flexibility to determine whether a complaint warrants an on-site inspection.
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			<p>RATIONALE: The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> (i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>; and (ii) encouraging efficient and effective use of agency resources in responding to complaints. <p>LIKELY IMPACT: The likely impact of these proposed changes is improved readability of the section and a more adaptive and efficient complaint process.</p>
N/A	381-105	N/A	<p>CHANGE: The Board is proposing to add a new section as follows:</p> <p><u>12VAC5-381-105. 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 licensing 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 business days after receipt of the inspection report. The plan of correction shall contain for each licensing violation cited:</u></p> <ul style="list-style-type: none"> <u>1. A description of the corrective action or actions to be taken and the position title of the employees to implement the corrective action. If employees share the same position title, the administrator shall assign the employees a unique identifier to distinguish them;</u> <u>2. The expected correction date, not to exceed 45 business days from the exit date of the inspection; and</u> <u>3. A description of the measures implemented to prevent a recurrence of the licensing violation.</u> <p><u>An HCO shall ensure that the person responsible for the validity of</u></p>

			<p><u>the plan of correction signs, dates, and indicates their title on the plan of correction.</u></p> <p><u>C. The OLC shall:</u></p> <ol style="list-style-type: none"><u>1. Notify the administrator or his designee if the OLC determines any item in the plan of correction is unacceptable;</u><u>2. Grant the administrator or his designee two opportunities 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 submission is due to the OLC no more than 15 business days after the OLC has notified the administrator or his designee pursuant to subdivision 1 of this subsection.</u> <p><u>D. Upon request of the OLC, an applicant or licensee shall produce evidence, no more than two calendar days after the OLC's request, that all or part of a plan of correction has been implemented. The OLC may conduct an inspection to verify any portion of a plan of correction.</u></p> <p><u>E. The administrator shall ensure the plan of correction is implemented and monitored so that compliance is maintained.</u></p> <p><u>F. The commissioner may deny licensure, renewal of licensure, or reinstatement of licensure if an HCO's administrator fails to submit an acceptable plan of correction or fails implement an acceptable plan of correction.</u></p> <p><u>G. The OLC shall consider the submission date of a plan of correction to be the date it is postmarked or the date it is received, whichever is earlier.</u></p> <p>Statutory Authority <u>§§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</u></p>
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			<p>INTENT: The intent of these proposed changes is to:</p> <ul style="list-style-type: none"> (i) write this section in the active voice and break paragraphs with multiple requirements into subparts; and (ii) clarify the plan of correction process, including how many opportunities an HCO has to revise an unacceptable plan of correction and what the consequences of an unacceptable plan of correction are. <p>RATIONALE: The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> (i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>; and (ii) the plan of correction process needs to be more clearly explicated as current ambiguities in the regulation are cause for confusion. <p>LIKELY IMPACT: The likely impact of these proposed changes is improved readability of the section, improved consistency in oversight of HCOs following an inspection, and reduced confusion for regulators.</p>
381-110	N/A	<p>12VAC5-381-110. Criminal records checks.</p> <p>A. Section 32.1-162.9:1 of the Code of Virginia requires home care providers, as defined in § 32.1-162.7 of the Code of Virginia, to obtain a criminal record report on applicants for compensated employment from the Virginia Department of State Police. Section 32.1-162.9:1 of the Code of Virginia also requires that all applicants for employment in home care organizations provide a sworn disclosure statement regarding their criminal history.</p> <p>B. The criminal record report shall be obtained within 30 days of employment. It shall be the responsibility of the organization to ensure that its employees have not been convicted of any of the</p>	<p>CHANGE: The Board is proposing the following changes:</p> <p>12VAC5-381-110. Criminal records checks.</p> <p>A. Section 32.1-162.9:1 of the Code of Virginia requires home care providers, as defined in § 32.1-162.7 of the Code of Virginia, to <u>An HCO shall obtain a criminal record report on applicants for compensated employment from the Virginia Department of State Police no more than 30 calendar days after employment begins. An HCO shall not accept a criminal record report dated more than 90 calendar days prior to the start date of employment. Section 32.1-162.9:1 of the Code of Virginia also requires that all applicants for employment in home care</u></p>

	<p>barrier crimes listed in § 32.1-162.9:1 of the Code of Virginia.</p> <p>C. The organization shall not accept a criminal record report dated more than 90 days prior to the date of employment.</p> <p>D. Only the original criminal record report shall be accepted. An exception is permitted for organizations using temporary staffing agencies for the provision of substitute staff. The organization shall obtain a letter from the temporary staffing agency containing the following information:</p> <ol style="list-style-type: none"> 1. The name of the substitute staffing person; 2. The date of employment by the temporary staffing agency; and 3. A statement verifying that the criminal record report has been obtained within 30 days of employment, is on file at the temporary staffing agency, and does not contain any barrier crimes listed in § 32.1-162.9:1 of the Code of Virginia. <p>E. No employee shall be permitted to work in a position that involves direct contact with a patient until an original criminal record report has been received by the home care organization or temporary staffing agency, unless such person works under the direct supervision of another employee for whom a background check has been completed in accordance with subsection B of this section.</p> <p>F. A criminal record report remains valid as long as the employee remains in continuous service with the same organization.</p> <p>G. A new criminal record report and sworn statement shall be required when an individual terminates employment at one home care organization and begins work at another home care</p>	<p>organizations provide a sworn disclosure statement regarding their criminal history.</p> <p>B. The criminal record report shall be obtained within 30 days of employment. It shall be the responsibility of the organization to ensure that its employees have not been convicted of any of the barrier crimes listed in § 32.1-162.9:1 of the Code of Virginia.</p> <p>C. The organization shall not accept a criminal record report dated more than 90 days prior to the date of employment.</p> <p>D.B. An HCO may not accept duplicates or copies of Only the original criminal record report shall be accepted, except if the HCO uses: An exception is permitted for organizations</p> <ol style="list-style-type: none"> <u>1. using A temporary staffing agencies agency for the provision of substitute staff temporary employees. The organization An HCO shall obtain a letter from the temporary staffing agency containing the following information that includes:</u> <ol style="list-style-type: none"> <u>1-a. The name of the substitute staffing person temporary employee;</u> <u>2-b. The date of employment by the temporary staffing agency; and</u> <u>3-c. A statement verifying that the criminal record report has been obtained within 30 calendar days of employment at the temporary staffing agency, is on file at the temporary staffing agency, and does not contain any conviction of a barrier crimes crime listed in § 32.1-162.9:1 of the Code of Virginia.</u> <u>2. An independent contractor who will have or whose employees will have direct</u>
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	<p>organization. The following exceptions are permitted:</p> <ol style="list-style-type: none"> 1. When an employee transfers within 30 days to an organization owned and operated by the same entity. The employee's file shall contain a statement that the original criminal record report has been transferred or forwarded to the new work location. 2. When an individual takes a leave of absence, the criminal record report and sworn statement will remain valid as long as the period of separation does not exceed six consecutive months. If six consecutive months have passed, a new criminal record report and sworn disclosure statement are required. <p>H. A sworn disclosure statement shall be completed by all applicants for employment. The sworn disclosure statement shall be attached to and filed with the criminal record report.</p> <p>I. Any applicant denied employment because of convictions appearing on his criminal record report shall be provided a copy of the report by the hiring organization.</p> <p>J. All criminal record reports shall be confidential and maintained in locked files accessible only to the administrator or designee.</p> <p>K. Further dissemination of the criminal record report and sworn disclosure statement information is prohibited other than to the commissioner's representative or a federal or state authority or court as may be required to comply with an express requirement of law for such further dissemination.</p> <p>Statutory Authority</p>	<p><u>contact with a client or patient. An HCO shall obtain a letter from the independent contractor that includes:</u></p> <ol style="list-style-type: none"> a. <u>The name of the independent contractor or employee who will have direct contact with a client or patient;</u> b. <u>If the employee of the independent contractor will have direct contact with a client or patient, the date of employment with the independent contractor; and</u> c. <u>A statement verifying that the criminal record report has been obtained within 30 calendar days of becoming an independent contractor or of employment with the independent contractor, is on file with the independent contractor, and does not contain any conviction of a barrier crime.</u> <p>E.B. An HCO No employee shall be permitted to <u>may not permit a compensated employee, employee of a temporary staffing agency, or an independent contractor to work in a position that involves direct contact with a client or patient until an original criminal record report has been received by the home care organization HCO, or temporary staffing agency, or independent contractor unless such person the employee works under the direct supervision and in the presence of another HCO-compensated employee for whom a background check has been completed in accordance with subsection B A of this section.</u></p> <p>F. A criminal record report remains valid as long as the employee remains in continuous service with the same organization.</p>
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		<p>§§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p>	<p>G.C. An HCO shall obtain A a new criminal record report and a new sworn statement disclosure shall be required when if an individual:</p> <p>1. terminates Terminates compensated employment at one home care organization HCO and begins work compensated employment at another home care organization HCO, unless the HCOs are owned by the same entity. The employee's file shall contain a statement indicating the original criminal record report has been transferred or forwarded to the new work location; or. The following exceptions are permitted:</p> <p>1. When an employee transfers within 30 days to an organization owned and operated by the same entity. The employee's file shall contain a statement that the original criminal record report has been transferred or forwarded to the new work location.</p> <p>2. When an individual takes Takes a leave of absence, the criminal record report and sworn statement will remain valid as long as the period of separation does not exceed exceeding six consecutive months. If six consecutive months have passed, a new criminal record report and sworn disclosure statement are required.</p> <p>H.D. An HCO shall:</p> <p>1. Obtain from an applicant for compensated employment A a sworn disclosure statement shall be completed by all applicants for employment; and</p> <p>2. File The the sworn disclosure statement shall be attached to and filed with the criminal record report.</p>
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			<p><u>E. An HCO may not hire for compensated employment any person who has been convicted of a barrier crime, except if:</u></p> <ol style="list-style-type: none"><u>1. The person has been convicted of a single offense punishable as a misdemeanor;</u><u>2. The conviction does not involve abuse or neglect; and</u><u>3. Five years have elapsed since the conviction.</u> <p>I.F. <u>An HCO shall provide a copy of the criminal record report to Any an applicant denied compensated employment because of convictions appearing on his criminal record report shall be provided a copy of the report by the hiring organization.</u></p> <p>J.G. <u>An HCO shall maintain the confidentiality of All criminal record reports shall be confidential and maintained store criminal record reports in locked files accessible only to the administrator or designee. An HCO shall maintain an employee's criminal record report and sworn disclosure for no less than five years from the date of employment with the HCO or as otherwise provided by law.</u></p> <p>K.H. <u>An HCO may not Further dissemination disseminate of the criminal record report and sworn disclosure statement information is prohibited other than except to the commissioner's representative or a federal or state authority or court as may be required to comply with an express requirement of law for such further dissemination.</u></p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p> <p>INTENT: The intent of these proposed changes is to:</p> <ol style="list-style-type: none">(i) rewrite this section in the active voice and break paragraphs with multiple requirements into subparts;(ii) match regulatory language to statutory language; and
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			<p>(iii) address the applicability of the criminal records check requirement to independent contractors.</p> <p>RATIONALE: The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> (i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>; (ii) reducing conflicts between regulatory language and statutory language reduces confusion for readers; and (iii) there is not a significant enough difference between independent contractors and temporary staff to justify not requiring criminal records checks. <p>LIKELY IMPACT: The likely impact of these proposed changes is improved readability of this section and clarity on how to satisfy the regulatory requirements.</p>
381-120	N/A	<p>12VAC5-381-120. Variances.</p> <p>A. The OLC can authorize variances only to its own licensing regulations, not to regulations of another agency or to any requirements in federal, state, or local laws.</p> <p>B. A home care organization may request a variance to a particular regulation or requirement contained in this chapter when the standard or requirement poses a special hardship and when a variance to it would not endanger the safety or well-being of clients. The request for a variance must describe how compliance with the current regulation is economically burdensome and constitutes a special hardship to the home care organization and to the clients it serves. When applicable, the request should include proposed alternatives to meet the purpose of the requirements that will ensure the protection and well-being of clients. At no time shall a variance approved for one</p>	<p>CHANGE: The Board is proposing the following changes:</p> <p>12VAC5-381-120. Variances Allowable variances.</p> <p>A. The OLC commissioner can <u>may</u> authorize variances a variance <u>only to its own licensing regulations a specific standard or requirement of this chapter</u>, not to regulations of another agency or to any <u>standards or requirements</u> in federal, state, or local laws. <u>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 clients, patients, or the public.</u> <p>B. A home care organization A licensee <u>may request a variance at any time, to a particular regulation or requirement contained in this chapter when the standard or requirement</u></p>

	<p>individual be extended to general applicability. The home care organization may at any time withdraw a request for a variance.</p> <p>C. The OLC shall have the authority to waive, either temporarily or permanently, the enforcement of one or more of these regulations provided safety, client care and services are not adversely affected.</p> <p>D. The OLC may rescind or modify a variance if (i) conditions change; (ii) additional information becomes known that alters the basis for the original decision; (iii) the organization fails to meet any conditions attached to the variance; or (iv) results of the variance jeopardize the safety, comfort, or well-being of clients.</p> <p>E. Consideration of a variance is initiated when a written request is submitted to the Director, OLC. The OLC shall notify the home care organization in writing of the receipt of the request for a variance. The OLC may attach conditions to a variance to protect the safety and well-being of the client.</p> <p>F. The licensee shall be notified in writing if the requested variance is denied.</p> <p>G. If a variance is denied, expires, or is rescinded, routine enforcement of the regulation or portion of the regulation shall be resumed.</p> <p>H. The home care organization shall develop procedures for monitoring the implementation of any approved variances to assure the ongoing collection of any data relevant to the variance and the presentation of any later report concerning the variance as requested by the OLC.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p>	<p>poses a special hardship and when a variance to it would not endanger the safety or well-being of clients. The request for a variance must shall describe:</p> <p>1. how <u>How</u> compliance with the current regulation <u>standard or requirement is economically burdensome and constitutes a special an impractical hardship unique to the home care organization and to the clients it serves. HCO; and</u></p> <p>2. When applicable, the request should include proposed <u>Proposed</u> alternatives to meet the purpose of the <u>standard or requirements requirement</u> that will ensure the <u>protection health, safety, and well-being of clients, patients, and the public.</u></p> <p>At no time shall a variance approved for one individual be extended to general applicability. The home care organization The licensee may at any time withdraw a request for a variance at any time.</p> <p>C. The OLC shall have the authority to waive, either temporarily or permanently, the enforcement of one or more of these regulations provided safety, client care and services are not adversely affected. The commissioner shall notify the licensee 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 clients, patients, and the public.</p> <p>D. The OLC commissioner may rescind or modify a variance if:</p> <p>1. (i) conditions change The impractical hardship unique to the HCO changes or no longer exists;</p> <p>2. (ii) additional Additional information becomes known that alters the basis for the</p>
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			<p>original decision, including if the licensee failed to comply with the standard or requirement prior to receiving a variance;</p> <p>3. (iii) the organization <u>The licensee</u> fails to meet any conditions attached to the variance; or</p> <p>4. (iv) results <u>Results</u> of the variance jeopardize the <u>health, safety, comfort, or well-being of clients, patients, and the public.</u></p> <p>E. Consideration of a variance is initiated when a written request is submitted to the Director, OLC. The OLC shall notify the home care organization in writing of the receipt of the request for a variance. The OLC may attach conditions to a variance to protect the safety and well-being of the client.</p> <p>F. The licensee shall be notified in writing if the requested variance is denied.</p> <p>G. E. If a variance is denied, expires, or is rescinded, the commissioner or his designee shall routine enforcement of enforce the regulation or portion of the regulation shall be resumed standard or requirement to which the variance was granted.</p> <p>H. The home care organization The governing body of an HCO shall develop and document procedures for monitoring the implementation of any approved variances to assure the ongoing collection of any data relevant to the variance and the presentation of any later report concerning the variance as requested by the OLC variance.</p> <p>Statutory Authority</p> <p>§§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p> <p>INTENT: The intent of these proposed changes is to:</p> <p>(i) rewrite this section in the active voice and break paragraphs with</p>
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			<p>multiple requirements into subparts;</p> <ul style="list-style-type: none"> (ii) clarify that the State Health Commissioner grants variances; (iii) clarify the process for requesting a variance; and (iv) clarify that the State Health Commissioner can place conditions on variances and can rescind them. <p>RATIONALE: The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> (i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>; (ii) reducing conflicts between regulatory language and statutory language reduces confusion for readers; (iii) establishing a standardized process for variance requests ensures consistent treatment of requests; and (iv) regulants requesting variances should be given notice that variances are not permanent, the circumstances under which they may be repealed, and the consequences of losing a variance. <p>LIKELY IMPACT: The likely impact of these proposed changes is improved readability of this section and clarity on how to satisfy the regulatory requirements.</p>
130	N/A	<p>12VAC5-381-130. Revocation or suspension of a license.</p> <p>A. The commissioner is authorized to revoke or suspend any license if the licensee fails to comply with the provisions of Article 7.1 (§ 32.1-162.7 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia or the regulations of the board.</p> <p>B. If a license is revoked, the commissioner may issue a new license when the conditions upon which revocation was based have been corrected and compliance with all provisions of the law and this chapter has been achieved.</p>	<p>CHANGE: The Board is proposing the following changes:</p> <p><u>12VAC5-381-130. Violation of this chapter or applicable law; denial, Revocation revocation, or suspension of a license.</u></p> <p>A. The commissioner is authorized to <u>may deny,</u> revoke, or suspend any <u>the license to operate an HCO in accordance with the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia) if the commissioner determines that an applicant the or licensee is:</u></p>

		<p>C. When a license is revoked or suspended, the organization shall cease operations. If the organization continues to operate after its license has been revoked or suspended, the commissioner may request the Office of the Attorney General to petition the circuit court of the jurisdiction in which the home care organization is located for an injunction to cause such home care organization to cease operations.</p> <p>D. Suspension of a license shall in all cases be for an indefinite time. The suspension may be lifted and rights under the license fully or partially restored at such time as the commissioner determines that the rights of the licensee appear to so require and the interests of the public will not be jeopardized by resumption of operation.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p>	<p>1. In violation of this chapter or fails to comply with the provisions of Article 7.1 (§ 32.1-162.7 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia or the regulations of the board; or</p> <p>2. Permitting, aiding, or abetting the commission of any illegal act in the HCO.</p> <p><u>Suspension of a license shall in all cases be for an indefinite time.</u></p> <p>B. If a license is revoked, the commissioner may issue a new license when the conditions upon which revocation was based have been corrected and compliance with all provisions of the law and this chapter has been achieved. Upon receipt of a completed application and a nonrefundable application fee, the commissioner may issue a new license to an HCO that has had its license to operate an HCO revoked if the commissioner determines that:</p> <p>1. The conditions upon which revocation was based have been corrected; and</p> <p>2. The applicant is in compliance with this chapter and Article 7.1 (§ 32.1-162.7 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia.</p> <p><u>The HCO shall submit evidence relevant to subdivisions 1 and 2 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>C. When a license is revoked or suspended, the organization shall cease operations. If the organization continues to operate after its license has been revoked or suspended, the commissioner may request the Office of the Attorney General to petition the circuit court of the jurisdiction in which the home care organization is located for an injunction to cause such home care organization to cease operations.</p>
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			<p>D.C. Suspension of a license shall in all cases be for an indefinite time. The suspension may be lifted and rights under the license fully or partially restored at such time as the commissioner determines that the rights of the licensee appear to so require and the interests of the public will not be jeopardized by resumption of operation. The commissioner may partially or completely restore a suspended license to an HCO if the commissioner determines that:</p> <p><u>1. The rights of the licensee appear to require restoration; and</u></p> <p><u>2. The interests of the public will not be jeopardized by resumption of operation.</u></p> <p><u>The HCO shall submit evidence relevant to subdivisions 1 and 2 that is satisfactory to the commissioner or his designee. The commissioner or his designee may conduct an inspection prior to making a determination. No additional fee shall be required for restoring a license pursuant to this subsection.</u></p> <p><u>D. An applicant or licensee may contest the denial, revocation, or suspension of a license in accordance with the provisions of the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia).</u></p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p> <p>INTENT: The intent of these proposed changes is to:</p> <ul style="list-style-type: none"> (i) rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; and (ii) match regulatory language to statutory language. <p>RATIONALE: The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> (i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>; and
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			<p>(ii) reducing conflicts between regulatory language and statutory language reduces confusion for readers.</p> <p>LIKELY IMPACT: The likely impact of these proposed changes is improved readability of this section.</p>
381-140	N/A	<p>12VAC5-381-140. Return of a license.</p> <p>A. Circumstances under which a license must be returned include, but are not limited to (i) transfer of ownership and (ii) discontinuation of services.</p> <p>B. The licensee shall notify its clients and the OLC, in writing, 30 days before discontinuing services.</p> <p>C. If the organization is no longer operational, or the license has been suspended or revoked, the license shall be returned to the OLC within five working days. The licensee shall notify its clients and the OLC where all home care records will be located.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p>	<p>CHANGE: The Board is proposing to repeal this section in its entirety.</p> <p>INTENT: The intent of this proposed change is to consolidate relevant sections of the regulation by moving these requirements to 12VAC5-381-60.</p> <p>RATIONALE: The rationale behind this proposed change is that this repeal consolidates relevant sections of the regulation so regulants can more easily locate these requirements.</p> <p>LIKELY IMPACT: There is likely no impact as this repeal moving these requirements to 12VAC5-381-60.</p>
381-150	N/A	<p>Part II Administrative Services 12VAC5-381-150. Management and administration.</p> <p>A. No person shall establish or operate a home care organization, as defined in § 32.1-162.7 of the Code of Virginia, without having obtained a license.</p> <p>B. The organization must comply with:</p> <ol style="list-style-type: none"> 1. This chapter (12VAC5-381); 2. Other applicable federal, state or local laws and regulations; and 3. The organization's own policies and procedures. <p>C. The organization shall submit or make available reports and information necessary to establish compliance with this chapter and applicable law.</p>	<p>CHANGE: The Board is proposing the following changes:</p> <p>Part II Administrative Services 12VAC5-381-150. Management and administration.</p> <p>A. No person shall establish or operate a home care organization, as defined in § 32.1-162.7 of the Code of Virginia, without having obtained a license.</p> <p><u>B.A. The organization An HCO must shall</u> comply with:</p> <ol style="list-style-type: none"> 1. This chapter (12VAC5-381); 2. Other applicable federal, state or local laws and regulations <u>administered by the board</u>; and

	<p>D. The organization shall permit representatives from the OLC to conduct inspections to:</p> <ol style="list-style-type: none"> 1. Verify application information; 2. Determine compliance with this chapter; 3. Review necessary records and documents; and 4. Investigate complaints. <p>E. The organization shall notify the OLC 30 days in advance of changes affecting the organization, including the:</p> <ol style="list-style-type: none"> 1. Service area; 2. Mailing address of the organization; 3. Ownership; 4. Services provided; 5. Operator; 6. Administrator; 7. Organization name; and 8. Closure of the organization. <p>F. The current license from the department shall be posted for public inspection.</p> <p>G. Service providers or community affiliates under contract with the organization must comply with the organization's policies and this chapter.</p> <p>H. The organization shall not use any advertising that contains false, misleading or deceptive statements or claims, or false or misleading disclosures of fees and payment for services.</p> <p>I. The organization shall have regular posted business hours and be fully operational during such business hours. In addition, the organization shall provide or arrange for services to their clients on an on-call basis 24 hours a day, seven days a week.</p> <p>J. The organization shall accept a client only when the organization can adequately meet that client's needs in the client's place of residence.</p> <p>K. The organization must have a prepared plan for</p>	<p>3. The organization's HCO's own policies and procedures.</p> <p>C.B. <u>The organization applicant or licensee shall submit or make available to the commissioner or his designee any reports and information necessary to establish compliance with this chapter and applicable law.</u></p> <p>D. <u>The organization shall permit representatives from the OLC to conduct inspections to:</u></p> <ol style="list-style-type: none"> 1. Verify <u>Verify</u> application information; 2. Determine compliance with this chapter; 3. Review necessary records and documents; and 4. Investigate complaints. <p>E. <u>The organization shall notify the OLC 30 days in advance of changes affecting the organization, including the:</u></p> <ol style="list-style-type: none"> 1. Service area; 2. Mailing address of the organization; 3. Ownership; 4. Services provided; 5. Operator; 6. Administrator; 7. Organization name; and 8. Closure of the organization. <p><u>C. An HCO shall document in writing the authority, or limitations on the authority, of the agents of the HCO to enter into transactions with the department on behalf of the HCO and any other transactions, which the HCO shall include in its:</u></p> <ol style="list-style-type: none"> 1. <u>Bylaws, if it is a corporation;</u> 2. <u>An operating agreement, if it is a limited liability company;</u> 3. <u>A governing instrument, if it is a business trust;</u> 4. <u>A statement of partnership authority, if it is a partnership;</u> <u>or</u> 5. <u>Other written document, if it is a sole proprietorship.</u>
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		<p>emergency operations in case of inclement weather or natural disaster to include contacting and providing essential care to clients, coordinating with community agencies to assist as needed, and maintaining a current list of clients who would require specialized assistance.</p> <p>L. The organization shall encourage and facilitate the availability of flu shots for its staff and clients.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p>	<p>F. D. An HCO shall post its <u>The current active license from the department commissioner shall be posted for public inspection at all times in a place readily visible and accessible to the public at the parent HCO's office and any branch office locations.</u></p> <p>G. E. An HCO shall ensure that <u>Service service providers or community affiliates under contract with the organization HCO must comply with the organization's HCO's policies and this chapter.</u></p> <p>H. F. The organization <u>An HCO shall may not use any advertising that contains false, misleading, or deceptive statements or claims, or false or misleading disclosures of fees and payment for services.</u></p> <p>I. G. The organization <u>An HCO shall:</u></p> <ol style="list-style-type: none"> 1. have <u>Have</u> regular posted business hours and be fully operational during such business hours; and 2. In addition, the organization shall provide <u>Provide</u> or arrange for services to their <u>its</u> clients and patients on an on-call basis 24 hours a day, seven days a week. <p>J. H. The organization <u>An HCO shall may not accept a client or patient only when if the organization HCO can cannot adequately meet that client's or patient's needs in the client's place of his residence.</u></p> <p>K. I. The organization <u>An HCO must shall have a prepared plan for emergency operations in case of inclement weather or natural disaster to include that includes:</u></p> <ol style="list-style-type: none"> 1. contacting <u>Contacting</u> and providing essential care to clients and patients ; 2. coordinating <u>Coordinating</u> with community agencies to assist as needed; and 3. maintaining <u>Maintaining</u> a current list of clients and
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			<p><u>patients</u> who would require specialized assistance.</p> <p>E. J. The organization <u>An HCO</u> shall encourage and facilitate the availability of flu shots <u>influenza vaccination</u> for its <u>staff employees, and clients, and patients.</u></p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p> <p>INTENT: The intent of these proposed changes is to:</p> <ul style="list-style-type: none"> (i) rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; (ii) consolidate relevant sections of the regulation by moving these requirements about inspections and material changes to the license to 12VAC5-381-40, 12VAC5-381-60, 12VAC5-381-65, and 12VAC5-381-80; and (iii) require HCOs to document in writing who can take action on its behalf in its interactions with the agency. <p>RATIONALE: The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> (i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>; (ii) consolidating relevant sections of the regulation allows regulants to more easily locate these requirements; and (iii) the agency has encountered multiple situations where unauthorized persons attempted to modify or gain control of an HCO license and the HCO encountered difficulty demonstrating who had authority to act on its behalf. <p>LIKELY IMPACT: The likely impact of these proposed changes is improved readability of this section and less confusion for agency staff when interacting with HCOs.</p>
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<p>381-160</p>	<p>N/A</p>	<p>12VAC5-381-160. Governing body. A. The organization shall have a governing body that is legally responsible for the management, operation and fiscal affairs of the organization. The governing body of a hospital that operates a home care organization shall include in its internal organization structure an identified unit of home care services. B. The governing body shall: 1. Determine which services are to be provided by the organization; 2. Ensure that the organization is staffed and adequately equipped to provide the services it offers to clients, whether provided directly by the organization or through contract; 3. Comply with federal and state laws, regulations and local ordinances governing operations of the organization; and 4. Establish a quality improvement committee. C. The governing body shall review annually and approve the written policies and procedures of the organization. D. The governing body shall review annually and approve the recommendations of the quality improvement committee, when appropriate. Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p>	<p>CHANGE: The Board is proposing the following changes: 12VAC5-381-160. Governing body. A. The organization <u>Each HCO shall have designate in writing a governing body that is legally responsible for the overall management, operation and fiscal affairs and control of the organization HCO.</u> The governing body of a hospital that operates a home care organization <u>an HCO</u> shall include in its internal organization structure an identified unit of home care services. B. The governing body shall: 1. Determine which services are to be provided by the organization <u>HCO</u>; 2. Ensure that the organization is staffed and adequately equipped to provide the services it offers to clients <u>Provide employees and other resources necessary to meet client, patient, and program needs, whether provided directly by the organization HCO or through by contract; and</u> 3. Comply with federal and state laws, regulations and local ordinances governing operations of the organization; and 4. Establish a quality improvement committee. 3. <u>Have a formal organizational plan with written bylaws that clearly set forth organization, duties and responsibilities, accountability, and relationships of management, clinical employees, and other employees.</u> C. The governing body shall review annually and approve the written policies and procedures of the organization. D. C. <u>The governing body shall review annually and approve the</u></p>
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			<p>recommendations of the quality improvement committee, when appropriate.</p> <p><u>D. The bylaws shall include:</u></p> <ol style="list-style-type: none"> <u>1. A statement of purpose;</u> <u>2. Description of the functions and duties of the governing body;</u> <u>3. A statement of authority and responsibility delegated to the administrator and to the clinical employees;</u> <u>4. Provision for selection and appointment of clinical employees and granting of clinical privileges;</u> <u>5. Provision of guidelines for relationships among the governing body, the administrator, and the clinical employees; and</u> <u>6. The identity of the person or organizational body responsible for formulating policies and procedures pursuant to 12VAC5-381-180.</u> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p> <p>INTENT: The intent of these proposed changes is to:</p> <ol style="list-style-type: none"> (i) rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; (ii) clarify the respective roles of the governing body; and (iii) set minimum requirements for the organizational plan and plans. <p>RATIONALE: The rationale behind these proposed changes is:</p> <ol style="list-style-type: none"> (i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>; (ii) removing ambiguity about the respective responsibilities of administrators and governing bodies will make it easier for
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			<p>HCOs to comply with regulations; and</p> <p>(iii) requiring the governing body to establish clear lines of authority will standardize HCO operations and make it easier to identify responsible party if there is a breakdown in care or services.</p> <p>LIKELY IMPACT: The likely impact of these proposed changes is improved readability of this section and clarity on how to satisfy the regulatory requirements.</p>
<p>381-170</p>	<p>N/A</p>	<p>12VAC5-381-170. Administrator.</p> <p>A. The governing body shall appoint as administrator an individual who has evidence of at least one year of training and experience in direct health care service delivery with at least one year within the last five years of supervisory or administrative management experience in home health care or a related health program.</p> <p>B. The administrator shall be responsible for the day-to-day management of the organization, including but not limited to:</p> <ol style="list-style-type: none"> 1. Organizing and supervising the administrative function of the organization; 2. Maintaining an ongoing liaison with the governing body, the professional personnel and staff; 3. Employing qualified personnel and ensuring adequate staff orientation, training, education and evaluation; 4. Ensuring the accuracy of public information materials and activities; 5. Implementing an effective budgeting and accounting system; 6. Maintaining compliance with applicable laws and regulations and implementing corrective 	<p>CHANGE: The Board is proposing the following changes:</p> <p>12VAC5-381-170. Administrator.</p> <p>A. The governing body shall appoint as <u>designate in writing one person to be the primary administrator, who shall be responsible for the daily managerial, operational, financial, and reporting components of the HCO, including: an individual who has evidence of at least one year of training and experience in direct health care service delivery with at least one year within the last five years of supervisory or administrative management experience in home health care or a related health program.</u></p> <p>B. The administrator shall be responsible for the day-to-day management of the organization, including but not limited to:</p> <ol style="list-style-type: none"> 1. Organizing and supervising the administrative function of the organization; 2. Maintaining an ongoing liaison with the governing body, the professional personnel and staff; <u>1. Developing, implementing, and enforcing all policies and procedures, including client and patient rights;</u> 3-2. Employing qualified personnel employees; <u>3. and ensuring adequate staff employee</u>

		<p>action in response to reports of organization committees and regulatory agencies;</p> <p>7. Arranging and negotiating services provided through contractual agreement; and</p> <p>8. Implementing the policies and procedures approved by the governing body.</p> <p>C. The individual designated to perform the duties of the administrator when the administrator is absent from the organization shall be able to perform the duties of the administrator as identified in subsection B of this section.</p> <p>D. The administrator or his designee shall be available at all times during operating hours and for emergency situations.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p>	<p>orientation, training, education, and evaluation <u>upon an employee's hiring and annually thereafter;</u></p> <p>4. Ensuring the accuracy of public information materials and activities;</p> <p>5. Implementing <u>Ensuring</u> an effective budgeting and accounting system <u>is implemented;</u></p> <p>6. Maintaining compliance with applicable laws and regulations and implementing corrective action in response to reports of organization committees and regulatory agencies; and</p> <p>7. Arranging and negotiating services provided through contractual agreement; and,</p> <p>8. Implementing the policies and procedures approved by the governing body.</p> <p><u>B. The governing body shall ensure that the designated administrator is an individual who has evidence of at least one year of training and experience in direct health care service delivery with at least one year within the last five years of supervisory or administrative management experience in home health care or a related health program.</u></p> <p><u>C. An HCO shall notify the OLC in writing of a change of administrator no more than five business days after the change. An HCO shall provide to the OLC a copy of the administrator's résumé or curriculum vitae with its notice of change of administrator.</u></p> <p><u>D. The governing body or administrator shall appoint in writing a qualified person to act in the absence of the administrator.</u></p> <p>C. The individual designated to perform the duties of the administrator when the administrator is absent from the organization shall be able to perform the duties of the administrator as identified in subsection B of this section.</p>
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			<p>D. E. An HCO shall ensure that The <u>the</u> administrator or his designee shall be <u>is readily available on the premises or by telecommunications</u> at all times during operating hours and for emergency situations.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p> <p>INTENT: The intent of these proposed changes is to:</p> <ul style="list-style-type: none"> (i) rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; (ii) clarify the designation of administrators and alternates are to be in writing; and (iii) clarify the respective roles of the administrators and governing bodies. <p>RATIONALE: The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> (i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>; (ii) by requiring the designation to be written and the qualifications be provided, the agency can easily verify if the administrator requirement has been met; (iii) removing ambiguity about the respective responsibilities of administrators and governing bodies will make it easier for HCOs to comply with regulations. <p>LIKELY IMPACT: The likely impact of these proposed changes is improved readability of this section and clarity on how to satisfy the regulatory requirements.</p>
381-180	N/A	<p>12VAC5-381-180. Written policies and procedures. A. The organization shall implement written policies and procedures approved by the governing body. B. All policies and procedures shall be reviewed at least annually, with recommended</p>	<p>CHANGE: The Board is proposing the following changes:</p> <p>12VAC5-381-180. Written policies Policies and procedures. A. The organization <u>A governing body</u> shall:</p>

		<p>changes submitted to the governing body for approval, as necessary.</p> <p>C. Administrative and operational policies and procedures shall include, but are not limited to:</p> <ol style="list-style-type: none"> 1. Administrative records; 2. Admission and discharge or termination from service criteria; 3. Informed consent; 4. Advance directives, including Durable Do Not Resuscitate Orders; 5. Client rights; 6. Contract services; 7. Medication management, if applicable; 8. Quality improvement; 9. Mandated reporting of abuse, neglect and exploitation pursuant to § 63.2-1606 of the Code of Virginia; 10. Communicable and reportable diseases; 11. Client records, including confidentiality; 12. Record retention, including termination of services; 13. Supervision and delivery of services; 14. Emergency and on-call services; 15. Infection control; 16. Handling consumer complaints; 17. Telemonitoring; and 18. Approved variances. <p>D. Financial policies and procedures shall include, but are not limited to:</p> <ol style="list-style-type: none"> 1. Admission agreements; 2. Data collection and verification of services delivered; 3. Methods of billing for services by the organization and by contractors; 	<p><u>1. Approve and maintain documented implement written policies and procedures approved by the governing body as specified in this section that are based on recognized standards and guidelines, which shall be readily available on the premises of the parent HCO's office and all branch offices-;</u></p> <p><u>2. Review all policies and procedures at least biennially with the administrator and appropriate clinical employees;</u></p> <p><u>3. Updated policies and procedure, as deemed necessary by the governing body; and</u></p> <p><u>4. Document in writing the biennial review process and recommendations for changes or updates.</u></p> <p><u>A member of the clinical employees or an independent contractor with training and expertise in infection prevention shall participate in the biennial review of the infection prevention policies and procedures to ensure they comply with applicable regulations and standards.</u></p> <p>B. All policies and procedures shall be reviewed at least annually, with recommended changes submitted to the governing body for approval, as necessary.</p> <p>C.B. Administrative and operational policies and procedures shall include, but are not limited to:</p> <ol style="list-style-type: none"> <u>1. Administrative records, including granted variances;</u> 2. Admission and discharge or termination from service criteria; 3.2. Informed signed consent; <u>4.3. Advance Providing information regarding advance directives, including Durable Do Not Resuscitate Orders;</u> <u>5. Client rights;</u>
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		<p>4. Client notification of changes in fees and charges;</p> <p>5. Correction of billing errors and refund policy; and</p> <p>6. Collection of delinquent client accounts.</p> <p>E. Personnel policies and procedures shall include, but are not limited to a:</p> <ol style="list-style-type: none"> 1. Written job description that specifies authority, responsibility, and qualifications for each job classification; 2. Process for maintaining an accurate, complete and current personnel record for each employee; 3. Process for verifying current professional licensing or certification and training of employees or independent contractors; 4. Process for annually evaluating employee performance and competency; 5. Process for verifying that contractors and their employees meet the personnel qualifications of the organization; 6. Process for obtaining a criminal background check and maintaining a drug-free workplace pursuant to § 32.1-162.9:1 of the Code of Virginia; and 7. Process for reporting licensed and certified medical personnel for violations of their licensing or certification to the appropriate board within the Department of Health Professions. <p>F. Admission and discharge or termination from service policies and procedures shall include, but are not limited to:</p>	<p>6-4. Contract services;</p> <p>7. Medication management, if applicable <u>5. The monitoring of medications taken by a patient, if applicable, by a actively licensed nurse to confirm that the patient is complying with a medication regime, while also ensuring the patient avoids potentially dangerous drug interactions and other complications;</u></p> <p>8-6. Quality improvement;</p> <p>9-7. Mandated reporting of abuse, neglect, and exploitation pursuant to <u>§ 63.2-1509 or to § 63.2-1606 of the Code of Virginia;</u></p> <p>10-8. Communicable and reportable diseases <u>Reporting diseases and conditions to the local health department in accordance with the Regulations for Disease Reporting and Control (12VAC5-90);</u></p> <p>11-9. Client Clinical records, including confidentiality;</p> <p>12-10. Record retention <u>of adult and pediatric clients and patients, including termination of services;</u></p> <p>13-11. Supervision and delivery of services;</p> <p>14-12. Emergency and on-call services;</p> <p>15. Infection control;</p> <p>16-13. Handling consumer <u>the complaints of clients, patients, clients' and patients' family members, employees, and the public that meets the requirements of 12VAC5-381-240;</u></p> <p>17-14. Telemonitoring; and</p> <p>18-15. Approved variances <u>Identification of the administrator and methods established by the governing body for holding the</u></p>
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		<p>1. Criteria for accepting clients for services offered;</p> <p>2. The process for obtaining a plan of care or service;</p> <p>3. Criteria for determining discharge or termination from each service and referral to other agencies or community services; and</p> <p>4. Process for notifying clients of intent to discharge/terminate or refer, including:</p> <ul style="list-style-type: none"> a. Oral and written notice and explanation of the reason for discharge/termination or referral; b. The name, address, telephone number and contact name at the referral organization; and c. Documentation in the client record of the referral or notice. <p>G. Policies shall be made available for review, upon request, to clients and their designated representatives.</p> <p>H. Policies and procedures shall be readily available for staff use at all times.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p>	<p><u>administrator responsible and accountable;</u></p> <p>16. <u>An emergency management plan;</u></p> <p>17. <u>Electronic health record and electronic signature, if applicable;</u></p> <p>18. <u>Protocols to prevent the occurrence of pressure sores or decubitus ulcers; and</u></p> <p>19. <u>Identification of which prescription drugs and nonprescription drugs that the HCO permits to be self-administered; and</u></p> <p>20. <u>CBD oil and THC-A oil for medical treatment and abuse of prescription or illegal drugs by client or patient in the presence of an employee, volunteer, or independent contractor.</u></p> <p><u>C. Client and patient rights policies and procedures shall include:</u></p> <ul style="list-style-type: none"> 1. <u>A process by which clients and patients are informed of their rights under 12VAC5-381-230; and</u> 2. <u>Providing timely information in plain language to all clients and patients and in a manner that is accessible to any client or patient:</u> <ul style="list-style-type: none"> a. <u>With disabilities, including accessible websites and the provision of auxiliary aids and services at no cost to the client or patient; and</u> b. <u>With limited English proficiency through the provision of language services at no cost to the client or patient, including oral interpretation and written translations.</u> <p><u>D. Financial policies and procedures shall include, but are not limited to:</u></p> <ul style="list-style-type: none"> 1. Admission agreements;
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			<p>2. Data collection and verification of services delivered;</p> <p>3. Methods of billing for services by the <u>organization HCO</u> and by <u>independent contractors</u>;</p> <p>4. Client <u>and patient</u> notification of changes in fees and charges;</p> <p>5. Correction of billing errors and refund policy; and</p> <p>6. Collection of delinquent client <u>and patient</u> accounts.</p> <p>E. <u>Personnel Employee</u> policies and procedures shall include, but are not limited to a:</p> <p>1. <u>Written job description descriptions</u> that <u>specifies authority, responsibility, and qualifications for each job classification meet the requirements of 12VAC5-381-200</u>;</p> <p>2. Process for maintaining an accurate, complete and current personnel record for each employee;</p> <p>3. Process for verifying 2. Verifying current active professional licensing or certification and training of employees or independent contractors;</p> <p>4. Process for annually evaluating 3. Evaluating at least annually employee performance and competency;</p> <p>5. Process for verifying 4. Verifying that independent contractors and their employees meet the personnel employee qualifications of the organization HCO;</p> <p>6. Process for obtaining 5. Obtaining a criminal background check and maintaining a drug-free workplace pursuant to § 32.1-</p>
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			<p>162.9:1 of the Code of Virginia; and</p> <p>7. Process for reporting <u>6. Reporting licensed and certified medical personnel employees</u> for violations of their licensing or certification to the appropriate board within the Department of Health Professions;</p> <p>7. Reporting employees, employees of temporary staffing agencies, independent contractors, and volunteers to the director of the OLC pursuant to § 54.1-2400.6 of the Code of Virginia;</p> <p><u>8. Employee participation in initial and ongoing training and education that is directly related to employee duties and appropriate to the level, intensity, and scope of services provided;</u></p> <p><u>9. Employee participation in annual infection prevention in-service training and the process by which training is documented;</u></p> <p><u>10. Appropriate staffing by actively licensed health care practitioners based on the level, intensity, and scope of services provided and the process by which staffing is documented; and</u></p> <p><u>11. Standards of conduct, which shall include corrective action that may be taken to address violations of the standards and a method for enforcing the standards while an employee is in a client's or patient's residence.</u></p> <p>F. Admission and discharge or termination from service policies and procedures shall include, but are not limited to:</p> <p><u>1. Criteria for accepting clients and patients for services offered;</u></p>
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			<p>2. The process for obtaining a <u>medical plan of care or service plan of care</u>;</p> <p>3. <u>Admissions, including criteria for evaluating the client or patient before admission</u>;</p> <p>4. Criteria for determining discharge or termination from each service and referral to other agencies or community services; and</p> <p>4. <u>5. Process for notifying clients and patients of intent to discharge/terminate <u>discharge, terminate, or refer</u>, including:</u></p> <ul style="list-style-type: none">a. Oral and written notice and explanation of the reason for discharge/termination <u>discharge, termination, or referral</u>;b. The name, address, telephone number and contact name at the referral organization; andc. Documentation in the client <u>clinical</u> record of the referral or notice. <p><u>G. A member of the clinical staff or an independent contractor with training and expertise in infection prevention shall participate in the development of infection prevention policies and procedures. The governing body shall document the process for development, implementation, and maintenance of infection prevention policies and procedures and the regulations or guidance documents on which they are based. The infection prevention policies and procedures shall include:</u></p> <ul style="list-style-type: none">1. <u>Initial training, annual retraining, and use of standard precautions recommended by the U.S. Centers for Disease Control and Prevention by all employees, volunteers, and independent contractors, including:</u>
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			<p><u>a. Correct hand-washing technique, including indications for use of soap and water, and use of alcohol-based hand rubs;</u></p> <p><u>b. Compliance with bloodborne pathogen requirements of the U.S. Occupational Safety and Health Administration; and</u></p> <p><u>c. Use of personal protective equipment;</u></p> <p><u>2. Use of safe injection practices recommended by the U.S. Centers for Disease Control and Prevention;</u></p> <p><u>3. Monitoring employee adherence to standard precautions;</u></p> <p><u>4. Access to hand-washing equipment and adequate supplies (e.g., alcohol-based hand rubs or disposable towels);</u></p> <p><u>5. Handling, storing, and transporting clean or sterile supplies and equipment;</u></p> <p><u>6. Handling, storing, processing, and transporting regulated medical waste in accordance with applicable regulations;</u></p> <p><u>7. Processing of each type of reusable medical equipment between uses on different clients and patients, with reference to the manufacturer's recommendations and any applicable state or national infection control guidelines, and addressing:</u></p> <p><u>a. The level of cleaning, disinfecting, or sterilizing to be used for each type of equipment;</u></p> <p><u>b. The process by which cleanliness, disinfection, or sterilization is achieved; and</u></p>
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			<p><u>c. The method for verifying that the recommended level of cleanliness, disinfection, or sterilization has been achieved;</u></p> <p><u>8. Maintenance, repair, and disposal of equipment and supplies in accordance with manufacturer recommendations;</u></p> <p><u>9. Cleaning of environmental surfaces with appropriate cleaning products; and</u></p> <p><u>10. Other infection prevention procedures necessary to prevent or control transmission of an infectious agent between clients, patients, and employees as recommended or required by the department; and</u></p> <p><u>11. Monitoring employee performance in infection control practices.</u></p> <p><u>H. For an HCO that provides pharmaceutical services, pharmaceutical policies and procedures shall include:</u></p> <p><u>1. Developing a medical plan of care;</u></p> <p><u>2. Initiation of medication administration based on a prescriber's order and monitoring of the patient for response to the treatment and any adverse reactions or side effects;</u></p> <p><u>3. Assessment of any factors related to the home environment that may affect the prescriber's decisions for initiating, modifying, or discontinuing medications;</u></p> <p><u>4. Communication with the prescriber concerning assessment of the patient's response to therapy, any other patient specific needs, and any significant change in the patient's condition;</u></p>
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			<p><u>5. Communication with the patient's provider pharmacy concerning problems or needed changes in a patient's medication;</u></p> <p><u>6. Maintaining a complete and accurate record of medications prescribed, medication administration data, patient assessments, any laboratory tests ordered to monitor response to drug therapy and results, and communications with the prescriber and pharmacy provider;</u></p> <p><u>7. Educating or instructing the patient, family members, or other caregivers involved in the administration of infusion therapy in the proper storage of medication, in the proper handling of supplies and equipment, in any applicable safety precautions, in recognizing potential problems with the patient, and actions to take in an emergency; and</u></p> <p><u>8. Initial and retraining of all employees, including on procedures for first dosing of infusion therapy.</u></p> <p>G. I. An HCO shall make Policies policies and procedures shall be made available for review, upon request, to clients, patients, and their designated legal representatives.</p> <p>H. J. An HCO shall make Policies policies and procedures shall be readily available for staff employee use at all times at the parent HCO's office and all branch offices.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p> <p>INTENT: The intent of these proposed changes is to:</p> <p>(i) rewrite this section in the active voice and break paragraphs with multiple requirements into subparts;</p>
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			<ul style="list-style-type: none"> (ii) consolidate the requirements for policies and procedures into a single section; (iii) organize the required policies and procedures by topic; (iv) add additional topics or clarifying language to topics that have been unaddressed or ambiguously addressed; (v) correct out of date or missing statutory and regulatory references (vi) strengthen infection prevention policies and procedures; and (vii) provide accommodations for persons with disabilities and persons with limited or no English proficiency. <p>RATIONALE: The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> (i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>; (ii) housing all policies and procedures in the section entitled "Policies and procedures" makes it easier for regulants and the public to find the requirements; (iii) because of the number of required policies and procedures, readability is increased when organized by topic; (iv) the policies and procedures requirements in this chapter have gaps that been identified by regulants and agency staff, so requiring HCOs to formulate or revise policies and procedures to address these gaps will decrease the likelihood an HCO is presented with a situation for which it is unprepared to address; (v) reducing conflicts between this regulation and statutory and other regulatory language reduces confusion for readers; (vi) the COVID-19 pandemic and vaccine hesitancy has highlighted the need for more stringent infection prevention efforts, to protect clients, patients, and employees; and (vii) denying clients and patients information in plain and
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			<p>accessible language interferes with their ability to be informed about and participate in their own care.</p> <p>LIKELY IMPACT: The likely impact of these proposed changes is improved readability of this section and improved protection from infection for clients, patients, and employees.</p>
381-190	N/A	<p>12VAC5-381-190. Financial controls.</p> <p>A. Every applicant for an initial license to establish or operate a home care organization shall include as part of his application a detailed operating budget showing projected operating expenses for the three-month period after a license to operate has been issued. Further, every applicant for an initial license to establish or operate a home care organization shall include as part of his application proof of initial reserve operating funds in the amount sufficient to ensure operation of the home care organization for the three-month period after a license to operate has been issued. Such funds may include:</p> <ol style="list-style-type: none"> 1. Cash; 2. Cash equivalents that are readily convertible to known amounts of cash and that present insignificant risk of change in value; 3. Borrowed funds that are immediately available to the applicant; or 4. A line of credit that is immediately available to the applicant. <p>Proof of funds sufficient to meet these requirements shall include a current balance sheet demonstrating the availability of funds, a letter from the officer of the bank or other financial institution where the funds are held, or a letter of credit from a lender demonstrating the current</p>	<p>CHANGE: The Board is proposing the following changes:</p> <p>12VAC5-381-190. Financial controls.</p> <p>A. Every An applicant for an initial license to establish or operate a home care organization shall include as part of his application:</p> <ol style="list-style-type: none"> 1. a <u>1.</u> A detailed operating budget showing projected operating expenses for the three-month period after a license to operate has been issued-; <u>and</u> 2. Further, every applicant for an initial license to establish or operate a home care organization shall include as part of his application proof <u>2.</u> Further, every applicant for an initial license to establish or operate a home care organization shall include as part of his application proof <u>Proof</u> of initial reserve operating funds in the amount sufficient to ensure operation of the home care organization <u>HCO</u> for the three-month period after a license to operate has been issued. Such funds may include: <ol style="list-style-type: none"> 4-a. <u>4-a.</u> Cash; 2-b. <u>2-b.</u> Cash equivalents that are readily convertible to known amounts of cash and that present insignificant risk of change in value; 3-c. <u>3-c.</u> Borrowed funds that are immediately available to the applicant; or 4-d. <u>4-d.</u> A line of credit that is immediately available to the applicant.

		<p>availability of and amount of a line of credit.</p> <p>B. The organization shall document financial resources to operate based on a working budget showing projected revenue and expenses.</p> <p>C. All financial records shall be kept according to generally accepted accounting principles (GAAP).</p> <p>D. All financial records shall be audited at least triennially by an independent certified public accountant (CPA) or audited as otherwise provided by law.</p> <p>E. The organization shall have documented financial controls to minimize risk of theft or embezzlement.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p>	<p>B. The OLC shall accept as Proof of funds sufficient satisfactory evidence that an applicant has met the requirements of subdivision 2 of subsection A:</p> <ol style="list-style-type: none"> 1. to meet these requirements shall include a A current balance sheet demonstrating the availability of funds; 2. a A letter from the officer of the bank or other financial institution where the funds are held; or 3. a A letter of credit from a lender demonstrating the current availability of and amount of a line of credit. <p>B.C. The organization <u>An HCO</u> shall document financial resources to operate based on a working budget showing projected revenue and expenses.</p> <p>C.D. An HCO shall keep All all financial records shall be kept according to generally accepted accounting principles (GAAP).</p> <p>D.E. An HCO shall ensure All all financial records shall be are <u>audited subject to a review</u> at least triennially by an independent certified public accountant (CPA) or audited as otherwise provided by <u>law</u>, and shall <u>provide a copy of the CPA's review report upon request by the OLC.</u></p> <p>E. The organization <u>F. An HCO</u> shall have documented financial controls <u>in its policies and procedures</u> to minimize risk of theft or embezzlement.</p> <p><u>G. An HCO shall notify the OLC within two business days of being contacted by the Medicaid Fraud Control Unit in the Office of the Attorney General if it is the subject of a Medicaid fraud investigation.</u></p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p> <p>INTENT: The intent of these proposed changes is to:</p>
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			<ul style="list-style-type: none"> (i) rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; (ii) replace the audit requirement with a review by an independent CPA; and (iii) keep the agency informed if other state agencies are investigating its regulants <p>RATIONALE: The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> (i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>; (ii) a review by an independent CPA will provide sufficient assurance that an HCO has kept its records in accordance with GAAP and has sufficient financial controls, at a lesser cost compared to an audit; (iii) every HCO should provide this information to the agency as events that triggered a Medicaid fraud investigation may be grounds for an inspection protect to the health and safety of clients, patients, or the public. <p>LIKELY IMPACT: The likely impact of these proposed changes is improved readability of this section, a potential cost savings for HCOs, and increased transparency regarding an HCO's operations.</p>
381-200	N/A	<p>12VAC5-381-200. Personnel practices.</p> <p>A. Personnel management and employment practices shall comply with applicable state and federal laws and regulations.</p> <p>B. The organization shall design and implement a staffing plan that reflects the types of services offered and shall provide qualified staff in sufficient numbers to meet the assessed needs of all clients.</p> <p>C. Employees and contractors shall be licensed or certified as required by the</p>	<p>CHANGE: The Board is proposing the following changes:</p> <p>12VAC5-381-200. Personnel Employee practices.</p> <p>A. An HCO shall ensure that:</p> <ol style="list-style-type: none"> <u>1. Personnel Its employee management and employment practices shall comply with applicable state and federal laws and regulations; and</u> <u>2. Its employees, contractors, and volunteers are actively licensed or certified as required</u>

		<p>Department of Health Professions.</p> <p>D. The organization shall design and implement a mechanism to verify professional credentials.</p> <p>E. Any person who assumes the responsibilities of any staff position or positions shall meet the minimum qualifications for that position or positions.</p> <p>F. The organization shall obtain the required sworn statement and criminal record check for each compensated employee as specified in § 32.1-162.9:1 of the Code of Virginia.</p> <p>G. Each employee position shall have a written job description that includes:</p> <ol style="list-style-type: none"> 1. Job title; 2. Duties and responsibilities required of the position; 3. Job title of the immediate supervisor; and 4. Minimum knowledge, skills, and abilities or professional qualifications required for entry level. <p>H. Employees shall have access to their current position description. There shall be a mechanism for advising employees of changes to their job responsibilities.</p> <p>I. New employees and contract individuals shall be oriented commensurate with their function or job-specific responsibilities. Orientation shall include:</p> <ol style="list-style-type: none"> 1. Objectives and philosophy of the organization; 2. Confidentiality; 3. Client rights; 4. Mandated reporting of abuse, neglect, and exploitation; 5. Applicable personnel policies; 	<p><u>by the Department of Health Professions.</u></p> <p>B. The organization <u>The governing body of an HCO shall design and implement:</u></p> <ol style="list-style-type: none"> <u>1. a A staffing plan that reflects the types of services offered by the HCO;</u> <u>2. and shall provide Provide qualified staff employees in sufficient numbers to meet the assessed needs of all clients and patients.; and</u> <p>C. Employees and contractors shall be licensed or certified as required by the Department of Health Professions.</p> <ol style="list-style-type: none"> <u>3. D. The organization shall design and implement Design a mechanism to verify and document professional credentials.</u> <p>E. Any person who assumes the responsibilities of any staff position or positions shall meet the minimum qualifications for that position or positions.</p> <p>F. The organization shall obtain the required sworn statement and criminal record check for each compensated employee as specified in § 32.1-162.9:1 of the Code of Virginia.</p> <p>G. C. For each employee, independent contractor, and volunteer description, an HCO shall <u>Each employee position shall have a written job description that includes:</u></p> <ol style="list-style-type: none"> <u>1. Include the Job position title, authority, specific responsibilities, and minimum qualifications;</u> <u>2. Duties and responsibilities required of the position Review the job description at least annually and update as deemed necessary by the HCO; and</u> <u>3. Job title of the immediate supervisor Give a copy to each employee, independent contractor, and volunteer when</u>
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		<p>6. Emergency preparedness procedures;</p> <p>7. Infection control practices and measures;</p> <p>8. Cultural awareness; and</p> <p>9. Applicable laws, regulations, and other policies and procedures that apply to specific positions, specific duties and responsibilities.</p> <p>J. The organization shall develop and implement a policy for evaluating employee performance.</p> <p>K. Individual staff development needs and plans shall be a part of the performance evaluation.</p> <p>L. The organization shall provide opportunities for and record participation in staff development activities designed to enable staff to perform the responsibilities of their positions.</p> <p>M. All individuals who enter a client's home for or on behalf of the organization shall be readily identifiable by employee nametag, uniform or other visible means.</p> <p>N. The organization shall maintain an organized system to manage and protect the confidentiality of personnel files and records.</p> <p>O. Employee personnel records, whether hard copy or electronic, shall include:</p> <ol style="list-style-type: none"> 1. Identifying information; 2. Education and training history; 3. Employment history; 4. Results of the verification of applicable professional licenses or certificates; 5. Results of reasonable efforts to secure job-related references and reasonable verification of employment history; 6. Results of performance evaluations; 	<p><u>assigned to the position and when revised; and.</u></p> <p>4. Minimum knowledge, skills, and abilities or professional qualifications required for entry level.</p> <p>H. Employees shall have access to their current position description. There shall be a mechanism for advising employees of changes to their job responsibilities.</p> <p>I. D. An HCO shall provide orientation to New new employees, independent contractors, and contract individuals volunteers shall be oriented commensurate with their function or job-specific responsibilities. <u>Orientation, which shall include:</u></p> <ol style="list-style-type: none"> 1. Objectives and philosophy of the organization HCO; 2. Confidentiality; 3. Client <u>and patient</u> rights; 4. Mandated reporting of abuse, neglect, and exploitation; 5. Applicable <u>personnel policies and procedures, including administrative and employee policies and procedures;</u> 6. Emergency preparedness procedures; 7. Infection control practices and measures; 8. Cultural awareness; <u>9. How to report suspected Medicaid fraud; and</u> 9. <u>10.</u> Applicable laws, regulations, and other policies and procedures that apply to specific positions, <u>and</u> specific duties and responsibilities. <p>J. E. The organization <u>An HCO shall develop and implement a policy for annually evaluating employee and volunteer performance, which shall include individual employee or volunteer development needs and plans.</u></p>
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			<p>6. Results of performance evaluations <u>Ensure the employee file contains a current job description that reflects the employee's responsibilities and work assignments, and documentation of the employee's in-service education and professional licensure or certification, if applicable;</u></p> <p>7. A record of Record performance evaluations and disciplinary actions, if any, taken by the organization, if any HCO;</p> <p>8. A record of Record adverse action by any licensing bodies and organizations, if any; and</p> <p>9. A record of participation in staff development activities, including orientation; and</p> <p>10. <u>Maintain documentation of The the criminal record check report and sworn affidavit as required in 12VAC5-381-90.</u></p> <p>P. I. An HCO shall report All any positive results from drug testing shall be reported to the health regulatory boards responsible for licensing, certifying, or registering the person to practice, if any, pursuant to § 32.1-162.9:1 of the Code of Virginia.</p> <p>Q. J. An HCO shall retain Each an employee personnel record file shall be retained in its entirety for a minimum of no less than three years after termination of employment.</p> <p>R. Personnel record information shall be safeguarded against loss and unauthorized use.</p> <p>S. Employee health-related information shall be maintained separately within the employee's personnel file.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p>
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			<p>INTENT: The intent of these proposed changes is to:</p> <ul style="list-style-type: none"> (i) rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; and (ii) remove language about obtaining criminal records checks. <p>RATIONALE: The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> (i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>; (ii) language about obtaining criminal records checks has been moved in part to section 110, which is entitled "Criminal records checks." <p>LIKELY IMPACT: The likely impact of these proposed changes is improved readability of this section.</p>
381-210	N/A	<p>12VAC5-381-210. Indemnity coverage.</p> <p>A. The governing body shall ensure the organization and its contractors have appropriate indemnity coverage to compensate clients for injuries and losses resulting from services provided.</p> <p>B. The organization shall purchase and maintain the following types and minimum amounts of indemnity coverage at all times:</p> <ol style="list-style-type: none"> 1. Malpractice insurance consistent with § 8.01-581.15 of the Code of Virginia; 2. General liability insurance covering personal property damages, bodily injuries, product liability, and libel and slander of at least \$1 million comprehensive general liability per occurrence; and 3. Third-party crime insurance or a blanket fidelity bond of \$50,000 minimum. 	<p>CHANGE: The Board is proposing the following changes:</p> <p>12VAC5-381-210. Indemnity coverage.</p> <p>A. The governing body shall ensure the organization <u>HCO</u> and its contractors have appropriate indemnity coverage to compensate clients for injuries and losses resulting from services provided.</p> <p>B. The organization <u>HCO</u> shall purchase and maintain the following types and minimum amounts of indemnity coverage at all times:</p> <ol style="list-style-type: none"> 1. <u>Malpractice Professional liability insurance consistent with § 8.01-581.15 of the Code of Virginia of at least \$2.55 million per occurrence as of July 1, 2022. An HCO shall increase its minimum per occurrence professional liability coverage by at least \$50,000 on or before every July 1, beginning July 1, 2023;</u> 2. General liability insurance covering personal property

		<p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p>	<p>damages, bodily injuries, product liability, and libel and slander of at least \$1 million comprehensive general liability per occurrence; and</p> <p>3. Third-party crime insurance or a blanket fidelity bond of \$50,000 minimum.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p> <p>INTENT: The intent of these proposed changes is to:</p> <ul style="list-style-type: none"> (i) rewrite this section in the active voice; (ii) broaden the insurance required to professional liability instead of just malpractice insurance; and (iii) match the professional liability coverage to the maximum recovery amounts for malpractice. <p>RATIONALE: The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> (i) the active voice is the style preferred and recommended by <i>The Virginia Register of Regulations</i>; (ii) professional liability insurance would cover a broader spectrum of HCO employees than malpractice insurance; and (iii) because the insurance referenced in the proposed subdivision B 1 of this section is no longer malpractice insurance, the agency believes it is inaccurate to continue citing § 8.01-581.15 of the Code of Virginia. <p>LIKELY IMPACT: The likely impact of these proposed changes is improved readability of this section and HCOs may find it easier to obtain professional liability insurance.</p>
381-220	N/A	<p>12VAC5-381-220. Contract services. A. There shall be a written agreement for the provision of services not provided by employees of the organization.</p>	<p>CHANGE: The Board is proposing the following changes:</p> <p>12VAC5-381-220. Contract services. A. <u>An HCO</u> There shall <u>be have</u> a written agreement for the provision of</p>

		<p>B. The written agreement shall include, but is not limited to:</p> <ol style="list-style-type: none"> 1. The services to be furnished by each party to the contract; 2. The contractor's responsibility for participating in developing plans of care or service; 3. The manner in which services will be controlled, coordinated, and evaluated by the primary home care organization; 4. The procedures for submitting notes on the care or services provided, scheduling of visits, and periodic client evaluation; 5. The process for payment for services furnished under the contract; and 6. Adequate liability insurance and third-party crime insurance or a blanket fidelity bond. <p>C. The organization shall have a written plan for provision of care or services when a contractor is unable to deliver services.</p> <p>D. The contractor shall conform to applicable organizational policies and procedures as specified in the contract, including the required sworn disclosure statement and criminal record check.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p>	<p>services not provided by employees <u>or</u> <u>volunteers</u> of the organization <u>HCO</u>.</p> <p>B. The written agreement shall include, but is not limited to:</p> <ol style="list-style-type: none"> 1. The services to be furnished by each party to the contract; 2. The contractor's responsibility for participating in developing plans of care or service; 3. The manner in which services will be controlled, coordinated, and evaluated by the primary home care organization <u>HCO</u>; 4. The procedures for submitting notes on the care or services provided, scheduling of visits, and periodic client evaluation; 5. The process for payment for services furnished under the contract; and 6. Adequate <u>general and professional</u> liability insurance and third-party crime insurance or a blanket fidelity <u>bond, as prescribed by 12AC5-381-210</u>. <p>C. The organization <u>An HCO</u> shall have a written plan for provision of care or services when <u>if</u> a contractor is unable to deliver services.</p> <p>D. <u>An HCO shall require</u> The a contractor shall <u>to</u> conform to applicable organizational policies and procedures <u>of the HCO</u> as specified in the contract, including the required sworn disclosure statement and criminal record check <u>report</u>.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p> <p>INTENT: The intent of these proposed changes is to rewrite this section in the active voice.</p> <p>RATIONALE: The rationale behind these proposed changes is the active voice is the style preferred and</p>
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			<p>recommended by <i>The Virginia Register of Regulations</i>.</p> <p>LIKELY IMPACT: The likely impact of these proposed changes is improved readability of this section.</p>
381-230	N/A	<p>12VAC5-381-230. Client rights.</p> <p>A. The organization shall establish and implement written policies and procedures regarding the rights of clients.</p> <p>B. Client rights shall be reviewed with clients or client designees upon admission to the organization. The review shall be documented in the client's record.</p> <p>C. Written procedures to implement the policies shall ensure that each client is:</p> <ol style="list-style-type: none"> 1. Treated with courtesy, consideration and respect and is assured the right of privacy; 2. Assured confidential treatment of his medical and financial records as provided by law; 3. Free from mental and physical abuse, neglect, and property exploitation; 4. Assured the right to participate in the planning of the client's home care, including the right to refuse services; 5. Served by individuals who are properly trained and competent to perform their duties; 6. Assured the right to voice grievances and complaints related to organizational services without fear of reprisal; 7. Advised, before care is initiated, of the extent to which payment for the home care organization services may be expected from federal or state programs, and the extent to which payment may be required from the client; 	<p>CHANGE: The Board is proposing the following changes:</p> <p>12VAC5-381-230. Client and patient rights.</p> <p>A. The organization shall establish and implement written policies and procedures regarding the rights of clients.</p> <p>B. Client rights shall be reviewed with clients or client designees upon admission to the organization. The review shall be documented in the client's record.</p> <p>C. Written procedures to implement the policies shall ensure that each client is:</p> <ol style="list-style-type: none"> 1. Treated with courtesy, consideration and respect and is assured the right of privacy; 2. Assured confidential treatment of his medical and financial records as provided by law; 3. Free from mental and physical abuse, neglect, and property exploitation; 4. Assured the right to participate in the planning of the client's home care, including the right to refuse services; 5. Served by individuals who are properly trained and competent to perform their duties; 6. Assured the right to voice grievances and complaints related to organizational services without fear of reprisal; 7. Advised, before care is initiated, of the extent to which payment for the home care

		<p>8. Advised orally and in writing of any changes in fees for services that are the client's responsibility. The home care organization shall advise the client of these changes as soon as possible, but no later than 30 calendar days from the date the home care organization became aware of the change;</p> <p>9. Provided with advance directive information prior to start of services; and</p> <p>10. Given at least five days written notice when the organization determines to terminate services.</p> <p>D. Before care is initiated, the home care organization shall inform the client, orally and in writing, of:</p> <ol style="list-style-type: none"> 1. The nature and frequency of services to be delivered and the purpose of the service; 2. Any anticipated effects of treatment, as applicable; 3. A schedule of fees and charges for services; 4. The method of billing and payment for services, including the: <ol style="list-style-type: none"> a. Services to be billed to third party payers; b. Extent to which payment may be expected from third party payers known to the home care organization; and c. Charges for services that will not be covered by third party payers; 5. The charges that the individual may have to pay; 6. The requirements of notice for cancellation or reduction in services by 	<p>organization services may be expected from federal or state programs, and the extent to which payment may be required from the client;</p> <p>8. Advised orally and in writing of any changes in fees for services that are the client's responsibility. The home care organization shall advise the client of these changes as soon as possible, but no later than 30 calendar days from the date the home care organization became aware of the change;</p> <p>9. Provided with advance directive information prior to start of services; and</p> <p>10. Given at least five days written notice when the organization determines to terminate services.</p> <p>D. Before care is initiated, the home care organization shall inform the client, orally and in writing, of:</p> <ol style="list-style-type: none"> 1. The nature and frequency of services to be delivered and the purpose of the service; 2. Any anticipated effects of treatment, as applicable; 3. A schedule of fees and charges for services; 4. The method of billing and payment for services, including the: <ol style="list-style-type: none"> a. Services to be billed to third party payers; b. Extent to which payment may be expected from third party payers known to the home care organization; and c. Charges for services that will not be covered by third party payers; 5. The charges that the individual may have to pay; 6. The requirements of notice for cancellation or reduction in
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		<p>the organization and the client; and 7. The refund policies of the organization.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p>	<p>services by the organization and the client; and 7. The refund policies of the organization.</p> <p><u>A. The client or patient has the right to:</u></p> <ol style="list-style-type: none"> <u>1. Have his property and person treated with respect;</u> <u>2. Be free from verbal, mental, sexual, and physical abuse, including injuries of unknown source, neglect and misappropriation of property;</u> <u>3. Make complaints to the HCO regarding treatment or care that is or fails to be furnished, and the lack of respect for property or person by anyone who is furnishing services on behalf of the HCO;</u> <u>4. Be furnished services by individuals who are properly trained and competent to perform their duties;</u> <u>5. Participate in, be informed about, and consent or refuse care in advance of and during treatment, where appropriate, with respect to:</u> <ol style="list-style-type: none"> <u>a. Completion of all assessments;</u> <u>b. The care to be furnished, based on the comprehensive assessment;</u> <u>c. Establishing and revising the medical plan of care;</u> <u>d. The disciplines that will furnish the care;</u> <u>e. The frequency of visits;</u> <u>f. Expected outcomes of care, including client- or patient-identified goals, and anticipated risks and benefits;</u> <u>g. Any factors that could impact treatment effectiveness; and</u>
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			<p><u>h. Any changes in the care to be furnished;</u></p> <p><u>6. Receive all services outlined in the medical plan of care or plan of care;</u></p> <p><u>7. Have a confidential clinical record and financial record as provided by law;</u></p> <p><u>8. Be provided with advance directive information prior to the initiation of services;</u></p> <p><u>9. Be advised, orally and in writing, before services are initiated of:</u></p> <p><u>a. The extent to which payment for HCO services may be expected from Medicaid, or any other government-funded or government aid program known to the HCO;</u></p> <p><u>b. The charges for services that may not be covered by Medicaid, or any other government-funded or government aid program known to the HCO;</u></p> <p><u>c. The charges the client or patient may have to pay before care is initiated; and</u></p> <p><u>d. Any changes in the information provided in accordance with subdivision 9 of this section when they occur. The HCO shall advise the client, patient, and legal representative of these changes as soon as possible, in advance of the next home visit but no later than 30 days from the date the HCO becomes aware of the change;</u></p> <p><u>10. Receive written notice, at least five business days in advance of a specific service being furnished, if the HCO believes that the service may be non-covered care, or at least five business days in</u></p>
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			<p><u>advance of the HCO reducing or terminating on-going care:</u></p> <p><u>11. Be advised, orally and in writing, of the OLC toll free complaint telephone hot line, its contact information, its hours of operation, and that its purpose is to receive complaints about HCOs.</u></p> <p><u>12. Be advised of the names, addresses, and telephone numbers of the following federally-funded and state-funded entities that serve the area where the patient or client resides:</u></p> <ul style="list-style-type: none"><u>a. Agency on Aging;</u><u>b. Center for Independent Living; and</u><u>c. disAbility Law Center of Virginia;</u> <p><u>13. Be free from any discrimination or reprisal for exercising his rights or for voicing grievances to the HCO or an outside entity;</u></p> <p><u>14. Receive a written copy of the HCO's refund policies and receive written notice of any changes to those policies, at least five business days in advance of the change.</u></p> <p><u>B. An HCO shall review client and patient rights with clients, patients, or their legal representatives upon admission to the organization HCO, which shall be documented in the clinical record.</u></p> <p>Statutory Authority</p> <p>§§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p> <p>INTENT: The intent of these proposed changes is to:</p> <ul style="list-style-type: none">(i) rewrite this section in the active voice and break paragraphs with multiple requirements into subparts;(ii) remove language about policies and procedures; and
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			<p>(iii) more closely align the rights of HCO clients and patients with that of the rights afforded to patients of home health agencies.</p> <p>RATIONALE: The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> (i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>; (ii) language about policies and procedures has been moved in part to section 180, which is entitled "Policies and procedures"; and (iii) there is not a sufficient difference between HCO clients and patients and patients of home health agencies to justify material differences in the rights they are afforded. <p>LIKELY IMPACT: The likely impact of these proposed changes is improved readability of this section and protections for clients and patients of HCOs that are comparable to patients of home health agencies.</p>
381-240	N/A	<p>12VAC5-381-240. Handling complaints received from clients.</p> <p>A. The organization shall establish and maintain complaint handling procedures that specify the:</p> <ul style="list-style-type: none"> 1. System for logging receipt, investigation and resolution of complaints; and 2. Format of the written record of the findings of each complaint investigated. <p>B. The organization shall designate staff responsible for complaint resolution, including:</p> <ul style="list-style-type: none"> 1. Complaint intake, including acknowledgment of complaints; 2. Investigation of the complaint; 3. Review of the investigation of findings 	<p>CHANGE: The Board is proposing the following changes:</p> <p>12VAC5-381-240. Handling complaints received from clients <u>Complaint handling procedures.</u></p> <p>A. The organization <u>An HCO</u> shall establish and maintain complaint handling procedures that specify the:</p> <ul style="list-style-type: none"> 1. System for logging receipt, investigation and resolution of complaints; and 2. Format of the written record of the findings of each complaint investigated. <p>B. The organization shall designate <u>3. The staff position title of the employees</u> responsible for complaint resolution, including:</p> <ul style="list-style-type: none"> 1. <u>a.</u> Complaint intake, including acknowledgment of complaints;

		<p>and resolution for the complaint; and</p> <p>4. Notification to the complainant of the proposed resolution within 30 days from the date of receipt of the complaint.</p> <p>C. The client or his designee shall be given a copy of the complaint procedures at the time of admission to service. The organization shall provide each client or his designee with the name, mailing address, and telephone number of the:</p> <ol style="list-style-type: none"> 1. Organization contact person; 2. State Ombudsman; and 3. Complaint Unit of the OLC. <p>D. The organization shall maintain documentation of all complaints received and the status of each complaint from date of receipt through its final resolution. Records shall be maintained from the date of last inspection and for no less than three years.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p>	<p>2. b. Investigation of the complaint;</p> <p>3. c. Review of the investigation of findings and resolution for the complaint; and</p> <p>4. <u>d.</u> Notification to the complainant of the <u>written</u> proposed resolution within 30 days from the date of receipt of the complaint.</p> <p>C. B. <u>An HCO shall give The the</u> client, <u>patient,</u> or his designee shall be given a copy of the complaint procedures at the time of admission to service. The organization and shall provide each client, <u>patient,</u> or his designee with the name, mailing address, and telephone number of the:</p> <ol style="list-style-type: none"> 1. Organization <u>HCO</u> contact person; 2. State <u>Long-Term Care</u> Ombudsman <u>and the ombudsman</u> for their locality; and 3. Complaint Unit of the OLC. <p>D. The organization <u>C. An HCO</u> shall maintain documentation of all complaints received and the status of each complaint from date of receipt through its final resolution. Records shall be maintained from the date of last inspection and <u>for no less than three five years from the date of receipt.</u></p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p> <p>INTENT: The intent of these proposed changes is to rewrite this section in the active voice and break paragraphs with multiple requirements into subparts.</p> <p>RATIONALE: The rationale behind these proposed changes is the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>.</p> <p>LIKELY IMPACT: The likely impact of these proposed changes is improved readability of this section.</p>
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<p>381-250</p>	<p>N/A</p>	<p>12VAC5-381-250. Quality improvement. A. The organization shall implement an ongoing, comprehensive, integrated, self-assessment program of the quality and appropriateness of care or services provided, including services provided under contract or agreement. The findings shall be used to correct identified problems and revise policies and practices, as necessary. Exclusive concentration on administrative or cost-of-care issues does not fulfill this requirement. B. The following data shall be evaluated to identify unacceptable or unexpected trends or occurrences: 1. Staffing patterns and performance to assure adequacy and appropriateness of services delivered; 2. Supervision appropriate to the level of service; 3. On-call responses; 4. Client records for appropriateness of services provided; 5. Client satisfaction; 6. Complaint resolution; 7. Infections; 8. Staff concerns regarding client care; and 9. Provision of services appropriate to the clients' needs. C. A quality improvement committee responsible for the oversight and supervision of the program, shall consist of: 1. The director of skilled services or organization's register nurse as appropriate for the type of services provided; 2. A member of the administrative staff; 3. Representatives from each of the services provided by the</p>	<p>CHANGE: The Board is proposing the following changes: 12VAC5-381-250. Quality improvement. A. The organization <u>An HCO</u> shall implement an ongoing, comprehensive, integrated, self-assessment program of the quality and appropriateness of care or services provided, including services provided under contract or agreement. 1. <u>The findings shall be used to correct identified problems and revise policies and practices, as necessary.</u> 2. <u>Exclusive concentration on administrative or cost-of-care issues does not fulfill this requirement.</u> 3. <u>An HCO shall establish a quality improvement committee that is responsible for the oversight and supervision of the program.</u> B. <u>To identify unacceptable or unexpected trends or occurrences, an HCO</u> The following data shall be evaluated <u>evaluate</u> to identify unacceptable or unexpected trends or occurrences: 1. Staffing patterns and performance to assure adequacy and appropriateness of services delivered; 2. Supervision appropriate to the level of service; 3. On-call responses; 4. Client <u>Clinical</u> records for appropriateness of services provided; 5. Client <u>and patient</u> satisfaction; 6. Complaint resolution; 7. Infections; 8. Staff <u>Employee</u> concerns regarding client <u>or patient</u> care; and</p>
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		<p>organization, including contracted services; and</p> <p>4. An individual with demonstrated ability to represent the rights and concerns of clients. The individual may be a member of the organization's staff, a client, or a client's family member.</p> <p>In selecting members of this committee, consideration shall be given to a candidate's abilities and sensitivity to issues relating to quality of care and services provided to clients.</p> <p>D. Measures shall be implemented to resolve important problems or concerns that have been identified. Health care practitioners, as applicable, and administrative staff shall participate in the resolution of the problems or concerns that are identified.</p> <p>E. Results of the quality improvement program shall be reported annually to the governing body and the administrator and available in the organization. The report shall be acted upon by the governing body and the organization. All corrective actions shall be documented.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p>	<p>9. Provision of services appropriate to the clients' needs.</p> <p>C. A quality improvement committee responsible for the oversight and supervision of the program, shall consist of:</p> <ol style="list-style-type: none"> 1. The director of skilled services or organization's <u>the HCO's register registered nurse</u>, as appropriate for the type of services provided; 2. A member of the <u>An administrative staff employee</u>; 3. Representatives from each of the services provided by the organization <u>HCO</u>, including contracted services; and 4. An individual with demonstrated ability to represent the rights and concerns of clients. The individual <u>A client and patient advocate, who may be a member of the organization's staff an HCO employee, a client, a patient, or a client's or patient's family member.</u> <p>In selecting members of this <u>the</u> committee, consideration shall be given to a candidate's abilities and sensitivity to issues relating to quality of care and services provided to clients <u>and patients</u>.</p> <p>D. Measures shall be implemented to resolve important problems or concerns that have been identified. Health care practitioners, as applicable, and administrative staff shall participate in the resolution of the problems or concerns that are identified.</p> <p>E. D. <u>D. The quality improvement committee shall report to the governing body:</u></p> <ol style="list-style-type: none"> 1. <u>At least annually the Results results</u> of the quality improvement program shall be reported annually to the governing body and the administrator and available in the organization, which shall
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			<p><u>include the deficiencies it has identified and its recommendations for corrections and improvements and for maintaining compliance; and</u></p> <p><u>2. Immediately in writing the deficiencies it has identified that jeopardize client and patient safety.</u></p> <p><u>E. The administrator or his designee shall implement corrective action for any deficiencies identified by the quality improvement committee and</u> The report shall be acted upon by the governing body and the organization. <u>All corrective actions shall be documented document in writing all corrective actions.</u></p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p> <p>INTENT: The intent of these proposed changes is to:</p> <ul style="list-style-type: none"> (i) rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; and (ii) shift the responsibility for implementing corrective action to the administrator or his designee; and (iii) place more explicit requirements on what the committee's annual report to the governing body must include and to require immediate reporting of jeopardy to clients and patients. <p>RATIONALE: The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> (i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>; and (ii) the administrator is involved in the daily operation and management of an HCO and is better positioned to implement and monitor corrective actions; and (iii) Explicit requirements to include recommended corrective action in
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			<p>the annual report will make it easier for corrective action to be implemented and immediate reporting of jeopardy will better protect the health and safety of clients and patients.</p> <p>LIKELY IMPACT: The likely impact of these proposed changes is improved readability of this section and additional protection for the health and safety of clients and patients.</p>
381-260	N/A	<p>12VAC5-381-260. Infection control.</p> <p>A. The organization shall implement a program to reduce the risk of infection.</p> <p>B. Infection control activities shall include, but are not limited to:</p> <ol style="list-style-type: none"> 1. Staff education regarding infection risk-reduction behaviors; 2. Use of universal precautions; 3. Handling, storing, processing and transporting of regulated medical waste according to applicable procedures; 4. Handling, storing, processing and transporting supplies and equipment in a manner that prevents the spread of infections; and 5. Monitoring staff performance in infection control practices. <p>C. Accumulated waste, including all contaminated sharps, dressings, or similar infectious waste, shall be disposed of in a manner compliant with the OSHA Bloodborne Pathogens standard (29 CFR 1910.1030).</p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p>	<p>CHANGE: The Board is proposing the following changes:</p> <p>12VAC5-381-260. Infection control.</p> <p>A. The organization <u>An HCO shall implement have a an infection prevention program to reduce the risk of infection that encompasses the HCO and services provided by the HCO.</u></p> <p>B. Infection control activities shall include, but are not limited to:</p> <ol style="list-style-type: none"> 1. Staff education regarding infection risk-reduction behaviors; 2. Use of universal precautions; 3. Handling, storing, processing and transporting of regulated medical waste according to applicable procedures; 4. Handling, storing, processing and transporting supplies and equipment in a manner that prevents the spread of infections; and 5. Monitoring staff performance in infection control practices. <p>C. B. An HCO shall ensure that <u>Accumulated accumulated waste, including all contaminated sharps, dressings, or similar infectious waste, shall be are disposed of in a manner compliant with the OSHA Bloodborne Pathogens standard (29 CFR 1910.1030).</u></p> <p><u>C. An HCO shall have an employee health program that includes:</u></p>

			<p><u>1. Access to or referrals for recommended vaccines, including influenza, hepatitis B, and SARS-CoV-2;</u></p> <p><u>2. Procedures for ensuring that employees with communicable disease are identified and prevented from work activities that could result in transmission to other employees or clients;</u></p> <p><u>3. An exposure control plan for bloodborne pathogens;</u></p> <p><u>4. Documentation of screening and immunizations offered to or received by employees in accordance with statute, regulation, or recommendations of public health authorities, including documentation of screening for tuberculosis; and</u></p> <p><u>5. Compliance with requirements of the U.S. Occupational Safety and Health Administration for reporting of workplace-associated injuries or exposure to infection.</u></p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p> <p>INTENT: The intent of these proposed changes is to:</p> <ul style="list-style-type: none"> (i) rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; and (ii) remove language about infection control activities; and (iii) place more explicit requirements on HCOs regarding its care for its employees' health. <p>RATIONALE: The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> (i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>; and
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			<p>(ii) language about infection control activities has been moved to section 180, which is entitled “Policies and procedures”; and</p> <p>(iii) the minimum requirements of the employee health program will reduce likelihood of communicable diseases being transmitted by employees, clients, and patients.</p> <p>LIKELY IMPACT: The likely impact of these proposed changes is improved readability of this section and additional protection for the health and safety of clients, patients, and employees.</p>
381-270	N/A	<p>12VAC5-381-270. Drop sites.</p> <p>A. The organization may operate one or more drop sites for the convenience of staff providing direct client care or service. However, such sites shall not:</p> <ol style="list-style-type: none"> 1. Have staff assigned; 2. Accept referrals; or 3. Be advertised as part of the organization. <p>B. Any client records located at the site shall be safeguarded against loss or unauthorized use. Only authorized personnel shall have access to client records as specified by state and federal law. It shall be the responsibility of the organization to assure that records maintained at the site are readily available for inspection staff.</p> <p>C. Operation of a drop site as a business office shall constitute a separate organization and shall require licensure.</p> <p>D. Drop sites shall be subject to inspection at any time.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p>	<p>CHANGE: The Board is proposing the following changes:</p> <p>12VAC5-381-270. Drop sites.</p> <p>A. The organization <u>An HCO</u> may operate one or more drop sites for the convenience of staff <u>employees</u> providing direct client <u>and patient</u> care or service. However, such sites shall not:</p> <ol style="list-style-type: none"> 1. Have staff <u>employees</u> assigned; 2. Accept referrals; 3. Be a branch office; or 4. Be advertised as part of the organization <u>HCO.</u> <p>B. <u>An HCO shall safeguard</u> Any <u>any client clinical</u> records located at the a drop site shall be safeguarded against loss or unauthorized use. <u>An HCO shall ensure that</u></p> <ol style="list-style-type: none"> 1. Only authorized personnel <u>employees</u> shall have access to client <u>clinical</u> records as specified by state and federal law; <u>and</u> 2. It shall be the responsibility of the organization to assure that records <u>Records</u> maintained at the a drop site are readily available <u>and accessible</u> for inspection staff <u>inspectors</u>. <p>C. <u>If an HCO Operation intends to operate</u> of a drop site as a business</p>

			<p>office, it shall constitute a separate organization and shall require licensure either be separately licensed as an HCO or be licensed as a branch office of a parent HCO.</p> <p>D. An inspector may inspect Drop a drop sites site shall be subject to inspection at any time pursuant to 12VAC5-381-80 or 12VAC5-381-100.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p> <p>INTENT: The intent of these proposed changes is to rewrite this section in the active voice and break paragraphs with multiple requirements into subparts.</p> <p>RATIONALE: The rationale behind these proposed changes is the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>.</p> <p>LIKELY IMPACT: The likely impact of these proposed changes is improved readability of this section.</p>
381-280	N/A	<p>12VAC5-381-280. Client record system.</p> <p>A. The organization shall maintain an organized client record system according to accepted standards of practice. Written policies and procedures shall specify retention, reproduction, access, storage, content, and completion of the record.</p> <p>B. The client record information shall be safeguarded against loss or unauthorized use.</p> <p>C. Client records shall be confidential. Only authorized personnel shall have access as specified by state and federal law.</p> <p>D. Provisions shall be made for the safe storage of the original record and for accurate and legible reproductions of the original.</p> <p>E. Policies shall specify arrangements for retention and protection of records if the</p>	<p>CHANGE: The Board is proposing the following changes:</p> <p>12VAC5-381-280. Client <u>Clinical</u> record system.</p> <p>A. The organization <u>An HCO shall maintain an organized client clinical record system according to accepted standards of practice that includes the safe storage of the original record, and the accurate and legible reproductions of the original.</u></p> <p>B. <u>Unless otherwise specified by state or federal requirements, an HCO shall maintain originals or reproductions of clinical records in their entirety:</u></p> <ol style="list-style-type: none"> <u>1. For adult clients or patients, no less than five years from the date of discharge or of last contact; and</u> <u>2. For minor clients or patients, no less than five years after the minor reaches 18 years of age.</u>

	<p>organization discontinues operation and shall provide for notification to the OLC and the client of the location of the records.</p> <p>F. An accurate and complete client record shall be maintained for each client receiving services and shall include, but shall not be limited to:</p> <ol style="list-style-type: none"> 1. Client identifying information; 2. Identification of the primary care physician; 3. Admitting information, including a client history; 4. Information on the composition of the client's household, including individuals to be instructed in assisting the client; 5. An initial assessment of client needs to develop a plan of care or services; 6. A plan of care or service that includes the type and frequency of each service to be delivered either by organization personnel or contract services; 7. Documentation of client rights review; and 8. A discharge or termination of service summary. <p>In addition, client records for skilled and pharmaceutical services shall include:</p> <ol style="list-style-type: none"> 9. Documentation and results of all medical tests ordered by the physician or other health care professional and performed by the organization's staff; 10. A medical plan of care including appropriate assessment and pain management; 11. Medication sheets that include the name, dosage, frequency of administration, possible side effects, route of 	<p>Written policies and procedures shall specify retention, reproduction, access, storage, content, and completion of the record.</p> <p>B. <u>An HCO shall safeguard The the client clinical record information shall be safeguarded against loss or unauthorized use.</u></p> <p>C. <u>An HCO shall ensure that Client clinical records shall be are confidential. and that Only only authorized personnel employees shall have access as specified by state and federal law.</u></p> <p>D. Provisions shall be made for the safe storage of the original record and for accurate and legible reproductions of the original.</p> <p>E. Policies shall specify arrangements for retention and protection of records if the organization discontinues operation and shall provide for notification to the OLC and the client of the location of the records.</p> <p>F. <u>D. An HCO shall maintain An an accurate and complete client clinical record shall be maintained for each client or patient receiving services and shall include, but shall not be limited to:</u></p> <ol style="list-style-type: none"> 1. Client <u>or patient</u> identifying information; 2. Identification of the primary care physician; 3. Admitting information, including a client <u>or patient</u> history; 4. Information on the composition of the client's <u>or patient's</u> household, including individuals to be instructed in assisting the client <u>or patient</u>; 5. An initial <u>and all subsequent</u> assessment of client <u>or patient</u> needs to develop a <u>medical plan of care or services plan of care</u>; 6. A <u>medical plan of care or service plan of care</u> that includes;
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		<p>administration, date started, and date changed or discontinued for each medication administered; and</p> <p>12. Copies of all summary reports sent to the primary care physician.</p> <p>G. Signed and dated notes on the care or services provided by each individual delivering service shall be written on the day the service is delivered and incorporated in the client record within seven working days.</p> <p>H. Entries in the client record shall be current, legible, dated and authenticated by the person making the entry. Errors shall be corrected by striking through and initialing.</p> <p>I. Originals or reproductions of individual client records shall be maintained in their entirety for a minimum of five years following discharge or date of last contact unless otherwise specified by state or federal requirements. Records of minors shall be kept for at least five years after the minor reaches 18 years of age.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p>	<p>a. the <u>The</u> type and frequency of each service to be delivered <u>furnished</u>:</p> <p>b. Who shall furnish the services and when either by organization personnel or contract services;</p> <p>c. Prescription drugs or nonprescription drugs to be administered and the route of administration, including if self-administered;</p> <p>d. Documentation of supervisory visits, including date, time, review of the medical plan of care or plan of care, services provided to date, and client or patient assessments; and</p> <p>e. Interruptions in service and an explanation for any such interruption;</p> <p>7. Documentation of client <u>and</u> <u>patient</u> rights review; and</p> <p>8. A <u>written</u> discharge or termination of service summary <u>that records the service delivered and final disposition at the time of client's or patient's discharge or termination from service.</u></p> <p>E. In addition, An HCO shall include in client clinical records for skilled and pharmaceutical services shall include:</p> <p>9. 1. <u>1.</u> Documentation and results of all medical tests ordered by the physician or other health care professional and performed by the organization's staff <u>HCO employees</u>;</p> <p>10. 2. <u>2.</u> A medical plan of care including appropriate assessment and pain management;</p> <p>11. 3. <u>3.</u> Medication sheets that include the name, dosage, frequency of administration,</p>
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			<p>possible side effects, route of administration, date started, and date changed or discontinued for each medication administered; and</p> <p>42. <u>4.</u> Copies of all summary reports sent to the primary care physician <u>who signed the medical plan of care.</u></p> <p>G. <u>F.</u> An HCO shall ensure that:</p> <p style="padding-left: 20px;">1. <u>1.</u> Signed and dated notes on the care or services provided by each individual delivering service shall be <u>are</u> written on the day the service is delivered;</p> <p style="padding-left: 20px;">2. and incorporated <u>Signed and dated notes on the care or services provide are incorporated</u> in the <u>client clinical</u> record within seven <u>working calendar days</u>;</p> <p style="padding-left: 20px;">H. <u>3.</u> Entries in the <u>client clinical</u> record shall be <u>are</u> current, legible, dated and authenticated by the person making the entry; <u>and</u></p> <p style="padding-left: 20px;">4. <u>4.</u> Errors shall be <u>are</u> corrected by striking through and initialing.</p> <p style="padding-left: 20px;">I. <u>Originals or reproductions of individual client records shall be maintained in their entirety for a minimum of five years following discharge or date of last contact unless otherwise specified by state or federal requirements. Records of minors shall be kept for at least five years after the minor reaches 18 years of age.</u></p> <p>Statutory Authority</p> <p>§§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p> <p>INTENT: The intent of these proposed changes is to:</p> <p style="padding-left: 20px;">(i) rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; and</p>
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			<p>(ii) improve clarity about minimum documentation for the medical plans of care and plans of care.</p> <p>RATIONALE: The rationale behind these proposed changes is:</p> <p>(i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>; and</p> <p>(ii) requiring medical plans of care and plans of care to only address type and frequency of service provides an incomplete accounting of care to be provided, which can complicate inspections, particularly of complaints.</p> <p>LIKELY IMPACT: The likely impact of these proposed changes is improved readability of this section and clearer documentation for the client, the patient, the HCO, and the agency to review when there is a complaint.</p>
381-290	N/A	<p>12VAC5-381-290. Home attendants.</p> <p>Home attendants shall be able to speak, read and write English and shall meet one of the following qualifications:</p> <ol style="list-style-type: none"> 1. Have satisfactorily completed a nursing education program preparing for registered nurse licensure or practical nurse licensure; 2. Have satisfactorily completed a nurse aide education program approved by the Virginia Board of Nursing; 3. Have certification as a nurse aide issued by the Virginia Board of Nursing; 4. Be successfully enrolled in a nursing education program preparing for registered nurse or practical nurse licensure and have currently completed at least one nursing course that includes clinical 	<p>CHANGE: The Board is proposing the following changes:</p> <p>12VAC5-381-290. Home attendants.</p> <p><u>A. An HCO shall ensure that its Home <u>home</u> attendants shall be <u>are</u> able to speak, read, and write English and shall meet one of the following qualifications:</u></p> <ol style="list-style-type: none"> 1. Have satisfactorily completed a nursing education program preparing for registered nurse licensure or practical nurse licensure; 2. Have satisfactorily completed a nurse aide education program approved by the Virginia Board of Nursing; 3. Have <u>active</u> certification as a nurse aide issued by the Virginia Board of Nursing; 4. Be successfully enrolled in a nursing education program preparing for registered nurse or practical nurse licensure and have currently completed at

		<p>experience involving direct client care;</p> <p>5. Have satisfactorily passed a competency evaluation program that meets the criteria of 42 CFR 484.36 (b). Home attendants of personal care services need only be evaluated on the tasks in 42 CFR 484.36 (b) as those tasks relate to the personal care services to be provided; or</p> <p>6. Have satisfactorily completed training using the "Personal Care Aide Training Curriculum," 2003 edition, of the Department of Medical Assistance Services. However, this training is permissible for home attendants of personal care services only.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p>	<p>least one nursing course that includes clinical experience involving direct client care;</p> <p>5. Have satisfactorily passed a competency evaluation program that meets the criteria of 42 CFR 484.36 (b) <u>42 CFR 484.80(c)</u>. Home attendants of personal care services need only be evaluated on the tasks <u>subjects</u> in 42 CFR 484.36 (b) <u>42 CFR 484.80(c)</u> as those tasks <u>subjects</u> relate to the personal care services to be provided; or</p> <p>6. Have satisfactorily completed training using the "Personal Care Aide Training Curriculum," 2003 edition, of the Department of Medical Assistance Services <u>provided by an HCO that meets the requirements of subsection B.</u> However, this training is permissible for home attendants <u>and volunteers</u> of personal care services only.</p> <p><u>B. An HCO may develop a 40-hour training program for home attendants and volunteers of personal care services that shall:</u></p> <p><u>1. Include education addressing:</u></p> <ul style="list-style-type: none"> <u>a. Goals of personal care;</u> <u>b. Personal care and rehabilitative services;</u> <u>c. Observation, reporting and documentation of patient status and the care or service furnished;</u> <u>d. Documentation requirements for Medicaid individuals</u> <u>e. Reading and recording temperature, pulse, and respiration;</u> <u>f. Prevention of skin breakdown, including recognizing and reporting changes in skin condition such as pressure ulcers;</u>
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			<p><u>g. Physical and biological aspects of aging;</u></p> <p><u>h. Orientation to types of physical disabilities;</u></p> <p><u>i. The physical, emotional, and developmental needs of and ways to work with the populations served including the need for respect for the client or patient, his or her privacy and his or her property</u></p> <p><u>j. Body mechanics, including normal range of motion and positioning;</u></p> <p><u>k. Basic elements of body functioning and changes in body function that must be reported to a home attendant's or volunteer's supervisor</u></p> <p><u>l. Home management, including maintenance of a clean, safe, and healthy environment;</u></p> <p><u>m. Basic infection control policies and procedures</u></p> <p><u>n. Safety and accident prevention in the home, including safe transfer techniques and ambulation;</u></p> <p><u>o. Policies and procedures regarding accidents or injuries;</u></p> <p><u>p. Recognizing emergencies and knowledge of emergency policies and procedures</u></p> <p><u>q. Food, nutrition, and meal preparation, including adequate nutrition and fluid intake;</u></p> <p><u>r. Special considerations in preparation of special diets;</u></p> <p><u>s. Appropriate and safe techniques in personal hygiene and grooming that include nail and skin care,</u></p>
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			<p><u>oral hygiene, toileting and elimination, and bathing and hair care of clients and patients with limited mobility;</u></p> <p><u>t. Care of the home and personal belongings.</u></p> <p><u>2. Be conducted by a registered nurse who meets the requirements in 18VAC90-26-30.</u></p> <p><u>3. Issue and maintain certificates of completion containing:</u></p> <p><u>a. The instructor's printed name and signature;</u></p> <p><u>b. The participant's printed name; and</u></p> <p><u>c. The date of completion of the program.</u></p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p> <p>INTENT: The intent of these proposed changes is to:</p> <ul style="list-style-type: none"> (i) rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; and (ii) replace the reference to an outdated training manual to allow HCOs to set up in-house training for volunteer and home attendants of personal care services. <p>RATIONALE: The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> (i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>; and (ii) The reference to 2003 DMAS Personal Care Aide Training Curriculum is out of date and needs to be replaced by a current curriculum, which is based on federal home health agency requirements and on a curriculum that appears in the hospice
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			<p>licensure regulations (12VAC5-391-10 <i>et seq.</i>).</p> <p>LIKELY IMPACT: The likely impact of these proposed changes is improved readability of this section and HCOs creating their own training for volunteers and home attendants of personal care services, which is transferrable between HCOs.</p>
381-300	N/A	<p style="text-align: center;">Part III Skilled Services</p> <p>12VAC5-381-300. Skilled services.</p> <p>A. The organization shall provide a program of home health services that shall include one or more of the following:</p> <ol style="list-style-type: none"> 1. Nursing services; 2. Physical therapy services; 3. Occupational therapy services; 4. Speech therapy services; 5. Respiratory therapy services; or 6. Medical social services. <p>B. All skilled services delivered shall be prescribed in a medical plan of care that contains at least the following information:</p> <ol style="list-style-type: none"> 1. Diagnosis and prognosis; 2. Functional limitations; 3. Orders for all skilled services, including: (i) specific procedures, (ii) treatment modalities, and (iii) frequency and duration of the services ordered; 4. Orders for medications, when applicable; and 5. Orders for special dietary or nutritional needs, when applicable. <p>The medical plan of care shall be approved and signed by the client's primary care physician.</p> <p>C. Verbal orders shall be documented within 24 consecutive hours in the client's</p>	<p>CHANGE: The Board is proposing the following changes:</p> <p style="text-align: center;">Part III Skilled Services <u>and Personal Care Services</u></p> <p>12VAC5-381-300. Skilled services.</p> <p>A. The organization <u>An HCO</u> shall <u>may</u> provide a program of home health <u>skilled</u> services that shall include <u>includes</u> one or more of the following:</p> <ol style="list-style-type: none"> 1. Nursing services; 2. Physical therapy services; 3. Occupational therapy services; 4. Speech therapy <u>language pathology</u> services; 5. Respiratory therapy services; or 6. Medical social services; <u>or</u> 7. <u>Pharmaceutical services.</u> <p>B. <u>An HCO</u> shall ensure that All <u>all</u> skilled services delivered shall be <u>are</u> prescribed in a medical plan of care that contains at least the following information <u>includes</u>:</p> <ol style="list-style-type: none"> 1. Diagnosis and prognosis; 2. Functional limitations; 3. Orders for all skilled services, including: <ol style="list-style-type: none"> (i) <u>a. specific</u> <u>Specific</u> procedures; (ii) <u>b. treatment</u> <u>Treatment</u> modalities; <u>i</u> and (iii) <u>c. frequency</u> <u>Frequency</u> and duration of the services ordered; 4. Orders for medications, when applicable; and

	<p>record by the health care professional receiving the order and shall be countersigned by the prescribing person.</p> <p>D. The primary care physician shall be notified immediately of any changes in the client's condition that indicates a need to alter the medical plan of care.</p> <p>E. The medical plan of care shall be reviewed, approved, and signed by the primary care physician at least every 60 days.</p> <p>F. There shall be a director of skilled services, who shall be a physician licensed by the Virginia Board of Medicine or a registered nurse, responsible for the overall direction and management of skilled services including the availability of services, the quality of services and appropriate staffing. The individual shall have the appropriate experience for the scope of services provided by the organization.</p> <p>G. The organization shall develop and implement policies and procedures for the handling of drugs and biologicals, including procurement, storage, administration, self-administration, and disposal of drugs and shall allow clients to procure their medications from a pharmacy of their choice.</p> <p>H. All prescription drugs shall be prescribed and properly dispensed to clients according to the provisions of Chapters 33 (§ 54.1-3300 et seq.) and 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia and the regulations of the Virginia Board of Pharmacy, except for prescription drugs authorized by § 54.1-3408 of the Drug Control Act, such as epinephrine for emergency administration, normal saline and heparin flushes for the maintenance of IV lines, and adult immunizations, which may be given by a nurse pursuant to established protocol.</p> <p>Statutory Authority</p>	<p>5. Orders for special dietary or nutritional needs, when applicable.</p> <p><u>An HCO shall ensure The the medical plan of care shall be is approved and signed by the client's primary-care patient's physician.</u></p> <p>C. <u>An HCO shall ensure Verbal oral orders shall be are:</u></p> <ol style="list-style-type: none"> <u>1. documented Documented within no more than 24 consecutive hours in the client's clinical record by the actively licensed health care professional practitioner receiving the order; and</u> <u>2. shall be countersigned Countersigned by the prescribing person actively licensed health care practitioner.</u> <p>D. <u>An HCO shall immediately notify a patient's The primary-care physician shall be notified immediately of any changes in the client's patient's condition that indicates a need to alter the medical plan of care.</u></p> <p>E. <u>An HCO shall ensure The the medical plan of care shall be is reviewed, approved, and signed by the patient's primary-care physician at least every 60 calendar days.</u></p> <p>F. <u>An HCO shall appoint in writing There shall be a director of skilled services, who shall:</u></p> <ol style="list-style-type: none"> <u>1. be Be a physician actively licensed by the Virginia Board of Medicine or a registered nurse actively licensed by the Virginia Board of Nursing;</u> <u>2. Be responsible for the overall direction and management of skilled services including the availability of services, the quality of services and appropriate staffing; and</u> <u>3. The individual shall have Have the appropriate experience for the scope of</u>
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		<p>§§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p>	<p>services provided by the organization <u>HCO</u>.</p> <p>G. The organization shall develop and implement policies and procedures for the handling of drugs and biologicals, including procurement, storage, administration, self-administration, and disposal of drugs and shall allow clients to procure their medications from a pharmacy of their choice.</p> <p>H. All prescription drugs shall be prescribed and properly dispensed to clients according to the provisions of Chapters 33 (§ 54.1-3300 et seq.) and 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia and the regulations of the Virginia Board of Pharmacy, except for prescription drugs authorized by § 54.1-3408 of the Drug Control Act, such as epinephrine for emergency administration, normal saline and heparin flushes for the maintenance of IV lines, and adult immunizations, which may be given by a nurse pursuant to established protocol.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p> <p>INTENT: The intent of these proposed changes is to:</p> <ul style="list-style-type: none"> (i) rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; (ii) remove language regarding drug policies and procedures; and (iii) rewrite this section so as to avoid scope of practice conflicts with health profession regulations. <p>RATIONALE: The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> (i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>; (ii) language about drug policies and procedures has been moved to section 180, which is entitled "Policies and procedures"; and
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			<p>(iii) scope of practice of health care practitioners is the regulatory purview of the Department of Health Professions.</p> <p>LIKELY IMPACT: The likely impact of these proposed changes is improved readability of this section.</p>
381-310	N/A	<p>12VAC5-381-310. Nursing services.</p> <p>A. All nursing services shall be directly provided by an appropriately qualified registered nurse or licensed practical nurse, except for those nursing tasks that may be delegated by a registered nurse according to 18VAC90-20-420 through 18VAC90-20-460 of the regulations of the Virginia Board of Nursing and with a plan developed and implemented by the organization.</p> <p>B. Supervision of services shall be provided as often as necessary as determined by the client's needs, the assessment by the registered nurse, and the organization's written policies not to exceed 90 days.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p>	<p>CHANGE: The Board is proposing the following changes:</p> <p>12VAC5-381-310. Nursing services.</p> <p>A. <u>An HCO shall ensure that All all nursing services shall be are:</u></p> <ol style="list-style-type: none"> 1. <u>directly</u> Directly provided by an <u>actively licensed and</u> appropriately qualified registered nurse or licensed practical nurse; <u>or</u> 2. <u>By a person to whom except for these nursing tasks that may be are</u> delegated by a registered nurse <u>according to in accordance with 18VAC90-20-420 through 18VAC90-20-460 of the regulations of the Virginia Board of Nursing Part VI (18VAC90-19-240 et seq.) of the Regulations Governing the Practice of Nursing</u> and with a plan developed and implemented by the organization <u>HCO.</u> <p>B. <u>An HCO shall ensure that nursing services are supervised in person in the patient's residence</u> Supervision of services shall be provided as often as necessary, but not less often than every 60 calendar days, as determined by:</p> <ol style="list-style-type: none"> 1. the <u>The client's patient's</u> needs; i 2. the <u>The</u> assessment by the registered nurse; i and 3. the <u>The</u> organization's HCO's written policies not to exceed 90 days. <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p>

			<p>INTENT: The intent of these proposed changes is to:</p> <ul style="list-style-type: none"> (i) rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; and (ii) match in-person supervision interval to the update interval for medical plans of care. <p>RATIONALE: The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> (i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>; and (ii) in-person supervision of nursing services can be conducted at the same time of assessments of patient needs for the medical plan of care . <p>LIKELY IMPACT: The likely impact of these proposed changes is improved readability of this section and reduce burden to the HCOs who can combine medical plan of care updates and in-person supervision into a single visit.</p>
381-320	N/A	<p>12VAC5-381-320. Therapy services.</p> <p>A. Physical therapy, occupational therapy, speech therapy, or respiratory therapy services shall be provided according to the medical plan of care by or under the direction of an appropriately qualified therapist currently licensed in Virginia and may include, but are not limited to:</p> <ol style="list-style-type: none"> 1. Assessing client needs or admission for service as appropriate; 2. Implementing a medical plan of care and revising as necessary; 3. Initiating appropriate preventive, therapeutic, and rehabilitative techniques according to the medical plan of care; 4. Educating the client and family regarding 	<p>CHANGE: The Board is proposing the following changes:</p> <p>12VAC5-381-320. Therapy services.</p> <p>A. <u>An HCO shall ensure that</u> Physical physical therapy, occupational therapy, speech therapy language pathology, or respiratory therapy services shall be <u>are</u> provided according to the medical plan of care by or under the direction of an appropriately qualified therapist currently <u>actively</u> licensed in Virginia and may shall include, but are not limited to:</p> <ol style="list-style-type: none"> 1. Assessing client the <u>patient's</u> needs or admission for service as appropriate; 2. Implementing a medical plan of care and revising as necessary; 3. Initiating appropriate preventive, therapeutic, and

	<p>treatment modalities and use of equipment and devices;</p> <p>5. Providing consultation to other health care professionals;</p> <p>6. Communicating with the physician and other health care professionals regarding changes in the client's needs;</p> <p>7. Supervising therapy assistants and home attendants as appropriate; and</p> <p>8. Preparing clinical notes.</p> <p>B. Therapy assistants may be used to provide therapy services.</p> <p>1. The occupational therapy assistant shall be currently certified by the National Board for Certification in Occupational Therapy and shall practice under the supervision of a licensed occupational therapist.</p> <p>2. The physical therapy assistant shall be currently licensed by the Virginia Board of Physical Therapy and shall practice under the supervision of a licensed physical therapist.</p> <p>C. Duties of therapy assistants shall be within their scope of practice and may include, but are not limited to:</p> <p>1. Performing services planned, delegated, and supervised by the appropriately licensed therapist; and</p> <p>2. Preparing clinical notes.</p> <p>D. Supervision of services shall be provided as often as necessary as determined by the client's needs, the assessment of the licensed therapist, and the organization's written policies not to exceed 90 days.</p>	<p>rehabilitative techniques according to the medical plan of care;</p> <p>4. Educating the client <u>patient</u> and family regarding treatment modalities and use of equipment and devices;</p> <p>5. Providing consultation to other <u>actively licensed</u> health care professionals <u>practitioners, as applicable</u>;</p> <p>6. Communicating with the physician and other <u>actively licensed</u> health care professionals <u>practitioners</u> regarding changes in the client's <u>patient's</u> needs;</p> <p>7. Supervising therapy assistants and home attendants as appropriate; and</p> <p>8. Preparing clinical notes.</p> <p>B. <u>An HCO may employ or contract with Therapy</u> therapy assistants may be used to provide therapy services. <u>An HCO shall ensure that:</u></p> <p>1. The An occupational therapy assistant shall be <u>is currently</u> <u>actively</u> certified by the National Board for Certification in Occupational Therapy and shall practice <u>practices</u> under the supervision of a <u>an actively</u> licensed occupational therapist; <u>and</u></p> <p>2. The A physical therapy assistant shall be <u>is currently</u> <u>actively</u> licensed by the Virginia Board of Physical Therapy and shall practice <u>practices</u> under the supervision of a <u>an actively</u> licensed physical therapist.</p> <p>C. Duties of therapy assistants shall be within their scope of practice and may include, but are not limited to:</p> <p>1. Performing services planned, delegated, and supervised by the appropriately licensed therapist; and</p> <p>2. Preparing clinical notes.</p>
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		<p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p>	<p>D. C. An HCO shall ensure that therapy services are supervised in-person in the patient's residence. Supervision of services shall be provided as often as necessary, but not less often than prescribed by the applicable therapy licensing board, as determined by:</p> <ol style="list-style-type: none"> 1. the The client's patient's needs; 2. the The assessment of the actively licensed therapist; and 3. the The organization's HCO's written policies not to exceed 90 days. <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p> <p>INTENT: The intent of these proposed changes is to:</p> <ol style="list-style-type: none"> (i) rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; and (ii) rewrite this section so as to avoid scope of practice conflicts with health profession regulations. <p>RATIONALE: The rationale behind these proposed changes is:</p> <ol style="list-style-type: none"> (i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>; and (ii) scope of practice of health care practitioners is the regulatory purview of the Department of Health Professions. <p>LIKELY IMPACT: The likely impact of these proposed changes is improved readability of this section.</p>
381-330	N/A	<p>12VAC5-381-330. Home attendants assisting with skilled services. A. Home attendants assisting with providing skilled services may:</p>	<p>CHANGE: The Board is proposing the following changes:</p> <p>12VAC5-381-330. Home attendants assisting with skilled services. A. <u>An HCO that employs or contracts with Home home attendants</u></p>

		<p>1. Assist clients with (i) activities of daily living, (ii) ambulation and prescribed exercise, and (iii) other special duties with appropriate training and demonstrated competency;</p> <p>2. Administer normally self-administered drugs as allowed by § 54.1-3408 of the Virginia Drug Control Act (Chapter 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia);</p> <p>3. Measure and record fluid intake and output;</p> <p>4. Take and record blood pressure, pulse and respiration;</p> <p>5. Record and report to the appropriate health care professional changes in the client's condition;</p> <p>6. Document services and observations in the client's record; and</p> <p>7. Perform any other duties that the attendant is qualified to do by additional training and demonstrated competency as allowed by state or federal guidelines.</p> <p>B. Prior to the initial delivery of services, the home attendant shall receive specific written instructions for the client's care from the appropriate health care professional responsible for the care.</p> <p>C. Home attendants shall work under the supervision of the appropriate health care professional responsible for the client's care.</p> <p>D. Relevant in-service education or training for home attendants shall consist of at least 12 hours annually. In-service training may be in conjunction with on-site supervision.</p>	<p>assisting to assist with providing skilled services may <u>permit home attendants, consistent with the medical plan of care, to:</u></p> <p>1. Assist clients <u>patients</u> with (i) activities of daily living, (ii) ambulation, and prescribed <u>restorative</u> exercise, and (iii) <u>other special duties</u> with appropriate training and demonstrated competency;</p> <p>2. Administer normally self-administered drugs as allowed by § 54.1-3408 of the Virginia Drug Control Act (Chapter 34 (§ 54.1-3400 et seq.) <u>§ 54.1-3400 et seq.</u> of Title 54.1 of the Code of Virginia);</p> <p>3. Measure and record fluid intake and output;</p> <p>4. Take and record blood pressure, pulse and respiration;</p> <p>5. Record and report to the appropriate <u>actively licensed</u> health care professional <u>practitioner</u> changes in the client's <u>patient's</u> condition;</p> <p>6. Document services and observations in the client's <u>clinical</u> record; and</p> <p>7. Perform any other duties that the attendant is qualified to do by additional training and demonstrated competency as allowed by state or federal guidelines.</p> <p>B. Prior to the initial delivery of services, <u>an HCO shall ensure that the home attendant</u> shall receive <u>receives</u> specific written instructions for the client's <u>patient's</u> care from the appropriate <u>actively licensed</u> health care professional <u>practitioner</u> responsible for the care.</p> <p>C. <u>An HCO shall ensure that a Home attendants home attendant:</u></p> <p><u>1. shall work</u> <u>Works</u> under the supervision of the appropriate <u>actively licensed</u> health care professional <u>practitioner</u></p>
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		<p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p>	<p>responsible for the client's <u>patient's</u> care, with supervision being conducted in-person at least once every 60 calendar days; and</p> <p>D. Relevant in-service education or training for home attendants shall consist of at least 2. Completes no less than 12 hours annually of in-service education or training, which in-service training may be in conjunction with on-site supervision.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p> <p>INTENT: The intent of these proposed changes is to:</p> <ul style="list-style-type: none"> (i) rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; and (ii) specify that home attendants that assist in skilled services are subject to in-person supervision. <p>RATIONALE: The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> (i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>; and (ii) to resolve ambiguity in the current regulation about how frequently home attendants that assist in skilled services are subject to in-person supervision. <p>LIKELY IMPACT: The likely impact of these proposed changes is improved readability of this section and reduced confusion for regulants on minimum supervision standards.</p>
381-340	N/A	<p>12VAC5-381-340. Medical social services. A. Medical social services shall be provided according to the medical plan of care by or under the direction of a qualified social worker who holds, at a minimum,</p>	<p>CHANGE: The Board is proposing the following changes:</p>

		<p>a bachelor's degree with major studies in social work, sociology, or psychology from a four-year college or university accredited by the Council on Social Work Education and has at least two years experience in case work or counseling in a health care or social services delivery system.</p> <p>The organization shall have one year from January 1, 2006, to ensure the designated individual meets the qualifications of this standard.</p> <p>B. The duties of a social worker may include, but are not limited to:</p> <ol style="list-style-type: none"> 1. Assessing the client's psychological status; 2. Implementing a medical plan of care and revising, as necessary; 3. Providing social work services including (i) short-term individual counseling, (ii) community resource planning, and (iii) crisis intervention; 4. Providing consultation with the primary care physician and other health care professionals regarding changes in the client's needs; 5. Preparing notes on the care or services provided; and 6. Participating in discharge planning. <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p>	<p>12VAC5-381-340. Medical social services.</p> <p>A. <u>An HCO shall ensure that</u> Medical <u>medical</u> social services shall be <u>are</u> provided according to the medical plan of care by or under the direction of a qualified <u>an actively licensed clinical</u> social worker <u>or an individual who has master's degree in social work from a school accredited by the Council on Social Work Education, both of which shall have</u> who holds, at a minimum, a bachelor's degree with major studies in social work, sociology, or psychology from a four-year college or university accredited by the Council on Social Work Education and has at least two years <u>one year's</u> experience in case work or counseling in a health care or social services delivery system.</p> <p>The organization shall have one year from January 1, 2006, to ensure the designated individual meets the qualifications of this standard.</p> <p>B. <u>An HCO may assign</u> The duties <u>of</u> to a social worker, <u>including</u> may include, but are not limited to:</p> <ol style="list-style-type: none"> 1. Assessing the <u>client's</u> patient's psychological status; 2. Implementing a medical plan of care <u>and</u> revising, as necessary; <u>necessary;</u> 3. Providing social work services including (i) short-term individual counseling, (ii) community resource planning, and (iii) crisis intervention; 4. Providing consultation with the <u>patient's</u> primary care physician and other <u>actively licensed</u> health care <u>professionals</u> practitioners regarding changes in the <u>client's</u> patient's needs; 5. Preparing notes on the care or services provided; and 6. Participating in discharge planning. <p>Statutory Authority</p>
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			<p>§§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p> <p>INTENT: The intent of these proposed changes is to:</p> <ul style="list-style-type: none"> (i) rewrite this section in the active voice; and (ii) provide clarity and flexibility about who may direct medical social services. <p>RATIONALE: The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> (i) the active voice is the style preferred and recommended by <i>The Virginia Register of Regulations</i>; and (ii) to make it easier for HCO to find qualified candidates to direct medical social services. <p>LIKELY IMPACT: The likely impact of these proposed changes is improved readability of this section and a wider pool of qualified candidates to direct medical social services.</p>
381-350	N/A	<p style="text-align: center;">Part IV Pharmaceutical Services</p> <p>12VAC5-381-350. Pharmacy services.</p> <p>A. All prescription drugs shall be prescribed and properly dispensed to the client according to the provisions of the Chapters 33 (§ 54.1-3300 et seq.) and 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia and the regulations of the Virginia Board of Pharmacy, except for prescription drugs authorized by § 54.1-3408 of the Drug Control Act, such as epinephrine for emergency administration, normal saline and heparin flushes for the maintenance of IV lines, and adult immunizations, which may be given by a nurse pursuant to established protocol.</p> <p>B. Home attendants may administer normally self-administered drugs as allowed by § 54.1-3408 of the Virginia Drug Control Act (Chapter 34 (§ 54.1-3400 et seq.) of Title 54.1 of the</p>	<p>CHANGE: The Board is proposing the following changes:</p> <p style="text-align: center;">Part IV Pharmaceutical Services</p> <p>12VAC5-381-350. Pharmacy Pharmaceutical services.</p> <p>A. <u>An HCO shall ensure that All all</u> prescription drugs shall be <u>are</u> prescribed and properly dispensed to the client <u>patient</u> according to the provisions of the Chapters 33 (§ 54.1-3300 et seq.) and 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia and the regulations of the Virginia Board of Pharmacy, except for prescription drugs authorized by § 54.1-3408 of the Drug Control Act, such as epinephrine for emergency administration, normal saline and heparin flushes for the maintenance of IV lines, and adult immunizations, which may be given by a nurse pursuant to established protocol.</p> <p>B. <u>An HCO may permit Home</u> home attendants <u>may to</u> administer normally self-administered drugs as</p>

		<p>Code of Virginia). Any other drug shall be administered only by a licensed nurse or physician assistant.</p> <p>C. The organization shall develop written policies and procedures for the administration of home infusion therapy medications that include, but are not limited to:</p> <ol style="list-style-type: none"> 1. Developing a plan of care or service; 2. Initiation of medication administration based on a prescriber's order and monitoring of the client for response to the treatment and any adverse reactions or side effects; 3. Assessment of any factors related to the home environment that may affect the prescriber's decisions for initiating, modifying, or discontinuing medications; 4. Communication with the prescriber concerning assessment of the client's response to therapy, any other client specific needs, and any significant change in the client's condition; 5. Communication with the client's provider pharmacy concerning problems or needed changes in a client's medication; 6. Maintaining a complete and accurate record of medications prescribed, medication administration data, client assessments, any laboratory tests ordered to monitor response to drug therapy and results, and communications with the prescriber and pharmacy provider; 7. Educating or instructing the client, 	<p>allowed by § 54.1-3408 of the Virginia Drug Control Act (Chapter 34 (§ 54.1-3400 et seq.) (§ 54.1-3400 et seq. of Title 54.1 of the Code of Virginia). Any other drug shall be administered only by a licensed nurse or physician assistant.</p> <p>C. The organization shall develop written policies and procedures for the administration of home infusion therapy medications that include, but are not limited to:</p> <ol style="list-style-type: none"> 1. Developing a plan of care or service; 2. Initiation of medication administration based on a prescriber's order and monitoring of the client for response to the treatment and any adverse reactions or side effects; 3. Assessment of any factors related to the home environment that may affect the prescriber's decisions for initiating, modifying, or discontinuing medications; 4. Communication with the prescriber concerning assessment of the client's response to therapy, any other client specific needs, and any significant change in the client's condition; 5. Communication with the client's provider pharmacy concerning problems or needed changes in a client's medication; 6. Maintaining a complete and accurate record of medications prescribed, medication administration data, client assessments, any laboratory tests ordered to monitor response to drug therapy and results, and communications with the prescriber and pharmacy provider; 7. Educating or instructing the client, family members, or
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		<p>family members, or other caregivers involved in the administration of infusion therapy in the proper storage of medication, in the proper handling of supplies and equipment, in any applicable safety precautions, in recognizing potential problems with the client, and actions to take in an emergency; and</p> <p>8. Initial and retraining of all organization staff providing infusion therapy.</p> <p>D. The organization shall employ a registered nurse, who has completed training in infusion therapy, and has the knowledge, skills, and competencies to safely administer infusion therapy, to supervise medication administration by staff. This person shall be responsible for ensuring compliance with applicable laws and regulations, adherence to the policies and procedures related to administration of medications, and conducting periodic assessments of staff competency in performing infusion therapy.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p>	<p>other caregivers involved in the administration of infusion therapy in the proper storage of medication, in the proper handling of supplies and equipment, in any applicable safety precautions, in recognizing potential problems with the client, and actions to take in an emergency; and</p> <p>8. Initial and retraining of all organization staff providing infusion therapy.</p> <p>D. C. The organization <u>An HCO</u> shall employ a registered nurse, who has completed training in infusion therapy, and has the knowledge, skills, and competencies to safely administer infusion therapy, to:</p> <ol style="list-style-type: none"> <u>1. supervise</u> <u>Supervise</u> medication administration by <u>staff employees consistent with the type of medication being administered;</u> <u>2. This person shall be responsible for ensuring</u> <u>Ensure employee</u> compliance with applicable laws and regulations; <u>3. Ensure</u> adherence to the policies and procedures related to administration of medications; and <u>4. conducting</u> <u>Conduct periodic annual</u> assessments of <u>staff employee</u> competency in performing infusion therapy. <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p> <p>INTENT: The intent of these proposed changes is to:</p> <ol style="list-style-type: none"> (i) rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; (ii) rewrite this section so as to avoid scope of practice conflicts with health profession regulations; and
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			<p>(iii) remove language regarding home infusion therapy policies and procedures.</p> <p>RATIONALE: The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> (i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>; (ii) scope of practice of health care practitioners is the regulatory purview of the Department of Health Professions; and (iii) language about home infusion therapy policies and procedures has been moved to section 180, which is entitled "Policies and procedures." <p>LIKELY IMPACT: The likely impact of these proposed changes is improved readability of this section.</p>
381-DIBR	N/A	Personal Care Aide Training Curriculum, 2003 Edition, Virginia Department of Medical Assistance Services.	<p>CHANGE: The Board is proposing to repeal this section in its entirety:</p> <p>INTENT: The intent of these proposed changes is to remove the DIBR section.</p> <p>RATIONALE: The rationale behind these proposed changes is that there is no document incorporated by reference in the proposed regulatory text, so there is no need for this section.</p> <p>LIKELY IMPACT: The likely impact of these proposed changes is reduced confusion for regulants.</p>

1 **Project 5779 - NOIRA**

2 **Department Of Health**

3 **Amend the Regulation after Assessment and Receipt of Public Comment**

4 Chapter 381

5 ~~REGULATIONS FOR THE LICENSURE OF HOME CARE ORGANIZATIONS~~ ORGANIZATION
6 LICENSURE REGULATION

7 **12VAC5-381-10. Definitions.**

8 Part I
9 Definitions and General Information

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

12 "Activities of daily living" ~~or "ADLs"~~ means bathing, dressing, toileting, transferring, bowel
13 control, bladder control and eating/feeding. ~~A person's~~ An individual's degree of independence
14 in performing these activities is part of determining the appropriate level of care and services. A
15 need for assistance exists when the client or patient is unable to complete an activity due to
16 cognitive impairment, functional disability, physical health problems, or safety. The client's or
17 patient's functional level is based on ~~the client's~~ his need for assistance most or all of the time to
18 perform personal care tasks in order to live independently.

19 "Administer" means the direct application of a ~~controlled substance~~ prescription drug as
20 defined in § 54.1-3401 of the Code of Virginia or a nonprescription drug, whether by injection,
21 inhalation, ingestion or any other means, to the body of a client or patient by (i) a practitioner or
22 by his authorized agent and under his direction or (ii) the client or patient at the direction and in
23 the presence of the practitioner ~~as defined in § 54.1-3401 of the Code of Virginia.~~

24 "Administrator" means ~~a person~~ an individual designated in writing by the governing body as
25 having the responsibility and necessary authority for the ~~day-to-day~~ daily management of ~~the~~
26 organization an HCO or a branch office of an HCO. The administrator must be an employee of
27 the organization HCO. The administrator, the skilled services director ~~of nursing~~, or other clinical
28 director may be the same individual if that individual is dually qualified.

29 ~~"Available at all times during operating hours" means an individual is readily available on the~~
30 ~~premises or by telecommunications.~~

31 ~~"Barrier crimes" "Barrier crime" means certain offenses~~ any offense set forth in clause (i) of
32 the definition of barrier crime in § 19.2-392.02, specified in § 32.1-162.9:1 of the Code of
33 Virginia, that automatically bar an individual convicted of those offenses from employment with a
34 home care organization.

35 "Blanket fidelity bond" means a bond that provides coverage that protects an ~~organization's~~
36 HCO's losses as a result of employee theft or fraud.

37 "Branch office" means a geographically separate office of ~~the home care organization~~ an
38 HCO that performs all or part of the primary functions of the ~~home care organization~~ parent
39 HCO on a smaller scale.

40 ~~"Chore services" means assistance with nonroutine, heavy home maintenance for persons~~
41 ~~unable to perform such tasks. Chore services include minor repair work on furniture and~~
42 ~~appliances; carrying coal, wood and water; chopping wood; removing snow; yard maintenance;~~
43 ~~and painting.~~

44 "Business day" means any day that is not a Saturday, Sunday, legal holiday, or day on
45 which the department is closed. For the purposes of this chapter, any day on which the
46 Governor authorizes the closing of the state government shall be considered a legal holiday.

47 "Client" means an individual who only receives personal care services from an HCO.

48 ~~"Client record"~~ "Clinical record" means the centralized location for documenting information
49 about the client or patient and the care and services provided to the client him by the
50 organization an HCO. A client clinical record is a continuous and accurate account of care or
51 services, whether hard copy or electronic, provided to a client or patient, including information
52 that has been dated and signed by the individuals who prescribed or delivered the care or
53 service.

54 ~~"Client's residence" means the place where the individual or client makes his home such as~~
55 ~~his own apartment or house, a relative's home or an assisted living facility, but does not include~~
56 ~~a hospital, nursing facility or other extended care facility.~~

57 "Commissioner" means the State Health Commissioner.

58 ~~"Companion services" means assisting persons unable to care for themselves without~~
59 ~~assistance. Companion services include transportation, meal preparation, shopping, light~~
60 ~~housekeeping, companionship, and household management.~~

61 "Contract services" means services provided through agreement with another agency,
62 organization, or individual on behalf of ~~the organization~~ an HCO. The agreement specifies the
63 services or ~~personnel~~ employees to be provided on behalf of ~~the organization~~ an HCO and the
64 fees to provide these services or ~~personnel~~ employees.

65 "Criminal record report" means the statement issued by the Central Criminal Record
66 Exchange, Virginia Department of State Police.

67 "Department" means the Virginia Department of Health.

68 ~~"Discharge or termination summary" means a final written summary filed in a closed client~~
69 ~~record of the service delivered, goals achieved and final disposition at the time of client's~~
70 ~~discharge or termination from service.~~

71 "Dispense" means to deliver a drug to an ultimate user by or pursuant to the lawful order of
72 a practitioner, including the prescribing and administering, packaging, labeling or compounding
73 necessary to prepare the substance for that delivery.

74 "Drop site" means a location that HCO staff employees use in the performance of daily tasks
75 such as obtaining supplies, using fax and copy machines, charting notes on care or services
76 provided, and storing ~~client~~ clinical records. These locations may also be called charting
77 stations, workstations, or convenience sites.

78 "Employee" means ~~an individual who has the status of an employee as defined by the U.S.~~
79 ~~Internal Revenue Service~~ an individual in the service of an HCO under any contract of hire,
80 express or implied, oral or written, where the HCO has the power or right to control and direct
81 the employee in the material details of how the work is to be performed. This excludes
82 individuals who receives a 1099-NEC from the HCO.

83 "Functional limitations" means the level of a client's or patient's need for assistance based
84 on an assessment conducted by the supervising nurse who shall be a registered nurse holding
85 an active license issued by the Virginia Department of Health Professions or an active multistate
86 licensure privilege to practice nursing in Virginia as a registered nurse. There are three criteria
87 to assessing functional status: (i) the client's impairment level and need for personal assistance,
88 (ii) the client's lack of capacity, and (iii) how the client usually performed the activity over a
89 period of time. If a person is mentally and physically free of impairment, there is not a safety risk
90 to the individual, or the person chooses not to complete an activity due to personal preference
91 or choice, then that person does not need assistance.

92 "Governing body" means the individual, group, entity, or governmental agency that has been
93 designated in writing by the owner and who has legal responsibility and authority over for the
94 overall management and operation of the home care organization an HCO.

95 "HCO" or "organization" means a home care organization, which is public or private entity
96 providing an organized program of home health, skilled, pharmaceutical, or personal care
97 services in the residence of a client or patient to maintain his health and safety in his residence.
98 An HCO does not include any family members, relatives or friends providing caregiving services
99 to individuals who need assistance to remain independent and in their own residences.

100 "Home attendant" means ~~a nonlicensed~~ an individual without an active health care
101 practitioner license or an active multistate licensure privilege to practice who performing
102 performs skilled, pharmaceutical and personal care services, under the supervision of the
103 appropriate actively licensed health professional care practitioner, to a client or patient in the
104 client's his residence. Home attendants are also known as certified nurse aides or CNAs, home
105 care aides, home health aides, or personal care aides, or nursing assistants.

106 "~~Home care organization" or "HCO" means a public or private entity providing an organized~~
107 ~~program of home health, pharmaceutical, or personal care services, according to § 32.1-162.1~~
108 ~~of the Code of Virginia in the residence of a client or individual to maintain the client's health and~~
109 ~~safety in his home. A home care organization does not include any family members, relatives or~~
110 ~~friends providing caregiving services to persons who need assistance to remain independent~~
111 ~~and in their own homes.~~

112 "Home health agency" means ~~a public or private agency or organization, or part of an~~
113 ~~agency or organization, that meets the requirements for participation in Medicare under~~ has the
114 same meaning ascribed to the term in 42 CFR 440.70-(d), by providing skilled nursing services
115 and at least one other therapeutic service, for example, physical, speech, or occupational
116 therapy; medical social services; or home health aide services, and also meets the capitalization
117 requirements under 42 CFR 489.28.

118 "~~Homemaker services" means assistance to persons with the inability to perform one or~~
119 ~~more instrumental activities of daily living. Homemaker services may also include assistance~~
120 ~~with bathing areas the client cannot reach, fastening client's clothing, combing hair, brushing~~
121 ~~dentures, shaving with an electric razor, and providing stabilization to a client while walking.~~
122 ~~Homemaker services do not include feeding, bed baths, transferring, lifting, putting on braces or~~
123 ~~other supports, cutting nails or shaving with a blade.~~

124 "Home health services" means services provided by or under the direct supervision of any
125 health care professional under a medical plan of care in a patient's residence on a visit or hourly
126 basis to patients who have or are at risk of injury, illness, or a disabling condition and require
127 short- or long-term interventions.

128 "Independent contractor" means an individual in the service of an HCO under any contract
129 of hire, express or implied, oral or written, where the HCO has the power or right to control and
130 direct the employee in the material details of how the work is to be performed and who receives
131 a 1099-NEC from the HCO.

132 "Infusion therapy" means the procedures or processes that involve the administration of
133 injectable medications to ~~clients~~ the patient via the intravenous, subcutaneous, epidural, or
134 intrathecal routes. Infusion therapy does not include oral, enteral, or topical medications.

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

137 "Instrumental activities of daily living" means meal preparation, ~~housekeeping/light~~
138 housekeeping or light housework, shopping for personal items, laundry, or using the telephone.

139 A client's or patient's degree of independence in performing these activities is part of
140 determining the appropriate level of care and services.

141 "Legal representative" means a person legally responsible for representing or standing in
142 the place of the client or patient for the conduct of his affairs. This may include a guardian,
143 conservator, attorney-in-fact under durable power of attorney, trustee, or other person expressly
144 named by a court of competent jurisdiction or by the client or patient as his agency in a legal
145 document that specifies the scope of the representative's authority to act. A legal representative
146 may only represent or stand in the place of a client or patient for the function or functions for
147 which he has legal authority to act.

148 "Licensed practical nurse" means ~~a person~~ an individual who holds ~~a current~~ an active
149 license issued by the Virginia Board of Nursing or ~~a current~~ an active multistate licensure
150 privilege to practice nursing in Virginia as a licensed practical nurse.

151 "Licensee" means ~~a licensed home care provider~~ an HCO that has received and maintains
152 an active license under the provisions of Article 7.1 (§ 32.1-162.7 et seq.) of Chapter 5 of Title
153 32.1 of the Code of Virginia and this chapter.

154 "Medical plan of care" means a written plan of skilled services, personal care services, and
155 items needed to treat a ~~client's~~ patient's medical condition, that is prescribed, signed and
156 periodically reviewed by the ~~client's~~ patient's ~~primary care~~ physician.

157 "Nursing services" means ~~client~~ patient care services, including, ~~but not limited to,~~ the
158 curative, restorative, or preventive aspects of nursing that are performed or supervised by a
159 registered nurse according to a medical plan of care.

160 "OLC" means the Office of Licensure and Certification of the ~~Virginia Department of Health~~
161 department.

162 ~~"Operator" means any individual, partnership, association, trust, corporation, municipality,~~
163 ~~county, local government agency or any other legal or commercial entity that is responsible for~~
164 ~~the day-to-day administrative management and operation of the organization.~~

165 ~~"Organization" means a home care organization.~~

166 "Owner" means the person who has ultimate legal responsibility and authority to own,
167 operate, manage, or otherwise control the conduct of an HCO.

168 ~~"Person" means any individual, partnership, association, trust, corporation, municipality,~~
169 ~~county, local government agency or any other legal or commercial entity that operates a home~~
170 ~~care organization.~~

171 "Parent HCO" means the HCO that develops and maintains administrative controls of
172 branch offices, and is ultimately responsible for the implementation of the plan of care or
173 medical plan of care and for services furnished to patients and clients.

174 "Patient" means an individual who receives skilled services and may receive personal care
175 services from an HCO.

176 "Personal care services" means the provision of nonskilled services, including assistance in
177 the activities of daily living, and may include instrumental activities of daily living, related to the
178 needs of the client or patient, who has or is at risk of an illness, injury or disabling condition. A
179 need for assistance exists when the client or patient is unable to complete an activity due to
180 cognitive impairment, functional disability, physical health problems, or safety. The client's or
181 patient's functional level is based on ~~the client's~~ his need for assistance most or all of the time to
182 perform the tasks of daily living in order to live independently.

183 "Pharmaceutical services" means dispensing and administration of a drug or drugs,
184 parenteral nutritional support, and associated patient instruction.

185 ~~"Primary care physician"~~ "Physician" means a physician actively licensed in Virginia,
186 according pursuant to Chapter 29 (§ 54.1-2900 et seq.) of Title 54.1 of the Code of Virginia, or
187 actively licensed in an adjacent state and identified by the client or patient as having the primary
188 responsibility in determining the delivery of the client's or patient's medical care. The
189 responsibility of physicians contained in this chapter may be implemented by nurse practitioners
190 or physician assistants ~~as assigned by the supervising physician~~ and within the parameters of
191 professional licensing.

192 "Plan of care" means a written plan of personal care services to provide direction on the type
193 of care to be provided that address the client's care needs and that is developed, signed, and
194 periodically reviewed by a registered nurse employed or contracted by an HCO.

195 "Qualified" means meeting current legal requirements of licensure, registration or
196 certification in Virginia or having appropriate training, including competency testing, and
197 experience commensurate with assigned responsibilities.

198 "Quality improvement" means ongoing activities designed to objectively and systematically
199 evaluate the quality of client and patient care and services, pursue opportunities to improve
200 client and patient care and services, and resolve identified problems. Quality improvement is an
201 approach to the ongoing study and improvement of the processes of providing health care
202 services to meet the needs of clients, patients, and others.

203 "Registered nurse" means ~~a person~~ an individual who holds ~~a current~~ an active license
204 issued by the Virginia Board of Nursing or ~~a current~~ an active multistate licensure privilege to
205 practice nursing in Virginia as a registered nurse.

206 "Residence" means the place where the client or patient makes his home such as his own
207 apartment or house, a relative's home or an assisted living facility, but does not include a
208 general hospital, nursing home, certified nursing facility, or other extended care facility.

209 ~~"Service area"~~ ~~means a clearly delineated geographic area in which the organization~~
210 ~~arranges for the provision of home care services, personal care services, or pharmaceutical~~
211 ~~services to be available and readily accessible to persons.~~

212 "Skilled services" means the provision of the home health services listed subsection A in of
213 12VAC5-381-300.

214 "Skilled services director" means an actively licensed health care practitioner who is an
215 employee of an HCO and is responsible for the daily direction and management of skilled
216 services. The administrator and the skilled services director may be the same individual if that
217 individual is dually qualified.

218 "Supervision" means the ongoing process of monitoring the skills, competencies and
219 performance of the individual supervised and providing regular, documented, face-to-face
220 guidance and instruction.

221 ~~"Sworn disclosure statement"~~ "Sworn disclosure" means a ~~document~~ written statement or
222 affirmation disclosing ~~an applicant's any~~ any criminal convictions ~~and or any~~ or any pending criminal
223 charges, ~~whether occurring in within or outside Virginia the Commonwealth or any other state,~~
224 by an applicant for compensated employment with an HCO.

225 "Third-party crime insurance" means insurance coverage that protects an ~~organization's~~
226 HCO's losses as a result of employee theft or fraud.

227 **Statutory Authority**

228 §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.

229 **Historical Notes**

230 Derived from Virginia Register Volume 22, Issue 3, eff. January 1, 2006; amended, Virginia
231 Register Volume 24, Issue 11, eff. March 5, 2008; Volume 31, Issue 10, eff. February 12, 2015.

232 **12VAC5-381-20. License.**

233 A. ~~A license to operate a home care organization is issued to a person. The commissioner~~
234 ~~may issue a license to establish an HCO if:~~

- 235 1. The applicant and the applicant's proposed HCO are in compliance this chapter;
236 2. The application fee prescribed by subsection A of 12VAC5-381-70 has been received
237 by the OLC; and
238 3. The applicant and any person having ownership interest in the proposed HCO
239 ~~However, no license shall be issued to a person who has have not been sanctioned~~
240 ~~pursuant to 42 USC § 1320a-7b. Persons planning to seek federal certification or~~
241 ~~national accreditation pursuant to § 32.1-162.8 of the Code of Virginia must first obtain~~
242 ~~state licensure.~~

243 ~~B. The commissioner shall issue or renew a license to establish or operate a home care~~
244 ~~organization if the commissioner finds that the home care organization is in compliance with the~~
245 ~~law and this regulation.~~

246 B. A person may not establish, conduct, maintain, or operate in this Commonwealth an HCO
247 without having obtained a license unless exempted by § 32.1-162.8 of the Code of Virginia.
248 Persons planning to seek federal certification as a home health agency or national accreditation
249 pursuant to § 32.1-162.8 of the Code of Virginia shall first obtain an HCO license.

250 ~~C. The commissioner may issue a license to a home care organization authorizing the~~
251 ~~licensee to provide services at A licensee may establish one or more branch offices for~~
252 ~~portions of the total geographic area served by the licensee parent HCO, provided if:~~

- 253 1. The area served by the branch office is located within the same total geographic area
254 as the parent HCO;
255 2. each Each branch office operates under the supervision and administrative control of
256 the licensee. parent HCO;
257 3. The parent HCO submits the address of each branch office at which services are
258 provided by the licensee shall be included on any license issued to the licensee and the
259 name of each branch office's administrator to the OLC.;
260 4. The parent HCO submits policies and procedures demonstrating how it will exercise
261 supervision and administrative control over each branch office; and
262 5. The parent HCO complies with 12VAC5-381-60.

263 A parent HCO shall operate a branch office under the parent HCO's license.

264 ~~D. Every home care organization shall be designated by an appropriate name. The name~~
265 ~~shall not be changed without first notifying the OLC.~~

266 ~~E. Licenses An HCO shall may not be transferred transfer or assigned assign its license.~~

267 ~~F. Any person establishing, conducting, maintaining, or operating a home care organization~~
268 ~~without a license shall be guilty of a Class 6 felony according to § 32.1-162.15 of the Code of~~
269 ~~Virginia.~~

270 **Statutory Authority**

271 §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.

272 **Historical Notes**

273 Derived from Virginia Register Volume 22, Issue 3, eff. January 1, 2006; amended, Virginia
274 Register Volume 24, Issue 11, eff. March 5, 2008; Volume 29, Issue 8, eff. January 17, 2013;
275 Volume 31, Issue 10, eff. February 12, 2015.

276 **12VAC5-381-30. Exemption from licensure.**

277 ~~A. This chapter is not applicable to those individuals and home care organizations listed in §~~
278 ~~32.1-162.8 of the Code of Virginia; Organizations planning to seek federal certification as a~~
279 ~~home health agency or national accreditation must first obtain state licensure and provide~~
280 ~~services to clients before applying for national accreditation or federal certification.~~

281 ~~In addition, this chapter is not applicable to those providers of only homemaker, chore, or~~
282 ~~companion services as defined in 12VAC5-381-10.~~

283 A. This chapter may not apply to:

284 1. Natural persons who provide services to a client or patient on an individual basis if
285 such natural person is:

286 a. Acting alone under a medical plan of care and is licensed to provide such services
287 pursuant to Title 54.1 of the Code of Virginia; or

288 b. Retained by the client, patient, or by another natural person acting on the client's
289 or patient's behalf;

290 2. Organizations providing only homemaker, chore, or companion services as defined in
291 12VAC5-381-10;

292 3. Hospice and hospice facilities licensed pursuant to Article 7 (§ 32.1-162.1 et seq.) of
293 Chapter 5 of Title 32.1 of the Code of Virginia; and

294 4. HCOs that receive federal certification as a home health agency or are accredited by
295 any organization recognized by the U.S. Centers for Medicare and Medicaid Services for
296 the purposes of Medicare certification.

297 ~~B. A licensed organization~~ A person requesting an exemption pursuant to subdivisions 1, 2,
298 or 4 of subsection A of this section shall request exemption must file submit a written request
299 for exemption with the director of the OLC and pay the required fee stated in prescribed by
300 subsection D of 12VAC5-381-70 ~~D.~~ The OLC shall consider the submission date of an
301 exemption request to be the date it is postmarked or the date it is received, whichever is earlier.

302 ~~C. The OLC home care organization shall be notified~~ notify in writing the person
303 requesting an exemption pursuant to subsection B of this section in writing if the exemption from
304 licensure has been granted. The basis for the exemption approval will be stated and the
305 organization will be advised to contact the OLC to request licensure should it no longer meet the
306 requirement for exemption.

307 ~~D. Exempted organizations~~ D. An HCO that has been granted an exemption pursuant to
308 subdivisions 4 of subsection A of this section are shall:

309 1. Be subject to complaint investigations in keeping with state law;; and

310 2. Notify the OLC in writing no more than two business days after losing licensure
311 exemption eligibility.

312 **Statutory Authority**

313 §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.

314 **Historical Notes**

315 Derived from Virginia Register Volume 22, Issue 3, eff. January 1, 2006; amended, Virginia
316 Register Volume 24, Issue 11, eff. March 5, 2008.

317 **12VAC5-381-35. Total geographic area and office location.**

318 A. On every application for licensure, an applicant or licensee shall indicate the total
319 geographic area it intends to serve, which the applicant or licensee shall elect to be either:

320 1. A single health planning region, as defined by 12VAC5-220-10; or

321 2. A single planning district, as defined by 12VAC5-220-10, and any planning districts
322 that are contiguous to the selected planning district.

323 B. The location of the parent HCO's office and of any branch office or drop site of an HCO
324 shall be located:

325 1. In a building that is zoned for business or commercial use or if in a mixed use zoned
326 building, in a unit zoned for business or commercial use; and

327 2. In the total geographic area it serves.

328 An HCO shall submit proof of valid occupancy, such as a lease, rental agreement, or deed,
329 of any building serving as the location of the parent HCO's office, of any branch office, or drop
330 site.

331 C. An HCO licensed on or before the effective date of this section shall comply with the
332 provisions of this section within one year of the effective date of this section.

333 **Statutory Authority**

334 §§ 32.1-162.9 and 32.1-162.12 of the Code of Virginia.

335 **Historical Notes**

336 Derived from Virginia Register Volume , Issue , eff. Month dd, yyyy.

337 **12VAC5-381-40. License application; Request for initial license issuance and renewal.**

338 ~~A. The OLC provides preclosure consultation and technical assistance regarding the~~
339 ~~licensure process. The purpose of such consultation is to explain the regulation and the survey~~
340 ~~process. Preclosure consultations are arranged after a completed initial application is on file~~
341 ~~with the OLC.~~

342 ~~B. Licensure applications are obtained from the OLC. The OLC shall consider an application~~
343 ~~complete when all requested information and the appropriate fee, stated in 12VAC5-381-70, is~~
344 ~~submitted. If the OLC finds the application incomplete, the applicant will be notified in writing.~~

345 ~~C. The activities and services of each applicant and licensee shall be subject to an~~
346 ~~inspection by the OLC to determine if the organization is in compliance with the provisions of~~
347 ~~this chapter and state law.~~

348 ~~D. A completed application for initial licensure must be submitted at least 60 days prior to~~
349 ~~the organization's planned opening date to allow the OLC time to process the application. An~~
350 ~~incomplete application shall become inactive six months after it is received by the OLC.~~
351 ~~Applicants must then reapply for licensure with a completed application and application fee. An~~
352 ~~application for a license may be withdrawn at any time.~~

353 ~~E. Licenses are renewed annually. The OLC shall make renewal applications available at~~
354 ~~least 60 days prior to the expiration date of the current license.~~

355 ~~F. It is the home care organization's responsibility to complete and return a renewal~~
356 ~~application to assure timely processing. Should a current license expire before a new license is~~
357 ~~issued, the current license shall remain in effect provided a complete and accurate application~~
358 ~~was filed on time.~~

359 A. An applicant shall:

360 1. Submit an application for initial licensure to the OLC;

361 2. Identify the services that it intends to perform at its proposed HCO;

362 3. Identify the total geographic area it intends to serve with its proposed HCO;

363 4. Disclose to the OLC the ownership interest of the proposed HCO and in the case of
364 corporations, identify by name and address all individuals or entities holding 5.0% or
365 more of total ownership; and

366 5. Shall pay the fee prescribed by 12VAC5-381-70.

367 B. Each HCO and any branch office disclose upon each application filed with the OLC:

368 1. Its legal business name, which shall be distinct; and

369 2. Any fictitious business name that the HCO or branch office may use.

370 C. The commissioner shall consider an application complete when all requested information
371 and the nonrefundable application fee are received by the OLC. The commissioner may deny
372 licensure to an applicant whose application has been incomplete for more than 180 calendar
373 days.

374 D. An applicant shall notify the OLC in writing that it is ready for the initial licensure
375 inspection. The commissioner may deny licensure to an applicant who delays or attempts to
376 delay its initial licensure inspection.

377 E. The OLC shall notify the applicant of the time and date of the initial licensure inspection.
378 The director of the OLC, at his discretion, may waive the initial licensure inspection for an
379 applicant seeking initial licensure due to a change of ownership of an HCO that is or was
380 licensed.

381 F. As part of the initial licensure inspection, an applicant shall:

382 1. Make available to an inspector any requested records;

383 2. Allow an inspector access to interview the agents, employees, independent
384 contractors, and any person under the applicant's control, direction, or supervision; and

385 3. Permit an inspector to enter upon and into the property of any proposed HCO to
386 inspect or investigate as the inspector reasonably deems necessary in order to
387 determine the state of compliance with the provisions of this chapter and all laws
388 administer by the board.

389 The commissioner may deny licensure to an applicant who does not comply with this
390 subsection.

391 G. An applicant may voluntarily terminate an initial licensure inspection at any time during
392 the inspection. The commissioner may deny licensure to any applicant who voluntarily
393 terminates an initial licensure inspection.

394 H. The OLC shall provide a written inspection report to the applicant after the initial licensure
395 inspection. If the OLC cites one or more licensing violations in the written inspection report, the
396 administrator shall submit a written plan of correction in accordance with the provisions of
397 12VAC5-381-105. The commissioner may deny licensure to an applicant who does not comply
398 with this subsection.

399 I. An applicant may:

400 1. Withdraw its application at any time; and

401 2. Reapply for licensure, provided that it pays the fee prescribed by 12VAC5-381-70, if:

402 a. It withdraws its application pursuant to subdivision 1 of this subsection; or

403 b. The commissioner denies it initial licensure pursuant to this section, except that if
404 the commissioner has denied an applicant licensure a total of three times, the
405 applicant may not reapply for a license for a period of two years from the date of the
406 third denial.

407 **Statutory Authority**

408 §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.

409 **Historical Notes**

410 Derived from Virginia Register Volume 22, Issue 3, eff. January 1, 2006; amended, Virginia
411 Register Volume 24, Issue 11, eff. March 5, 2008.

412 **12VAC5-381-45. License expiration and renewal.**

413 A. Licenses shall expire at midnight July 31st following the date of issue and may be
414 renewed annually, upon filing of a renewal application and payment of the nonrefundable
415 renewal application fee prescribed by 12VAC5-381-70. The commissioner shall renew a license
416 only after the OLC determines that the HCO is in compliance with this chapter and that the
417 licensee and any person having an ownership interest in the licensee have not been sanctioned
418 pursuant to 42 U.S.C. § 1320a-7b.

419 B. An HCO shall submit a license renewal application to the OLC no fewer than 60 calendar
420 days prior to the expiration date of the current license. An HCO that submits a license renewal
421 application fewer than 60 calendar days prior to the expiration date of the current license shall
422 pay the nonrefundable late fee prescribed by 12VAC5-381-70 in addition to the nonrefundable
423 renewal application fee prescribed by 12VAC5-381-70. The OLC shall consider the submission
424 date of an application to be the date it is postmarked or the date it is received, whichever is
425 earlier.

426 1. An HCO may not make any material change to its licensure record on its license
427 renewal application.

428 2. If an HCO intends to make a material change to its licensure record, the HCO shall
429 separately file for a material change to its license, which it may file concurrently with its
430 license renewal application, provided it pays the nonrefundable fee for material change
431 of license prescribed by 12VAC5-381-70

432 C. Should an active license expire before a new license is issued, the prior active license
433 shall remain in effect provided that the licensee submitted a complete and accurate application
434 prior to its expiration.

435 D. An HCO that fails to submit a plan of correction as required in 12VAC5-381-105 may not
436 renew its license.

437 E. An HCO whose license has expired for 30 calendar days or fewer shall comply with
438 12VAC5-381-65 to reinstate its license and shall pay the nonrefundable reinstatement fee
439 prescribed by 12VAC5-381-70. An HCO whose license has expired for more than 30 calendar
440 days shall comply with 12VAC5-381-40 to receive a new license.

441 1. The OLC shall notify in writing the Department of Medical Assistance Services on
442 September 15th of each calendar year with the names, license numbers, and locations
443 of any HCO that failed to timely renew its license and failed to apply for reinstatement of
444 its expired license.

445 F. An HCO that ceases operation for any period of time and wishes to resume may not
446 apply for reinstatement, but shall apply for a new license pursuant to 12VAC5-381-40.

447 **Statutory Authority**

448 §§ 32.1-12 and 32.1-162.9 of the Code of Virginia.

449 **Historical Notes**

450 Derived from Virginia Register Volume , Issue , eff. Month dd, yyyy.

451 **12VAC5-381-50. Compliance appropriate for all types of HCOs. (Repealed.)**

452 ~~All organizations shall be in compliance with Part I (12VAC5-381-10 et seq.) and Part II~~
453 ~~(12VAC5-381-150 et seq.) of this chapter. In addition, organizations shall be in compliance with~~
454 ~~Part III (12VAC5-381-300 et seq.), Part IV (12VAC5-381-350), or Part V (12VAC5-381-360 et~~
455 ~~seq.) of this chapter as applicable to the services provided by the organization.~~

456 **Statutory Authority**

457 ~~§§ 32.1-12 and 32.1-162.12 of the Code of Virginia.~~

458 **Historical Notes**

459 Derived from Virginia Register Volume 22, Issue 3, eff. January 1, 2006.

460 **12VAC5-381-60. ~~Changes to or reissue of a~~ Surrender of license; material change of**
461 **license.**

462 ~~A. It is the responsibility of the organization's governing body to~~ An HCO shall maintain a
463 current an active and accurate license at all times, which shall include a listing of all branch
464 offices an HCO may have. Licenses that are misplaced or lost must be replaced.

465 ~~B. An organization HCO shall give written notification~~ notify the director of the OLC in writing
466 by submitting an application no less than 30 working calendar days in advance of any proposed
467 changes that may require the reissuance of a license. Notices shall be sent to the attention of
468 the director of the OLC implementing any of the following material changes-;

469 ~~The following changes require the reissuance of a license and payment of a fee:~~

- 470 1. ~~Operator~~ Change of location of a parent HCO or any branch office;
- 471 2. ~~Organization name~~ Change of name of a parent HCO or any branch office; or
- 472 3. ~~Address~~ Change of services being provided-;
- 473 4. Change of total geographic area served;
- 474 5. Addition of any new branch office; or
- 475 6. Voluntary closure of a parent HCO or any branch office.

476 An HCO shall pay the nonrefundable fee for material change of license prescribed by
477 12VAC5-381-70 with each application filed. The OLC shall consider the submission date of an
478 application to be the date it is postmarked or the date it is received, whichever is earlier.

479 C. The commissioner may not consider a change of ownership of an HCO to be a material
480 change of license. If an HCO intends to implement a change of ownership, it shall file for a new
481 license, in accordance with 12VAC5-381-40, no less than 30 calendar days in advance of any
482 ownership change, and shall surrender its prior license issued by the commissioner to the OLC
483 upon receipt of the new license.

484 E. An HCO shall surrender the license issued by the commissioner to the OLC upon receipt
485 of the changed license.

486 F. If an HCO is no longer operational, it shall:

- 487 1. Surrender its license to the OLC no more than five calendar days after the HCO
488 ceases operations; and
- 489 2. Notify clients, patients, and the OLC where all clinical records are be located no more
490 than five calendar days after the HCO ceases operations.

491 ~~G. G. The OLC will evaluate written information about any planned changes in operation that~~
492 shall determine if any changes listed in subsection B affect the terms of the license or the
493 continuing eligibility for a license. A licensing representative An inspector may inspect the
494 organization HCO during the process of evaluating a proposed change.

495 ~~D.-F. The organization OLC will be notified shall notify in writing the HCO whether a new~~
496 application is needed if the commissioner will issue a changed license.

497 **Statutory Authority**

498 §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.

499 **Historical Notes**

500 Derived from Virginia Register Volume 22, Issue 3, eff. January 1, 2006; amended, Virginia
501 Register Volume 24, Issue 11, eff. March 5, 2008.

502 **12VAC5-381-65. License reinstatement.**

503 A. The commissioner shall reinstate a license only after the OLC determines that an HCO is
504 in compliance with this chapter and that the licensee and any person having an ownership
505 interest in the HCO have not been sanctioned pursuant to 42 U.S.C. § 1320a-7b.

506 B. An HCO applying for reinstatement of its license shall:

507 1. Submit an application for reinstatement of licensure to the OLC;

508 2. Identify the services that it intends to perform at its HCO;

509 3. Identify the total geographic area it intends to serve with its HCO;

510 4. Disclose to the OLC the ownership interest of the HCO and in the case of
511 corporations, identify by name and address all individuals or entities holding 5.0% or
512 more of total ownership; and

513 5. Shall pay the fee prescribed by 12VAC5-381-70.

514 The OLC shall consider the submission date of an application to be the date it is postmarked
515 or the date it is received, whichever is earlier.

516 C. The commissioner shall consider an application complete when all requested information
517 and the nonrefundable application fee are received by the OLC. The commissioner may deny
518 reinstatement of licensure to an HCO whose application has been incomplete for more than 60
519 calendar days.

520 D. The OLC may conduct a reinstatement licensure inspection. As part of a reinstatement
521 licensure inspection, an applicant shall:

522 1. Make available to an inspector any requested records;

523 2. Allow an inspector access to interview the agents, employees, independent
524 contractors, and any person under the applicant's control, direction, or supervision; and

525 3. Permit an inspector to enter upon and into the property of any HCO to inspect or
526 investigate as the inspector reasonably deems necessary in order to determine the state
527 of compliance with the provisions of this chapter and all laws administer by the board.

528 The commissioner may deny reinstatement of licensure to an HCO who does not comply
529 with this subsection.

530 E. An HCO may voluntarily terminate a reinstatement licensure inspection at any time during
531 the inspection. The commissioner may deny reinstatement of licensure to any HCO who
532 voluntarily terminates a reinstatement licensure inspection.

533 F. The OLC shall provide a written inspection report to the HCO. If the OLC cites one or
534 more licensing violations in the written inspection report, the administrator shall submit a written
535 plan of correction in accordance with the provisions of 12VAC5-381-105.

536 G. An HCO may:

537 1. Withdraw its reinstatement application at any time; and

538 2. Reapply for licensure pursuant to 12VAC5-381-40, provided that it pays the fee
539 prescribed by 12VAC5-381-70, if:

540 a. It withdraws its application pursuant to subdivision 1 of this subsection; or

541 b. The commissioner denies it reinstatement of licensure pursuant to this section,
542 except that if the commissioner has denied an HCO reinstatement of licensure three
543 times, the applicant may not apply for a new license for a period of two years from
544 the date of the third denial.

545 H. If the commissioner reinstates a license pursuant to this section, the effective date of the
546 license shall be August 1 of the calendar year in which the HCO's prior license expired.

547 **Statutory Authority**

548 §§32.1-12 and 32.1-162.9 of the Code of Virginia.

549 **12VAC5-381-70. Fees.**

550 A. ~~The OLC shall collect a fee of \$500 for each initial and renewal license application. Fees~~
551 ~~shall accompany the licensure application and are not refundable. The department shall charge~~
552 ~~the following fees related to licensure and inspection of HCOs:~~

<u>Application fee for initial licensure</u>	<u>\$2,000</u>
<u>Re-application fee for initial licensure</u>	<u>\$2,000</u>
<u>Base application fee for renewal of licensure</u>	<u>\$1,250</u>
<u>Additional renewal fee for each branch office</u>	<u>\$500</u>
<u>Application fee for reinstatement of licensure</u>	<u>\$2,500</u>
<u>Additional reinstatement fee for each branch office</u>	<u>\$750</u>
<u>Processing fee for exemption from licensure</u>	<u>\$125</u>
<u>Duplicate license fee</u>	<u>\$25</u>
<u>Fee for material change of license</u>	<u>\$250</u>
<u>Returned check fee</u>	<u>\$50</u>

553 B. ~~An additional late fee of \$50 shall be collected for an organization's failure to file a~~
554 ~~renewal application by the date specified.~~

555 C. ~~A processing fee of \$250 shall be collected for each reissuance or replacement of a~~
556 ~~license and shall accompany the written request for reissuance or replacement.~~

557 D. ~~A one time processing fee of \$75 for exemption from licensure shall accompany the~~
558 ~~written exemption request.~~

559 B. In addition to the fees described in subsection A, the department shall charge a late fee
560 of \$500 for any HCO that applies to renew its license fewer than 60 calendar days in advance of
561 the license's expiration date.

562 C. Unless otherwise provided, fees may not be refunded.

563 **Statutory Authority**

564 §§ 32.1-12, 32.1-162.9, and 32.1-162.12 of the Code of Virginia.

565 **Historical Notes**

566 Derived from Virginia Register Volume 22, Issue 3, eff. January 1, 2006; amended, Virginia
567 Register Volume 24, Issue 11, eff. March 5, 2008.

568 **12VAC5-381-80. On-site inspections.**

569 A. ~~An The OLC representative shall make periodic unannounced on-site inspections of each~~
570 ~~home care organization HCO as necessary but not less often than biennially triennially. The~~
571 ~~organization shall be responsible for correcting any deficiencies found during any on-site~~
572 ~~inspection. Compliance with all standards will be determined by the OLC according to applicable~~
573 ~~law.~~

574 B. ~~The home care organization HCO shall make available to the OLC's representative~~
575 ~~inspector any necessary requested records and shall allow access to interview the agents,~~
576 ~~employees, independent contractors, and any person under the organization's HCO's control,~~
577 ~~direction, or supervision.~~

578 1. If an inspector arrives on the premises to conduct an inspection and a person
579 authorized to give access to clinical records is not available on the premises, the person
580 or the designated alternate shall be available on the premises no more than one hour
581 after the inspector's arrival.

582 2. Upon request of the inspector and no more than two hours after the inspector's arrival,
583 the HCO shall provide to the inspector a list of all of the HCO's clients and patients for
584 the previous 12 months.

585 3. If copies of records are removed from the premises, the HCO may redact names and
586 addresses of clients or patients contained in such records prior to removal.

587 4. The inspector shall inform the HCO that it may redact names and addresses of clients
588 or patients prior to the inspector removing copies of records from the premises.

589 C. As part of any inspection, an inspector may conduct home visits with the consent of the
590 client, patient, or his legal representative. The HCO:

591 1. Shall arrange for the inspector in-home visits with the client, patient, or his legal
592 representative, upon the inspector's request;

593 2. Shall explain clearly to the client, patient, or his legal representative that a home visit
594 is voluntary and that refusing a home visit will not affect his care;

595 3. Shall obtain signed consent from the client, patient, or his legal representative;

596 4. May not terminate a client or patient if he or his legal representative consents to or
597 refuses a home visit; and

598 5. May not interfere or prevent an inspector's or the department's communication with or
599 to clients, patients, or their legal representatives, either as part of a home visit or as part
600 of the inspection process.

601 ~~D. After the on-site inspection, the OLC's representative OLC shall discuss the findings of~~
602 ~~the inspection with provide a written inspection report to the administrator or his designee. If the~~
603 ~~OLC cites one or more licensing violations in the written inspection report, the administrator~~
604 ~~shall submit a plan of correction in accordance with 12VAC5-381-105.~~

605 ~~D. The administrator shall submit, within 15 working days of receipt of the inspection report,~~
606 ~~an acceptable plan for correcting any deficiencies found. The plan of correction shall contain:~~

607 ~~1. A description of the corrective action or actions to be taken and the personnel to~~
608 ~~implement the corrective action;~~

609 ~~2. The expected correction date;~~

610 ~~3. A description of the measures implemented to prevent a recurrence of the violation;~~
611 ~~and~~

612 ~~4. The signature of the person responsible for the validity of the report.~~

613 ~~E. The administrator will be notified whenever any item in the plan of correction is~~
614 ~~determined to be unacceptable.~~

615 ~~F. The administrator shall be responsible for assuring the plan of correction is implemented~~
616 ~~and monitored so that compliance is maintained.~~

617 ~~G. Completion of corrective actions shall not exceed 45 working days from the last day of~~
618 ~~the inspection.~~

619 **Statutory Authority**

620 §§ 32.1-12, 32.1-162.9, and 32.1-162.12 of the Code of Virginia.

621 **Historical Notes**

622 Derived from Virginia Register Volume 22, Issue 3, eff. January 1, 2006; amended, Virginia
623 Register Volume 24, Issue 11, eff. March 5, 2008.

624 **12VAC5-381-90. Home visits. (Repealed.)**

625 A. As part of any inspection, an OLC representative may conduct home visits.

626 B. The home care organization shall be responsible for arranging in-home visits with clients,
627 family members, and caregivers for the OLC representative.

628 C. The organization shall explain clearly to the client, family or caretaker that the permission
629 for the representative's home visit is voluntary and that consent to the home visit will not affect
630 the client's care or other health benefits.

631 **Statutory Authority**

632 ~~§§ 32.1-12 and 32.1-162.12 of the Code of Virginia.~~

633 **Historical Notes**

634 Derived from Virginia Register Volume 22, Issue 3, eff. January 1, 2006; amended, Virginia
635 Register Volume 24, Issue 11, eff. March 5, 2008.

636 **12VAC5-381-100. Complaint investigations conducted by the OLC.**

637 A. The OLC ~~has the responsibility to~~ shall investigate any complaints regarding alleged
638 violations of this chapter ~~and applicable law.~~ The OLC shall determine if an investigation
639 requires an on-site inspection. In making this determination, the OLC shall consider several
640 factors, to include:

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

642 2. The HCO's regulatory history, including the number of substantiated prior complaints;

643 3. If the OLC has recently inspected the HCO, and if the incident would have been
644 observed during the prior inspection; and

645 4. The nature of the complaint, including degree of potential serious harm to clients or
646 patients.

647 B. The OLC may request records from an HCO to assist in making a determination pursuant
648 to subsection A of this section. An HCO shall provide the requested records no more than two
649 calendar days after OLC makes a request pursuant to this subsection.

650 C. When the investigation is complete, the OLC shall notify the HCO and the complainant, if
651 known, in writing of the findings of the investigation.

652 ~~B. Complaints may be received in writing or orally and may be anonymous.~~

653 ~~C. When the investigation is complete, the licensee and the complainant, if known, will be~~
654 ~~notified of the findings of the investigation.~~

655 ~~D. As applicable, the administrator shall submit, within 15 working days of receipt of the~~
656 ~~complaint report, an acceptable plan of correction for any deficiencies found during a complaint~~
657 ~~investigation. The plan of correction shall contain:~~

658 ~~1. A description of the corrective action or actions to be taken and the personnel to~~
659 ~~implement the corrective action;~~

660 ~~2. The expected correction date;~~

661 ~~3. A description of the measures implemented to prevent a recurrence of the violation;~~
662 ~~and~~

663 ~~4. The signature of the person responsible for the validity of the report.~~

664 ~~E. The administrator will be notified in writing whenever any item in the plan of correction is~~
665 ~~determined to be unacceptable.~~

666 ~~F. The administrator shall be responsible for assuring the plan of correction is implemented~~
667 ~~and monitored so that compliance is maintained.~~

668 D. For any licensing violation cited during a complaint investigation, the administrator shall
669 submit a plan of correction in accordance with 12VAC5-381-105.

670 **Statutory Authority**

671 §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.

672 **Historical Notes**

673 Derived from Virginia Register Volume 22, Issue 3, eff. January 1, 2006; amended, Virginia
674 Register Volume 24, Issue 11, eff. March 5, 2008.

675 **12VAC5-381-105. Plan of correction.**

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

678 B. The administrator shall submit to the OLC a written plan of correction no more than 15
679 business days after receipt of the inspection report. The plan of correction shall contain for each
680 licensing violation cited:

681 1. A description of the corrective action or actions to be taken and the position title of the
682 employees to implement the corrective action. If employees share the same position
683 title, the administrator shall assign the employees a unique identifier to distinguish them;

684 2. The expected correction date, not to exceed 45 business days from the exit date of
685 the inspection; and

686 3. A description of the measures implemented to prevent a recurrence of the licensing
687 violation.

688 An HCO shall ensure that the person responsible for the validity of the plan of correction
689 signs, dates, and indicates their title on the plan of correction.

690 C. The OLC shall:

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

693 2. Grant the administrator or his designee two opportunities to revise and resubmit a
694 plan of correction that the OLC initially determines to be unacceptable. If the
695 administrator or his designee revises and resubmits the plan of correction, the
696 submission is due to the OLC no more than 15 business days after the OLC has notified
697 the administrator or his designee pursuant to subdivision 1 of this subsection.

698 D. Upon request of the OLC, an applicant or licensee shall produce evidence, no more than
699 two calendar days after the OLC's request, that all or part of a plan of correction has been
700 implemented. The OLC may conduct an inspection to verify any portion of a plan of correction.

701 E. The administrator shall ensure the plan of correction is implemented and monitored so
702 that compliance is maintained.

703 F. The commissioner may deny licensure, renewal of licensure, or reinstatement of licensure
704 if an HCO's administrator fails to submit an acceptable plan of correction or fails implement an
705 acceptable plan of correction.

706 G. The OLC shall consider the submission date of a plan of correction to be the date it is
707 postmarked or the date it is received, whichever is earlier.

708 **Statutory Authority**

709 §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.

710 **Historical Notes**

711 Derived from Virginia Register Volume , Issue , eff. Month dd, yyyy.

712 **12VAC5-381-110. Criminal records checks.**

713 A. ~~Section 32.1-162.9:1 of the Code of Virginia requires home care providers, as defined in~~
714 ~~§ 32.1-162.7 of the Code of Virginia, to~~ An HCO shall obtain a criminal record report on
715 applicants for compensated employment from the Virginia Department of State Police no more
716 than 30 calendar days after employment begins. An HCO shall not accept a criminal record
717 report dated more than 90 calendar days prior to the start date of employment. ~~Section 32.1-~~
718 ~~162.9:1 of the Code of Virginia also requires that all applicants for employment in home care~~
719 ~~organizations provide a sworn disclosure statement regarding their criminal history.~~

720 B. ~~The criminal record report shall be obtained within 30 days of employment. It shall be the~~
721 ~~responsibility of the organization to ensure that its employees have not been convicted of any of~~
722 ~~the barrier crimes listed in § 32.1-162.9:1 of the Code of Virginia.~~

723 C. ~~The organization shall not accept a criminal record report dated more than 90 days prior~~
724 ~~to the date of employment.~~

725 ~~D.B. An HCO may not accept duplicates or copies of~~ Only the original criminal record report
726 shall be accepted, ~~except if the HCO uses:~~ An exception is permitted for organizations

727 1. using A temporary staffing agencies agency ~~for the provision of substitute staff~~
728 temporary employees. ~~The organization~~ An HCO shall obtain a letter from the temporary
729 staffing agency containing the following information that includes:

730 1-a. The name of the substitute staffing person temporary employee;

731 2-b. The date of employment by the temporary staffing agency; and

732 3-c. A statement verifying that the criminal record report has been obtained within 30
733 calendar days of employment at the temporary staffing agency, is on file at the
734 temporary staffing agency, and does not contain any conviction of a barrier crimes
735 crime listed in § 32.1-162.9:1 of the Code of Virginia.

736 2. An independent contractor who will have or whose employees will have direct contact
737 with a client or patient. An HCO shall obtain a letter from the independent contractor that
738 includes:

739 a. The name of the independent contractor or employee who will have direct contact
740 with a client or patient;

741 b. If the employee of the independent contractor will have direct contact with a client
742 or patient, the date of employment with the independent contractor; and

743 c. A statement verifying that the criminal record report has been obtained within 30
744 calendar days of becoming an independent contractor or of employment with the
745 independent contractor, is on file with the independent contractor, and does not
746 contain any conviction of a barrier crime.

747 ~~E.B. An HCO No employee shall be permitted to~~ may not permit a compensated employee,
748 employee of a temporary staffing agency, or an independent contractor to work in a position that
749 involves direct contact with a client or patient until an original criminal record report has been
750 received by the home care organization HCO, or temporary staffing agency, or independent
751 contractor unless such person the employee works under the direct supervision and in the
752 presence of another HCO-compensated employee for whom a background check has been
753 completed in accordance with subsection B A of this section.

754 F. ~~A criminal record report remains valid as long as the employee remains in continuous~~
755 ~~service with the same organization.~~

756 G.C. An HCO shall obtain A a new criminal record report and a new sworn statement
757 disclosure shall be required when if an individual;

758 ~~1. terminates~~ Terminates compensated employment at one home care organization
759 HCO and begins work compensated employment at another home care organization
760 HCO, unless the HCOs are owned by the same entity. The employee's file shall contain
761 a statement indicating the original criminal record report has been transferred or
762 forwarded to the new work location; or. The following exceptions are permitted:

763 ~~1. When an employee transfers within 30 days to an organization owned and operated~~
764 ~~by the same entity. The employee's file shall contain a statement that the original~~
765 ~~criminal record report has been transferred or forwarded to the new work location.~~

766 ~~2. When an individual takes~~ Takes a leave of absence, the criminal record report and
767 sworn statement will remain valid as long as the period of separation does not exceed
768 exceeding six consecutive months. If six consecutive months have passed, a new
769 criminal record report and sworn disclosure statement are required.

770 H.D. An HCO shall:

771 1. Obtain from an applicant for compensated employment A a sworn disclosure
772 statement shall be completed by all applicants for employment.; and

773 2. File The the sworn disclosure statement shall be attached to and filed with the criminal
774 record report.

775 E. An HCO may not hire for compensated employment any person who has been convicted
776 of a barrier crime, except if:

777 1. The person has been convicted of a single offense punishable as a misdemeanor;

778 2. The conviction does not involve abuse or neglect; and

779 3. Five years have elapsed since the conviction.

780 I.F. An HCO shall provide a copy of the criminal record report to Any an applicant denied
781 compensated employment because of convictions appearing on his criminal record report shall
782 be provided a copy of the report by the hiring organization.

783 J.G. An HCO shall maintain the confidentiality of All criminal record reports shall be
784 confidential and maintained store criminal record reports in locked files accessible only to the
785 administrator or designee. An HCO shall maintain an employee's criminal record report and
786 sworn disclosure for no less than five years from the date of employment with the HCO or as
787 otherwise provided by law.

788 K.H. An HCO may not Further dissemination disseminate of the criminal record report and
789 sworn disclosure statement information is prohibited other than except to the commissioner's
790 representative or a federal or state authority or court as may be required to comply with an
791 express requirement of law for such further dissemination.

792 **Statutory Authority**

793 §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.

794 **Historical Notes**

795 Derived from Virginia Register Volume 22, Issue 3, eff. January 1, 2006; amended, Virginia
796 Register Volume 31, Issue 10, eff. February 12, 2015.

797 **12VAC5-381-120. Variances Allowable variances.**

798 A. The OLC ~~commissioner can~~ may authorize variances a variance only to its own licensing
799 regulations a specific standard or requirement of this chapter, not to regulations of another
800 agency or to any standards or requirements in federal, state, or local laws. A variance shall:

801 1. Require advance written approval from the commissioner;

802 2. Not be extended to general applicability; and

803 3. Not endanger the health, safety, or well-being of clients, patients, or the public.

804 B. ~~A home care organization~~ A licensee may request a variance at any time, ~~to a particular~~
805 ~~regulation or requirement contained in this chapter when the standard or requirement poses a~~
806 ~~special hardship and when a variance to it would not endanger the safety or well-being of~~
807 ~~clients.~~ The request for a variance ~~must~~ shall describe:

808 1. ~~how~~ How compliance with the current ~~regulation~~ standard or requirement is
809 ~~economically burdensome and constitutes a special~~ an impractical hardship unique to
810 ~~the home care organization and to the clients it serves.~~ HCO; and

811 2. ~~When applicable, the request should include proposed~~ Proposed alternatives to meet
812 the purpose of the ~~standard or requirements~~ requirement that will ensure the ~~protection~~
813 health, safety, and well-being of clients, patients, and the public.

814 At no time shall a variance approved for one individual be extended to general applicability.
815 ~~The home care organization~~ The licensee may at any time withdraw a request for a variance at
816 any time.

817 C. ~~The OLC shall have the authority to waive, either temporarily or permanently, the~~
818 ~~enforcement of one or more of these regulations provided safety, client care and services are~~
819 ~~not adversely affected.~~ The commissioner shall notify the licensee in writing of the
820 commissioner's decision on the variance request. If granted, the commissioner may attach
821 conditions to a variance that, in the sole judgment of the commissioner, protects the health,
822 safety, and well-being of clients, patients, and the public.

823 D. The ~~OLC~~ commissioner may rescind or modify a variance if:

824 1. ~~(i) conditions change~~ The impractical hardship unique to the HCO changes or no
825 longer exists;

826 2. ~~(ii) additional~~ Additional information becomes known that alters the basis for the
827 original decision, including if the licensee failed to comply with the standard or
828 requirement prior to receiving a variance;

829 3. ~~(iii) the organization~~ The licensee fails to meet any conditions attached to the
830 variance; ~~or~~

831 4. ~~(iv) results~~ Results of the variance jeopardize the health, safety, comfort, or well-being
832 of clients, patients, and the public.

833 E. ~~Consideration of a variance is initiated when a written request is submitted to the~~
834 ~~Director, OLC. The OLC shall notify the home care organization in writing of the receipt of the~~
835 ~~request for a variance. The OLC may attach conditions to a variance to protect the safety and~~
836 ~~well-being of the client.~~

837 F. ~~The licensee shall be notified in writing if the requested variance is denied.~~

838 G. ~~E.~~ If a variance is denied, expires, or is rescinded, the commissioner or his designee shall
839 routine enforcement of enforce the regulation ~~or portion of the regulation shall be resumed~~
840 standard or requirement to which the variance was granted.

841 H. ~~The home care organization~~ The governing body of an HCO shall develop and document
842 procedures for monitoring the implementation of any approved variances to assure the ongoing
843 collection of any data relevant to the variance and the presentation of any later report
844 concerning the variance as requested by the OLC variance.

845 **Statutory Authority**

846 §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.

847 **Historical Notes**

848 Derived from Virginia Register Volume 22, Issue 3, eff. January 1, 2006; Errata, 22:4 VA.R. 659
849 October 31, 2005; amended, Virginia Register Volume 24, Issue 11, eff. March 5, 2008.

850 **12VAC5-381-130. Violation of this chapter or applicable law; denial, Revocation**
851 **revocation, or suspension of a license.**

852 A. ~~The commissioner is authorized to~~ may deny, revoke, or suspend any the license to
853 operate an HCO in accordance with the Administrative Process Act (§ 2.2-4000 et seq. of the
854 Code of Virginia) if the commissioner determines than an applicant the or licensee is:

855 1. In violation of this chapter or fails to comply with the provisions of Article 7.1 (§ 32.1-
856 162.7 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia or the regulations of the
857 board.; or

858 2. Permitting, aiding, or abetting the commission of any illegal act in the HCO.

859 Suspension of a license shall in all cases be for an indefinite time.

860 B. ~~If a license is revoked, the commissioner may issue a new license when the conditions~~
861 ~~upon which revocation was based have been corrected and compliance with all provisions of~~
862 ~~the law and this chapter has been achieved. Upon receipt of a completed application and a~~
863 ~~nonrefundable application fee, the commissioner may issue a new license to an HCO that has~~
864 ~~had its license to operate an HCO revoked if the commissioner determines that:~~

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

866 2. The applicant is in compliance with this chapter and Article 7.1 (§ 32.1-162.7 et seq.)
867 of Chapter 5 of Title 32.1 of the Code of Virginia.

868 The HCO shall submit evidence relevant to subdivisions 1 and 2 that is satisfactory to the
869 commissioner or his designee. The commissioner or his designee may conduct an inspection
870 prior to making a determination.

871 ~~C. When a license is revoked or suspended, the organization shall cease operations. If the~~
872 ~~organization continues to operate after its license has been revoked or suspended, the~~
873 ~~commissioner may request the Office of the Attorney General to petition the circuit court of the~~
874 ~~jurisdiction in which the home care organization is located for an injunction to cause such home~~
875 ~~care organization to cease operations.~~

876 ~~D.C. Suspension of a license shall in all cases be for an indefinite time. The suspension may~~
877 ~~be lifted and rights under the license fully or partially restored at such time as the commissioner~~
878 ~~determines that the rights of the licensee appear to so require and the interests of the public will~~
879 ~~not be jeopardized by resumption of operation. The commissioner may partially or completely~~
880 ~~restore a suspended license to an HCO if the commissioner determines that:~~

881 1. The rights of the licensee appear to require restoration; and

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

883 The HCO shall submit evidence relevant to subdivisions 1 and 2 that is satisfactory to the
884 commissioner or his designee. The commissioner or his designee may conduct an inspection
885 prior to making a determination. No additional fee shall be required for restoring a license
886 pursuant to this subsection.

887 D. An applicant or licensee may contest the denial, revocation, or suspension of a license in
888 accordance with the provisions of the Administrative Process Act (§ 2.2-4000 et seq. of the
889 Code of Virginia).

890 **Statutory Authority**

891 §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.

892 **Historical Notes**

893 Derived from Virginia Register Volume 22, Issue 3, eff. January 1, 2006.

894 **12VAC5-381-140. Return of a license. (Repealed.)**

895 A. Circumstances under which a license must be returned include, but are not limited to (i)
896 transfer of ownership and (ii) discontinuation of services.

897 B. The licensee shall notify its clients and the OLC, in writing, 30 days before discontinuing
898 services.

899 C. If the organization is no longer operational, or the license has been suspended or
900 revoked, the license shall be returned to the OLC within five working days. The licensee shall
901 notify its clients and the OLC where all home care records will be located.

902 **Statutory Authority**

903 ~~§§ 32.1-12 and 32.1-162.12 of the Code of Virginia.~~

904 **Historical Notes**

905 Derived from Virginia Register Volume 22, Issue 3, eff. January 1, 2006; amended, Virginia
906 Register Volume 24, Issue 11, eff. March 5, 2008.

907 **12VAC5-381-150. Management and administration.**

908 Part II
909 Administrative Services

910 A. ~~No person shall establish or operate a home care organization, as defined in § 32.1-~~
911 ~~162.7 of the Code of Virginia, without having obtained a license.~~

912 ~~B.A. The organization An HCO must shall comply with:~~

- 913 1. This chapter (~~12VAC5-381~~);
914 2. Other applicable federal, ~~state or local~~ laws and regulations administered by the
915 board; and
916 3. The organization's HCO's own policies and procedures.

917 ~~C.B. The organization applicant or licensee shall submit or make available to the~~
918 ~~commissioner or his designee any reports and information necessary to establish compliance~~
919 ~~with this chapter and applicable law.~~

920 D. ~~The organization shall permit representatives from the OLC to conduct inspections to:~~

- 921 1. ~~Verify application information;~~
922 2. ~~Determine compliance with this chapter;~~
923 3. ~~Review necessary records and documents; and~~
924 4. ~~Investigate complaints.~~

925 E. ~~The organization shall notify the OLC 30 days in advance of changes affecting the~~
926 ~~organization, including the:~~

- 927 1. ~~Service area;~~
928 2. ~~Mailing address of the organization;~~
929 3. ~~Ownership;~~
930 4. ~~Services provided;~~
931 5. ~~Operator;~~
932 6. ~~Administrator;~~
933 7. ~~Organization name; and~~
934 8. ~~Closure of the organization.~~

935 C. An HCO shall document in writing the authority, or limitations on the authority, of the
936 agents of the HCO to enter into transactions with the department on behalf of the HCO and any
937 other transactions, which the HCO shall include in its:

- 938 1. Bylaws, if it is a corporation;
939 2. An operating agreement, if it is a limited liability company;
940 3. A governing instrument, if it is a business trust;
941 4. A statement of partnership authority, if it is a partnership; or
942 5. Other written document, if it is a sole proprietorship.

943 ~~F. D.~~ An HCO shall post its The current active license from the department commissioner
944 shall be posted for public inspection at all times in a place readily visible and accessible to the
945 public at the parent HCO's office and any branch office locations.

946 ~~G. E.~~ An HCO shall ensure that Service service providers or community affiliates under
947 contract with the organization HCO must comply with the organization's HCO's policies and this
948 chapter.

949 ~~H. F.~~ The organization An HCO shall may not use any advertising that contains false,
950 misleading, or deceptive statements or claims, or false or misleading disclosures of fees and
951 payment for services.

952 ~~I. G.~~ The organization An HCO shall:

953 1. have Have regular posted business hours and be fully operational during such
954 business hours; and

955 2. In addition, the organization shall provide Provide or arrange for services to their its
956 clients and patients on an on-call basis 24 hours a day, seven days a week.

957 ~~J. H.~~ The organization An HCO shall may not accept a client or patient only when if the
958 organization HCO can cannot adequately meet that client's or patient's needs in the client's
959 place of his residence.

960 ~~K. I.~~ The organization An HCO must shall have a prepared plan for emergency operations in
961 case of inclement weather or natural disaster to include that includes:

962 1. contacting Contacting and providing essential care to clients and patients ;

963 2. coordinating Coordinating with community agencies to assist as needed; and

964 3. maintaining Maintaining a current list of clients and patients who would require
965 specialized assistance.

966 ~~L. J.~~ The organization An HCO shall encourage and facilitate the availability of flu shots
967 influenza vaccination for its staff employees, and clients, and patients.

968 **Statutory Authority**

969 §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.

970 **Historical Notes**

971 Derived from Virginia Register Volume 22, Issue 3, eff. January 1, 2006; amended, Virginia
972 Register Volume 24, Issue 11, eff. March 5, 2008.

973 **12VAC5-381-160. Governing body.**

974 ~~A. The organization~~ Each HCO shall have designate in writing a governing body that is
975 legally responsible for the overall management, operation and fiscal affairs and control of the
976 organization HCO. The governing body of a hospital that operates a home care organization an
977 HCO shall include in its internal organization structure an identified unit of home care services.

978 B. The governing body shall:

979 1. Determine which services are to be provided by the organization HCO;

980 2. Ensure that the organization is staffed and adequately equipped to provide the
981 services it offers to clients Provide employees and other resources necessary to meet

982 client, patient, and program needs, whether provided directly by the organization HCO or
983 through by contract; and

984 ~~3. Comply with federal and state laws, regulations and local ordinances governing~~
985 ~~operations of the organization; and~~

986 ~~4. Establish a quality improvement committee.~~

987 3. Have a formal organizational plan with written bylaws that clearly set forth
988 organization, duties and responsibilities, accountability, and relationships of
989 management, clinical employees, and other employees.

990 ~~C. The governing body shall review annually and approve the written policies and~~
991 ~~procedures of the organization.~~

992 ~~D. C.~~ The governing body shall review annually and approve the recommendations of the
993 quality improvement committee, when appropriate.

994 D. The bylaws shall include:

995 1. A statement of purpose;

996 2. Description of the functions and duties of the governing body;

997 3. A statement of authority and responsibility delegated to the administrator and to the
998 clinical employees;

999 4. Provision for selection and appointment of clinical employees and granting of clinical
1000 privileges;

1001 5. Provision of guidelines for relationships among the governing body, the administrator,
1002 and the clinical employees; and

1003 6. The identity of the person or organizational body responsible for formulating policies
1004 and procedures pursuant to 12VAC5-381-180.

1005 **Statutory Authority**

1006 §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.

1007 **Historical Notes**

1008 Derived from Virginia Register Volume 22, Issue 3, eff. January 1, 2006.

1009 **12VAC5-381-170. Administrator.**

1010 A. The governing body shall ~~appoint as~~ designate in writing one person to be the primary
1011 administrator, who shall be responsible for the daily managerial, operational, financial, and
1012 reporting components of the HCO, including: an individual who has evidence of at least one
1013 year of training and experience in direct health care service delivery with at least one year within
1014 the last five years of supervisory or administrative management experience in home health care
1015 or a related health program.

1016 B. ~~The administrator shall be responsible for the day-to-day management of the~~
1017 ~~organization, including but not limited to:~~

1018 ~~1. Organizing and supervising the administrative function of the organization;~~

1019 ~~2. Maintaining an ongoing liaison with the governing body, the professional personnel~~
1020 ~~and staff;~~

1021 1. Developing, implementing, and enforcing all policies and procedures, including client
1022 and patient rights;

1023 ~~2.~~ Employing qualified personnel employees;

1024 3. and ensuring Ensuring adequate staff employee orientation, training, education, and
1025 evaluation upon an employee's hiring and annually thereafter;

1026 4. Ensuring the accuracy of public information materials and activities;

- 1027 ~~5. Implementing~~ Ensuring an effective budgeting and accounting system is implemented;
- 1028 6. Maintaining compliance with applicable laws and regulations and implementing
- 1029 corrective action in response to reports of organization committees and regulatory
- 1030 agencies; and
- 1031 7. Arranging and negotiating services provided through contractual agreement; ~~and.~~
- 1032 ~~8. Implementing the policies and procedures approved by the governing body.~~

1033 B. The governing body shall ensure that the designated administrator is an individual who

1034 has evidence of at least one year of training and experience in direct health care service

1035 delivery with at least one year within the last five years of supervisory or administrative

1036 management experience in home health care or a related health program.

1037 C. An HCO shall notify the OLC in writing of a change of administrator no more than five

1038 business days after the change. An HCO shall provide to the OLC a copy of the administrator's

1039 résumé or curriculum vitae with its notice of change of administrator.

1040 D. The governing body or administrator shall appoint in writing a qualified person to act in

1041 the absence of the administrator.

1042 ~~C. The individual designated to perform the duties of the administrator when the~~

1043 ~~administrator is absent from the organization shall be able to perform the duties of the~~

1044 ~~administrator as identified in subsection B of this section.~~

1045 ~~D.E. An HCO shall ensure that~~ The the administrator or his designee shall be is readily

1046 available on the premises or by telecommunications at all times during operating hours and for

1047 emergency situations.

1048 **Statutory Authority**

1049 §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.

1050 **Historical Notes**

1051 Derived from Virginia Register Volume 22, Issue 3, eff. January 1, 2006; amended, Virginia

1052 Register Volume 26, Issue 26, eff. September 30, 2010.

1053 **12VAC5-381-180. ~~Written policies~~ Policies and procedures.**

1054 ~~A. The organization~~ A governing body shall:

1055 1. Approve and maintain documented ~~implement written~~ policies and procedures

1056 approved by the governing body as specified in this section that are based on

1057 recognized standards and guidelines, which shall be readily available on the premises of

1058 the parent HCO's office and all branch offices;.

1059 2. Review all policies and procedures at least biennially with the administrator and

1060 appropriate clinical employees;

1061 3. Updated policies and procedure, as deemed necessary by the governing body; and

1062 4. Document in writing the biennial review process and recommendations for changes or

1063 updates.

1064 A member of the clinical employees or an independent contractor with training and expertise

1065 in infection prevention shall participate in the biennial review of the infection prevention policies

1066 and procedures to ensure they comply with applicable regulations and standards.

1067 ~~B. All policies and procedures shall be reviewed at least annually, with recommended~~

1068 ~~changes submitted to the governing body for approval, as necessary.~~

1069 ~~C.B.~~ Administrative and operational policies and procedures shall include, but are not limited

1070 to:

1071 1. Administrative records, including granted variances;

- 1072 ~~2. Admission and discharge or termination from service criteria;~~
- 1073 ~~3.2. Informed signed consent;~~
- 1074 ~~4.3. Advance Providing information regarding advance directives, including Durable Do~~
- 1075 ~~Not Resuscitate Orders;~~
- 1076 ~~5. Client rights;~~
- 1077 ~~6.4. Contract services;~~
- 1078 ~~7. Medication management, if applicable~~ 5. The monitoring of medications taken by a
- 1079 patient, if applicable, by a actively licensed nurse to confirm that the patient is complying
- 1080 with a medication regime, while also ensuring the patient avoids potentially dangerous
- 1081 drug interactions and other complications;
- 1082 ~~8.6. Quality improvement;~~
- 1083 ~~9.7. Mandated reporting of abuse, neglect, and exploitation pursuant to § 63.2-1509 or to~~
- 1084 ~~§ 63.2-1606 of the Code of Virginia;~~
- 1085 ~~10.8. Communicable and reportable diseases~~ Reporting diseases and conditions to the
- 1086 local health department in accordance with the Regulations for Disease Reporting and
- 1087 Control (12VAC5-90);
- 1088 ~~11.9. Client Clinical records, including confidentiality;~~
- 1089 ~~12.10. Record retention of adult and pediatric clients and patients, including termination~~
- 1090 ~~of services;~~
- 1091 ~~13.11. Supervision and delivery of services;~~
- 1092 ~~14.12. Emergency and on-call services;~~
- 1093 ~~15. Infection control;~~
- 1094 ~~16.13. Handling ~~consumer~~ the complaints of clients, patients, clients' and patients' family~~
- 1095 ~~members, employees, and the public that meets the requirements of 12VAC5-381-240;~~
- 1096 ~~17.14. Telemonitoring; and~~
- 1097 ~~18.15. Approved variances~~ Identification of the administrator and methods established
- 1098 by the governing body for holding the administrator responsible and accountable-;
- 1099 16. An emergency management plan;
- 1100 17. Electronic health record and electronic signature, if applicable;
- 1101 18. Protocols to prevent the occurrence of pressure sores or decubitus ulcers;
- 1102 19. Identification of which prescription drugs and nonprescription drugs that the HCO
- 1103 permits to be self-administered; and
- 1104 20. CBD oil and THC-A oil for medical treatment and abuse of prescription or illegal
- 1105 drugs by client or patient in the presence of an employee, volunteer, or independent
- 1106 contractor.
- 1107 C. Client and patient rights policies and procedures shall include:
- 1108 1. A process by which clients and patients are informed of their rights under 12VAC5-
- 1109 381-230; and
- 1110 2. Providing timely information in plain language to all clients and patients and in a
- 1111 manner that is accessible to any client or patient:
- 1112 a. With disabilities, including accessible websites and the provision of auxiliary aids
- 1113 and services at no cost to the client or patient; and
- 1114 b. With limited English proficiency through the provision of language services at no
- 1115 cost to the client or patient, including oral interpretation and written translations.

- 1116 D. Financial policies and procedures shall include, ~~but are not limited to:~~
- 1117 1. Admission agreements;
- 1118 2. Data collection and verification of services delivered;
- 1119 3. Methods of billing for services by the organization HCO and by independent
- 1120 contractors;
- 1121 4. Client and patient notification of changes in fees and charges;
- 1122 5. Correction of billing errors and refund policy; and
- 1123 6. Collection of delinquent client and patient accounts.
- 1124 E. ~~Personnel~~ Employee policies and procedures shall include, ~~but are not limited to a:~~
- 1125 1. ~~Written job description~~ descriptions that ~~specifies authority, responsibility, and~~
- 1126 qualifications for each job classification meet the requirements of 12VAC5-381-200;
- 1127 2. ~~Process for maintaining an accurate, complete and current personnel record for each~~
- 1128 employee;
- 1129 3. ~~Process for verifying~~ 2. Verifying current active professional licensing or certification
- 1130 and training of employees, volunteers, or independent contractors;
- 1131 4. ~~Process for annually evaluating~~ 3. Evaluating at least annually employee performance
- 1132 and competency;
- 1133 5. ~~Process for verifying~~ 4. Verifying that independent contractors and their employees
- 1134 meet the personnel employee qualifications of the organization HCO;
- 1135 6. ~~Process for obtaining~~ 5. Obtaining a criminal background check and maintaining a
- 1136 drug-free workplace pursuant to § 32.1-162.9:1 of the Code of Virginia; and
- 1137 7. ~~Process for reporting~~ 6. Reporting licensed and certified medical ~~personnel~~
- 1138 employees, volunteers, and independent contractors for violations of their licensing or
- 1139 certification to the appropriate board within the Department of Health Professions;
- 1140 7. Reporting employees, employees of temporary staffing agencies, independent
- 1141 contractors, and volunteers to the director of the OLC pursuant to § 54.1-2400.6 of the
- 1142 Code of Virginia;
- 1143 8. Employee participation in initial and ongoing training and education that is directly
- 1144 related to employee duties and appropriate to the level, intensity, and scope of services
- 1145 provided;
- 1146 9. Employee participation in annual infection prevention in-service training and the
- 1147 process by which training is documented;
- 1148 10. Appropriate staffing by actively licensed health care practitioners based on the level,
- 1149 intensity, and scope of services provided and the process by which staffing is
- 1150 documented; and
- 1151 11. Standards of conduct, which shall include corrective action that may be taken to
- 1152 address violations of the standards and a method for enforcing the standards while an
- 1153 employee is in a client's or patient's residence.
- 1154 F. Admission and discharge or termination from service policies and procedures shall
- 1155 ~~include, but are not limited to:~~
- 1156 1. Criteria for accepting clients and patients for services offered;
- 1157 2. The process for obtaining a medical plan of care or ~~service~~ plan of care;
- 1158 3. Admissions, including criteria for evaluating the client or patient before admission;
- 1159 4. Criteria for determining discharge or termination from each service and referral to
- 1160 other agencies or community services; and

- 1161 4. 5. Process for notifying clients and patients of intent to discharge/terminate discharge,
1162 terminate, or refer, including:
- 1163 a. Oral and written notice and explanation of the reason for discharge/termination
1164 discharge, termination, or referral;
 - 1165 b. The name, address, telephone number and contact name at the referral
1166 organization; and
 - 1167 c. Documentation in the client clinical record of the referral or notice.
- 1168 G. A member of the clinical staff or an independent contractor with training and expertise in
1169 infection prevention shall participate in the development of infection prevention policies and
1170 procedures. The governing body shall document the process for development, implementation,
1171 and maintenance of infection prevention policies and procedures and the regulations or
1172 guidance documents on which they are based. The infection prevention policies and procedures
1173 shall include:
- 1174 1. Initial training, annual retraining, and use of standard precautions recommended by
1175 the U.S. Centers for Disease Control and Prevention by all employees, volunteers, and
1176 independent contractors, including:
 - 1177 a. Correct hand-washing technique, including indications for use of soap and water,
1178 and use of alcohol-based hand rubs;
 - 1179 b. Compliance with bloodborne pathogen requirements of the U.S. Occupational
1180 Safety and Health Administration; and
 - 1181 c. Use of personal protective equipment;
 - 1182 2. Use of safe injection practices recommended by the U.S. Centers for Disease Control
1183 and Prevention;
 - 1184 3. Monitoring employee, volunteer, and independent contractor adherence to standard
1185 precautions;
 - 1186 4. Access to hand-washing equipment and adequate supplies (e.g., alcohol-based hand
1187 rubbers or disposable towels);
 - 1188 5. Handling, storing, and transporting clean or sterile supplies and equipment;
 - 1189 6. Handling, storing, processing, and transporting regulated medical waste in
1190 accordance with applicable regulations;
 - 1191 7. Processing of each type of reusable medical equipment between uses on different
1192 clients and patients, with reference to the manufacturer's recommendations and any
1193 applicable state or national infection control guidelines, and addressing:
 - 1194 a. The level of cleaning, disinfecting, or sterilizing to be used for each type of
1195 equipment;
 - 1196 b. The process by which cleanliness, disinfection, or sterilization is achieved; and
 - 1197 c. The method for verifying that the recommended level of cleanliness, disinfection,
1198 or sterilization has been achieved;
 - 1199 8. Maintenance, repair, and disposal of equipment and supplies in accordance with
1200 manufacturer recommendations;
 - 1201 9. Cleaning of environmental surfaces with appropriate cleaning products; and
 - 1202 10. Other infection prevention procedures necessary to prevent or control transmission
1203 of an infectious agent between clients, patients, and employees as recommended or
1204 required by the department; and
 - 1205 11. Monitoring employee, volunteer, and independent contractor performance in
1206 infection control practices.

1207 H. For an HCO that provides pharmaceutical services, pharmaceutical policies and
1208 procedures shall include:

- 1209 1. Developing a medical plan of care;
1210 2. Initiation of medication administration based on a prescriber's order and monitoring of
1211 the patient for response to the treatment and any adverse reactions or side effects;
1212 3. Assessment of any factors related to the home environment that may affect the
1213 prescriber's decisions for initiating, modifying, or discontinuing medications;
1214 4. Communication with the prescriber concerning assessment of the patient's response
1215 to therapy, any other patient specific needs, and any significant change in the patient's
1216 condition;
1217 5. Communication with the patient's provider pharmacy concerning problems or needed
1218 changes in a patient's medication;
1219 6. Maintaining a complete and accurate record of medications prescribed, medication
1220 administration data, patient assessments, any laboratory tests ordered to monitor
1221 response to drug therapy and results, and communications with the prescriber and
1222 pharmacy provider;
1223 7. Educating or instructing the patient, family members, or other caregivers involved in
1224 the administration of infusion therapy in the proper storage of medication, in the proper
1225 handling of supplies and equipment, in any applicable safety precautions, in recognizing
1226 potential problems with the patient, and actions to take in an emergency; and
1227 8. Initial and retraining of all employees, including on procedures for first dosing of
1228 infusion therapy.

1229 ~~G. I. An HCO shall make Policies policies and procedures shall be made~~ available for
1230 ~~review, upon request, to clients, patients, and their designated legal~~ representatives.

1231 ~~H. J. An HCO shall make Policies policies and procedures shall be~~ readily available for staff
1232 ~~employee use at all times at the parent HCO's office and all branch offices.~~

1233 **Statutory Authority**

1234 §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.

1235 **Historical Notes**

1236 Derived from Virginia Register Volume 22, Issue 3, eff. January 1, 2006; amended, Virginia
1237 Register Volume 26, Issue 26, eff. September 30, 2010.

1238 **12VAC5-381-190. Financial controls.**

1239 ~~A. Every An~~ applicant ~~for an initial license to establish or operate a home care organization~~
1240 ~~shall include as part of his application:~~

1241 ~~1. a A~~ detailed operating budget showing projected operating expenses for the three-
1242 ~~month period after a license to operate has been issued-; and~~

1243 ~~2. Further, every applicant for an initial license to establish or operate a home care~~
1244 ~~organization shall include as part of his application proof Proof~~ of initial reserve operating
1245 funds in the amount sufficient to ensure operation of the ~~home care organization~~ HCO
1246 for the three-month period after a license to operate has been issued. Such funds may
1247 include:

1248 ~~1-a.~~ Cash;

1249 ~~2-b.~~ Cash equivalents that are readily convertible to known amounts of cash and that
1250 present insignificant risk of change in value;

1251 ~~3-c.~~ Borrowed funds that are immediately available to the applicant; or

1252 ~~4-d.~~ A line of credit that is immediately available to the applicant.

1253 B. The OLC shall accept as ~~Proof of funds sufficient~~ satisfactory evidence that an applicant
1254 has met the requirements of subdivision 2 of subsection A:

1255 1. ~~to meet these requirements shall include a~~ A current balance sheet demonstrating the
1256 availability of funds;

1257 2. a A letter from the officer of the bank or other financial institution where the funds are
1258 held; or

1259 3. a A letter of credit from a lender demonstrating the current availability of and amount
1260 of a line of credit.

1261 ~~B.C. The organization~~ An HCO shall document financial resources to operate based on a
1262 working budget showing projected revenue and expenses.

1263 ~~C.D. An HCO shall keep~~ All all financial records shall be kept according to generally
1264 accepted accounting principles (GAAP).

1265 ~~D.E. An HCO shall ensure~~ All all financial records shall be are audited subject to a review at
1266 least triennially by an independent certified public accountant (CPA) or audited as otherwise
1267 provided by law, and shall provide a copy of the CPA's review report upon request by the OLC.

1268 ~~E. The organization~~ F. An HCO shall have documented financial controls in its policies and
1269 procedures to minimize risk of theft or embezzlement.

1270 G. An HCO shall notify the OLC within two business days of being contacted by the
1271 Medicaid Fraud Control Unit in the Office of the Attorney General if it is the subject of a
1272 Medicaid fraud investigation.

1273 **Statutory Authority**

1274 §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.

1275 **Historical Notes**

1276 Derived from Virginia Register Volume 22, Issue 3, eff. January 1, 2006; amended, Virginia
1277 Register Volume 31, Issue 10, eff. February 12, 2015.

1278 **12VAC5-381-200. Personnel Employee practices.**

1279 A. An HCO shall ensure that:

1280 1. ~~Personnel~~ Its employee management and employment practices shall comply with
1281 applicable state and federal laws and regulations; and

1282 2. Its employees, contractors, and volunteers are actively licensed or certified as
1283 required by the Department of Health Professions.

1284 B. ~~The organization~~ The governing body of an HCO shall design and implement;

1285 1. a A staffing plan that reflects the types of services offered by the HCO;

1286 2. and shall provide Provide qualified staff employees in sufficient numbers to meet the
1287 assessed needs of all clients and patients; and

1288 ~~C. Employees and contractors shall be licensed or certified as required by the Department~~
1289 ~~of Health Professions.~~

1290 3. D. The organization shall design and implement Design a mechanism to verify and
1291 document professional credentials.

1292 ~~E. Any person who assumes the responsibilities of any staff position or positions shall meet~~
1293 ~~the minimum qualifications for that position or positions.~~

1294 ~~F. The organization shall obtain the required sworn statement and criminal record check for~~
1295 ~~each compensated employee as specified in § 32.1-162.9:1 of the Code of Virginia.~~

1296 ~~G. C. For each employee, independent contractor, and volunteer description, an HCO shall~~
1297 ~~Each employee position shall have a written job description that includes:~~

- 1298 1. Include the Job position title, authority, specific responsibilities, and minimum
1299 qualifications;
- 1300 2. Duties and responsibilities required of the position Review the job description at least
1301 annually and update as deemed necessary by the HCO; and
- 1302 3. Job title of the immediate supervisor Give a copy to each employee, independent
1303 contractor, and volunteer when assigned to the position and when revised; and.
- 1304 4. Minimum knowledge, skills, and abilities or professional qualifications required for
1305 entry level.
- 1306 ~~H. Employees shall have access to their current position description. There shall be a~~
1307 ~~mechanism for advising employees of changes to their job responsibilities.~~
- 1308 ~~I. D. An HCO shall provide orientation to New new employees, independent contractors, and~~
1309 ~~contract individuals volunteers shall be oriented commensurate with their function or job-specific~~
1310 ~~responsibilities. Orientation, which shall include:~~
- 1311 1. Objectives and philosophy of the organization HCO;
- 1312 2. Confidentiality;
- 1313 3. Client and patient rights;
- 1314 4. Mandated reporting of abuse, neglect, and exploitation;
- 1315 5. Applicable ~~personnel~~ policies and procedures, including administrative and employee
1316 policies and procedures;
- 1317 6. Emergency preparedness procedures;
- 1318 7. Infection control practices and measures;
- 1319 8. Cultural awareness;
- 1320 9. How to report suspected Medicaid fraud; and
- 1321 ~~9. 10.~~ Applicable laws, regulations, and other policies and procedures that apply to
1322 specific positions, and specific duties and responsibilities.
- 1323 ~~J. E. The organization An HCO shall develop and implement a policy for annually evaluating~~
1324 ~~employee and volunteer performance, which shall include individual employee or volunteer~~
1325 ~~development needs and plans.~~
- 1326 ~~K. Individual staff development needs and plans shall be a part of the performance~~
1327 ~~evaluation.~~
- 1328 ~~L. The organization F. An HCO shall provide or arrange opportunities for and record~~
1329 ~~participation in staff development activities designed to enable staff to perform the~~
1330 ~~responsibilities of their positions.~~
- 1331 ~~M. G. An HCO shall ensure that All all individuals employees, contractors, and volunteers~~
1332 ~~who enter a client's home for or on behalf of the organization HCO shall be are readily~~
1333 ~~identifiable by employee nametag, uniform or other visible and conspicuous means.~~
- 1334 ~~N. The organization shall maintain an organized system to manage and protect the~~
1335 ~~confidentiality of personnel files and records.~~
- 1336 ~~O. H. For each Employee personnel records employee file, whether hard copy or electronic,~~
1337 ~~an HCO shall include:~~
- 1338 1. ~~Identifying information~~ Ensure the employee file is complete and accurate;
- 1339 2. ~~Education and training history~~ Make the employee file readily available, including by
1340 electronic means;
- 1341 3. ~~Employment history~~ Systematically organize the employee file to facilitate the
1342 compilation and retrieval of information;

- 1343 4. ~~Results of the verification of applicable professional licenses or certificates~~ Safeguard
1344 the employee file against loss and unauthorized use;
- 1345 5. ~~Results~~ Document results of reasonable efforts to secure job-related references and
1346 reasonable verification of employment history;
- 1347 6. Maintain employee health information separately within the employee file;
- 1348 6. ~~Results of performance evaluations~~ Ensure the employee file contains a current job
1349 description that reflects the employee's responsibilities and work assignments, and
1350 documentation of the employee's in-service education and professional licensure or
1351 certification, if applicable;
- 1352 7. ~~A record of~~ Record performance evaluations and disciplinary actions, if any, taken by
1353 the organization, if any HCO;
- 1354 8. ~~A record of~~ Record adverse action by any licensing bodies and organizations, if any;
1355 and
- 1356 9. ~~A record of participation in staff development activities, including orientation; and~~
- 1357 10. Maintain documentation of ~~The~~ the criminal record check report and sworn affidavit
1358 as required in 12VAC5-381-90.

1359 P. I. An HCO shall report ~~All~~ any positive results from drug testing ~~shall be reported to the~~
1360 health regulatory boards responsible for licensing, certifying, or registering the person to
1361 practice, if any, pursuant to ~~§ 32.1-162.9:1 of the Code of Virginia.~~

1362 Q. J. An HCO shall retain ~~Each~~ an employee personnel record file shall be retained in its
1363 entirety for a ~~minimum of~~ no less than three years after termination of employment.

1364 R. ~~Personnel record information shall be safeguarded against loss and unauthorized use.~~

1365 S. ~~Employee health-related information shall be maintained separately within the employee's~~
1366 ~~personnel file.~~

1367 **Statutory Authority**

1368 §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.

1369 **Historical Notes**

1370 Derived from Virginia Register Volume 22, Issue 3, eff. January 1, 2006; amended, Virginia
1371 Register Volume 26, Issue 26, eff. September 30, 2010.

1372 **12VAC5-381-210. Indemnity coverage.**

1373 A. The governing body shall ensure the ~~organization~~ HCO and its contractors have
1374 appropriate indemnity coverage to compensate clients for injuries and losses resulting from
1375 services provided.

1376 B. The ~~organization~~ HCO shall purchase and maintain the following types and minimum
1377 amounts of indemnity coverage at all times:

1378 1. ~~Malpractice~~ Professional liability insurance consistent with ~~§ 8.01-581.15 of the Code~~
1379 ~~of Virginia~~ of at least \$2.55 million per occurrence as of July 1, 2022. An HCO shall
1380 increase its minimum per occurrence professional liability coverage by at least \$50,000
1381 on or before every July 1, beginning July 1, 2023;

1382 2. General liability insurance covering personal property damages, bodily injuries,
1383 product liability, and libel and slander of at least \$1 million comprehensive general
1384 liability per occurrence; and

1385 3. Third-party crime insurance or a blanket fidelity bond of \$50,000 minimum.

1386 **Statutory Authority**

1387 §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.

1388 **Historical Notes**

1389 Derived from Virginia Register Volume 22, Issue 3, eff. January 1, 2006; amended, Virginia
1390 Register Volume 31, Issue 10, eff. February 12, 2015.

1391 **12VAC5-381-220. Contract services.**

1392 A. ~~An HCO~~ There shall be have a written agreement for the provision of services not
1393 provided by employees or volunteers of the ~~organization~~ HCO.

1394 B. The written agreement shall include, ~~but is not limited to:~~

1395 1. The services to be furnished by each party to the contract;

1396 2. The contractor's responsibility for participating in developing plans of care or service;

1397 3. The manner in which services will be controlled, coordinated, and evaluated by the
1398 ~~primary home care organization~~ HCO;

1399 4. The procedures for submitting notes on the care or services provided, scheduling of
1400 visits, and periodic client evaluation;

1401 5. The process for payment for services furnished under the contract; and

1402 6. Adequate general and professional liability insurance and third-party crime insurance
1403 or a blanket fidelity bond, as prescribed by 12AC5-381-210.

1404 C. ~~The organization~~ An HCO shall have a written plan for provision of care or services ~~when~~
1405 if a contractor is unable to deliver services.

1406 D. An HCO shall require ~~The a~~ contractor shall to conform to applicable ~~organizational~~
1407 policies and procedures of the HCO as specified in the contract, including the required sworn
1408 disclosure statement and criminal record check report.

1409 **Statutory Authority**

1410 §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.

1411 **Historical Notes**

1412 Derived from Virginia Register Volume 22, Issue 3, eff. January 1, 2006; amended, Virginia
1413 Register Volume 31, Issue 10, eff. February 12, 2015.

1414 **12VAC5-381-230. Client and patient rights.**

1415 A. ~~The organization shall establish and implement written policies and procedures regarding~~
1416 ~~the rights of clients.~~

1417 B. ~~Client rights shall be reviewed with clients or client designees upon admission to the~~
1418 ~~organization. The review shall be documented in the client's record.~~

1419 C. ~~Written procedures to implement the policies shall ensure that each client is:~~

1420 1. ~~Treated with courtesy, consideration and respect and is assured the right of privacy;~~

1421 2. ~~Assured confidential treatment of his medical and financial records as provided by~~
1422 ~~law;~~

1423 3. ~~Free from mental and physical abuse, neglect, and property exploitation;~~

1424 4. ~~Assured the right to participate in the planning of the client's home care, including the~~
1425 ~~right to refuse services;~~

1426 5. ~~Served by individuals who are properly trained and competent to perform their duties;~~

1427 6. ~~Assured the right to voice grievances and complaints related to organizational~~
1428 ~~services without fear of reprisal;~~

1429 7. ~~Advised, before care is initiated, of the extent to which payment for the home care~~
1430 ~~organization services may be expected from federal or state programs, and the extent to~~
1431 ~~which payment may be required from the client;~~

- 1432 ~~8. Advised orally and in writing of any changes in fees for services that are the client's~~
1433 ~~responsibility. The home care organization shall advise the client of these changes as~~
1434 ~~soon as possible, but no later than 30 calendar days from the date the home care~~
1435 ~~organization became aware of the change;~~
1436 ~~9. Provided with advance directive information prior to start of services; and~~
1437 ~~10. Given at least five days written notice when the organization determines to terminate~~
1438 ~~services.~~
- 1439 ~~D. Before care is initiated, the home care organization shall inform the client, orally and in~~
1440 ~~writing, of:~~
- 1441 ~~1. The nature and frequency of services to be delivered and the purpose of the service;~~
1442 ~~2. Any anticipated effects of treatment, as applicable;~~
1443 ~~3. A schedule of fees and charges for services;~~
1444 ~~4. The method of billing and payment for services, including the:~~
1445 ~~a. Services to be billed to third party payers;~~
1446 ~~b. Extent to which payment may be expected from third party payers known to the~~
1447 ~~home care organization; and~~
1448 ~~c. Charges for services that will not be covered by third party payers;~~
1449 ~~5. The charges that the individual may have to pay;~~
1450 ~~6. The requirements of notice for cancellation or reduction in services by the~~
1451 ~~organization and the client; and~~
1452 ~~7. The refund policies of the organization.~~
- 1453 A. The client or patient has the right to:
- 1454 1. Have his property and person treated with respect;
1455 2. Be free from verbal, mental, sexual, and physical abuse, including injuries of unknown
1456 source, neglect and misappropriation of property;
1457 3. Make complaints to the HCO regarding treatment or care that is or fails to be
1458 furnished, and the lack of respect for property or person by anyone who is furnishing
1459 services on behalf of the HCO;
1460 4. Be furnished services by individuals who are properly trained and competent to
1461 perform their duties;
1462 5. Participate in, be informed about, and consent or refuse care in advance of and during
1463 treatment, where appropriate, with respect to:
1464 a. Completion of all assessments;
1465 b. The care to be furnished, based on the comprehensive assessment;
1466 c. Establishing and revising the medical plan of care;
1467 d. The disciplines that will furnish the care;
1468 e. The frequency of visits;
1469 f. Expected outcomes of care, including client- or patient-identified goals, and
1470 anticipated risks and benefits;
1471 g. Any factors that could impact treatment effectiveness; and
1472 h. Any changes in the care to be furnished;
1473 6. Receive all services outlined in the medical plan of care or plan of care;
1474 7. Have a confidential clinical record and financial record as provided by law;
1475 8. Be provided with advance directive information prior to the initiation of services;

- 1476 9. Be advised, orally and in writing, before services are initiated of:
- 1477 a. The extent to which payment for HCO services may be expected from Medicaid,
- 1478 or any other government-funded or government aid program known to the HCO;
- 1479 b. The charges for services that may not be covered by Medicaid, or any other
- 1480 government-funded or government aid program known to the HCO,
- 1481 c. The charges the client or patient may have to pay before care is initiated; and
- 1482 d. Any changes in the information provided in accordance with subdivision 9 of this
- 1483 section when they occur. The HCO shall advise the client, patient, and legal
- 1484 representative of these changes as soon as possible, in advance of the next home
- 1485 visit but no later than 30 days from the date the HCO becomes aware of the change;
- 1486 10. Receive written notice, at least five business days in advance of a specific service
- 1487 being furnished, if the HCO believes that the service may be non-covered care, or at
- 1488 least five business days in advance of the HCO reducing or terminating on-going care;
- 1489 11. Be advised, orally and in writing, of the OLC toll free complaint telephone hot line, its
- 1490 contact information, its hours of operation, and that its purpose is to receive complaints
- 1491 about HCOs.
- 1492 12. Be advised of the names, addresses, and telephone numbers of the following
- 1493 federally-funded and state-funded entities that serve the area where the patient or client
- 1494 resides:
- 1495 a. Agency on Aging;
- 1496 b. Center for Independent Living; and
- 1497 c. disAbility Law Center of Virginia;
- 1498 13. Be free from any discrimination or reprisal for exercising his rights or for voicing
- 1499 grievances to the HCO or an outside entity;
- 1500 14. Receive a written copy of the HCO's refund policies and receive written notice of any
- 1501 changes to those policies, at least five business days in advance of the change.
- 1502 B. An HCO shall review client and patient rights with clients, patients, or their legal
- 1503 representatives upon admission to the organization HCO, which shall be documented in the
- 1504 clinical record.
- 1505 **Statutory Authority**
- 1506 §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.
- 1507 **Historical Notes**
- 1508 Derived from Virginia Register Volume 22, Issue 3, eff. January 1, 2006.
- 1509 **12VAC5-381-240. ~~Handling complaints received from clients~~ Complaint handling**
- 1510 **procedures.**
- 1511 ~~A. The organization~~ An HCO shall establish and maintain complaint handling procedures
- 1512 that specify the:
- 1513 1. System for logging receipt, investigation and resolution of complaints; and
- 1514 2. Format of the written record of the findings of each complaint investigated.
- 1515 ~~B. The organization shall designate~~ 3. The staff position title of the employees
- 1516 responsible for complaint resolution, including:
- 1517 1- a. Complaint intake, including acknowledgment of complaints;
- 1518 2- b. Investigation of the complaint;
- 1519 3- c. Review of the investigation of findings and resolution for the complaint; and

1520 4. d. Notification to the complainant of the written proposed resolution within 30 days
1521 from the date of receipt of the complaint.

1522 ~~G.~~ B. An HCO shall give ~~The~~ the client, patient, or his designee ~~shall be given~~ a copy of the
1523 complaint procedures at the time of admission to service. ~~The organization~~ and shall provide
1524 each client, patient, or his designee with the name, mailing address, and telephone number of
1525 the:

- 1526 1. ~~Organization~~ HCO contact person;
- 1527 2. State Long-Term Care Ombudsman and the ombudsman for their locality; and
- 1528 3. Complaint Unit of the OLC.

1529 ~~D.~~ ~~The organization~~ C. An HCO shall maintain documentation of all complaints received and
1530 the status of each complaint ~~from date of receipt through its final resolution. Records shall be~~
1531 ~~maintained from the date of last inspection and for no less than three~~ five years from the date of
1532 receipt.

1533 **Statutory Authority**

1534 §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.

1535 **Historical Notes**

1536 Derived from Virginia Register Volume 22, Issue 3, eff. January 1, 2006; amended, Virginia
1537 Register Volume 24, Issue 11, eff. March 5, 2008.

1538 **12VAC5-381-250. Quality improvement.**

1539 A. ~~The organization~~ An HCO shall implement an ongoing, comprehensive, integrated, self-
1540 assessment program of the quality and appropriateness of care or services provided, including
1541 services provided under contract or agreement.

- 1542 1. The findings shall be used to correct identified problems and revise policies and
1543 practices, as necessary.
- 1544 2. Exclusive concentration on administrative or cost-of-care issues does not fulfill this
1545 requirement.
- 1546 3. An HCO shall establish a quality improvement committee that is responsible for the
1547 oversight and supervision of the program.

1548 B. To identify unacceptable or unexpected trends or occurrences, an HCO ~~The following~~
1549 ~~data shall be evaluated~~ evaluate ~~to identify unacceptable or unexpected trends or occurrences:~~

- 1550 1. Staffing patterns and performance to assure adequacy and appropriateness of
1551 services delivered;
- 1552 2. Supervision appropriate to the level of service;
- 1553 3. On-call responses;
- 1554 4. ~~Client~~ Clinical records for appropriateness of services provided;
- 1555 5. Client and patient satisfaction;
- 1556 6. Complaint resolution;
- 1557 7. Infections;
- 1558 8. Staff Employee concerns regarding client or patient care; and
- 1559 9. Provision of services appropriate to the clients' needs.

1560 C. A quality improvement committee ~~responsible for the oversight and supervision of the~~
1561 ~~program~~, shall consist of:

- 1562 1. The director of skilled services or ~~organization's~~ the HCO's register registered nurse,
1563 as appropriate for the type of services provided;

- 1564 2. A member of the An administrative staff employee;
- 1565 3. Representatives from each of the services provided by the organization HCO,
- 1566 including contracted services; and
- 1567 4. An individual with demonstrated ability to represent the rights and concerns of clients.
- 1568 The individual A client and patient advocate, who may be a member of the organization's
- 1569 staff an HCO employee, a client, a patient, or a client's or patient's family member.

1570 In selecting members of this the committee, consideration shall be given to a candidate's

1571 abilities and sensitivity to issues relating to quality of care and services provided to clients and

1572 patients.

1573 ~~D. Measures shall be implemented to resolve important problems or concerns that have~~

1574 ~~been identified. Health care practitioners, as applicable, and administrative staff shall participate~~

1575 ~~in the resolution of the problems or concerns that are identified.~~

1576 E. D. The quality improvement committee shall report to the governing body:

1577 1. At least annually the Results results of the quality improvement program shall be

1578 reported annually to the governing body and the administrator and available in the

1579 organization, which shall include the deficiencies it has identified and its

1580 recommendations for corrections and improvements and for maintaining compliance;

1581 and

1582 2. Immediately in writing the deficiencies it has identified that jeopardize client and

1583 patient safety.

1584 E. The administrator or his designee shall implement corrective action for any deficiencies

1585 identified by the quality improvement committee and The report shall be acted upon by the

1586 governing body and the organization. All corrective actions shall be documented document in

1587 writing all corrective actions.

1588 **Statutory Authority**

1589 §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.

1590 **Historical Notes**

1591 Derived from Virginia Register Volume 22, Issue 3, eff. January 1, 2006.

1592 **12VAC5-381-260. Infection control.**

1593 A. ~~The organization~~ An HCO shall implement have a an infection prevention program to

1594 reduce the risk of infection that encompasses the HCO and services provided by the HCO.

1595 B. ~~Infection control activities shall include, but are not limited to:~~

1596 1. ~~Staff education regarding infection risk reduction behaviors;~~

1597 2. ~~Use of universal precautions;~~

1598 3. ~~Handling, storing, processing and transporting of regulated medical waste according~~

1599 ~~to applicable procedures;~~

1600 4. ~~Handling, storing, processing and transporting supplies and equipment in a manner~~

1601 ~~that prevents the spread of infections; and~~

1602 5. ~~Monitoring staff performance in infection control practices.~~

1603 G. ~~B. An HCO shall ensure that Accumulated accumulated~~ waste, including all contaminated

1604 sharps, dressings, or similar infectious waste, ~~shall be~~ are disposed of in a manner compliant

1605 with the OSHA Bloodborne Pathogens standard (29 CFR 1910.1030).

1606 C. An HCO shall have an employee health program that includes:

1607 1. Access to or referrals for recommended vaccines, including influenza, hepatitis B, and

1608 SARS-CoV-2;

- 1609 2. Procedures for ensuring that employees with communicable disease are identified
- 1610 and prevented from work activities that could result in transmission to other employees
- 1611 or clients;
- 1612 3. An exposure control plan for bloodborne pathogens;
- 1613 4. Documentation of screening and immunizations offered to or received by employees
- 1614 in accordance with statute, regulation, or recommendations of public health authorities,
- 1615 including documentation of screening for tuberculosis; and
- 1616 5. Compliance with requirements of the U.S. Occupational Safety and Health
- 1617 Administration for reporting of workplace-associated injuries or exposure to infection.

1618 **Statutory Authority**

1619 §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.

1620 **Historical Notes**

1621 Derived from Virginia Register Volume 22, Issue 3, eff. January 1, 2006.

1622 **12VAC5-381-270. Drop sites.**

1623 A. ~~The organization~~ An HCO may operate one or more drop sites for the convenience of

1624 ~~staff employees~~ providing direct client and patient care or service. However, such sites shall not:

- 1625 1. Have ~~staff employees~~ assigned;
- 1626 2. Accept referrals;
- 1627 3. Be a branch office; or
- 1628 ~~3.~~ 4. Be advertised as part of the organization HCO.

1629 B. An HCO shall safeguard Any any client clinical records located at the a drop site shall be

1630 safeguarded against loss or unauthorized use. An HCO shall ensure that

- 1631 1. Only authorized personnel employees shall have access to client clinical records as
- 1632 specified by state and federal law.; and
- 1633 2. It shall be the responsibility of the organization to assure that records Records
- 1634 maintained at the a drop site are readily available and accessible for inspection staff
- 1635 inspectors.

1636 C. ~~If an HCO Operation intends to operate~~ of a drop site as a business office, it shall

1637 constitute a separate organization and shall require licensure either be separately licensed as

1638 an HCO or be licensed as a branch office of a parent HCO.

1639 D. An inspector may inspect Drop a drop sites site shall be subject to inspection at any time

1640 pursuant to 12VAC5-381-80 or 12VAC5-381-100.

1641 **Statutory Authority**

1642 §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.

1643 **Historical Notes**

1644 Derived from Virginia Register Volume 22, Issue 3, eff. January 1, 2006.

1645 **12VAC5-381-280. Client Clinical record system.**

1646 A. ~~The organization~~ An HCO shall maintain an organized ~~client clinical~~ record system

1647 according to accepted standards of practice that includes the safe storage of the original record,

1648 and the accurate and legible reproductions of the original.

1649 B. Unless otherwise specified by state or federal requirements, an HCO shall maintain

1650 originals or reproductions of clinical records in their entirety:

- 1651 1. For adult clients or patients, no less than five years from the date of discharge or of
- 1652 last contact; and

1653 2. For minor clients or patients, no less than five years after the minor reaches 18 years
1654 of age.

1655 ~~Written policies and procedures shall specify retention, reproduction, access, storage,~~
1656 ~~content, and completion of the record.~~

1657 B. An HCO shall safeguard ~~The the client clinical~~ record information ~~shall be safeguarded~~
1658 ~~against loss or unauthorized use.~~

1659 C. An HCO shall ensure that Client clinical records ~~shall be~~ are confidential, ~~and that~~ Only
1660 only authorized personnel employees shall have access as specified by state and federal law.

1661 ~~D. Provisions shall be made for the safe storage of the original record and for accurate and~~
1662 ~~legible reproductions of the original.~~

1663 ~~E. Policies shall specify arrangements for retention and protection of records if the~~
1664 ~~organization discontinues operation and shall provide for notification to the OLC and the client of~~
1665 ~~the location of the records.~~

1666 F. D. An HCO shall maintain An an accurate and complete client clinical record ~~shall be~~
1667 ~~maintained for each client or patient~~ receiving services and shall include, ~~but shall not be limited~~
1668 ~~to:~~

- 1669 1. Client or patient identifying information;
- 1670 2. Identification of the primary care physician;
- 1671 3. Admitting information, including a client or patient history;
- 1672 4. Information on the composition of the client's or patient's household, including
1673 individuals to be instructed in assisting the client or patient;
- 1674 5. An initial and all subsequent assessment of client or patient needs to develop a
1675 medical plan of care or ~~services~~ plan of care;
- 1676 6. A medical plan of care or ~~service~~ plan of care that includes:
 - 1677 a. ~~the~~ The type and frequency of each service to be ~~delivered~~ furnished;
 - 1678 b. Who shall furnish the services and when either by organization personnel or
1679 ~~contract services~~;
 - 1680 c. Prescription drugs or nonprescription drugs to be administered and the route of
1681 administration, including if self-administered;
 - 1682 d. Documentation of supervisory visits, including date, time, review of the medical
1683 plan of care or plan of care, services provided to date, and client or patient
1684 assessments; and
 - 1685 e. Interruptions in service and an explanation for any such interruption;
- 1686 7. Documentation of client and patient rights review; and
- 1687 8. A written discharge or termination of service summary that records the service
1688 delivered and final disposition at the time of client's or patient's discharge or termination
1689 from service.

1690 E. ~~In addition,~~ An HCO shall include in client clinical records for skilled and pharmaceutical
1691 services shall include:

- 1692 9. 1. Documentation and results of all medical tests ordered by the physician or other
1693 health care professional and performed by the ~~organization's staff~~ HCO employees;
- 1694 10. 2. A medical plan of care including appropriate assessment and pain management;
- 1695 11. 3. Medication sheets that include the name, dosage, frequency of administration,
1696 possible side effects, route of administration, date started, and date changed or
1697 discontinued for each medication administered; and

1698 ~~12.~~ 4. Copies of all summary reports sent to the ~~primary care~~ physician who signed the
1699 medical plan of care.

1700 ~~G.~~ F. An HCO shall ensure that:

1701 1. Signed and dated notes on the care or services provided by each individual delivering
1702 service shall be are written on the day the service is delivered;

1703 2. and incorporated Signed and dated notes on the care or services provide are
1704 incorporated in the client clinical record within seven working calendar days.;

1705 ~~H.~~ 3. Entries in the ~~client clinical~~ record shall be are current, legible, dated and
1706 authenticated by the person making the entry. and

1707 4. Errors shall be are corrected by striking through and initialing.

1708 ~~I. Originals or reproductions of individual client records shall be maintained in their entirety~~
1709 ~~for a minimum of five years following discharge or date of last contact unless otherwise~~
1710 ~~specified by state or federal requirements. Records of minors shall be kept for at least five years~~
1711 ~~after the minor reaches 18 years of age.~~

1712 **Statutory Authority**

1713 §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.

1714 **Historical Notes**

1715 Derived from Virginia Register Volume 22, Issue 3, eff. January 1, 2006; amended, Virginia
1716 Register Volume 24, Issue 11, eff. March 5, 2008.

1717 **12VAC5-381-290. Home attendants.**

1718 A. An HCO shall ensure that its Home home attendants shall be are able to speak, read,
1719 and write English and shall meet one of the following qualifications:

1720 1. Have satisfactorily completed a nursing education program preparing for registered
1721 nurse licensure or practical nurse licensure;

1722 2. Have satisfactorily completed a nurse aide education program approved by the
1723 Virginia Board of Nursing;

1724 3. Have active certification as a nurse aide issued by the Virginia Board of Nursing;

1725 4. Be successfully enrolled in a nursing education program preparing for registered
1726 nurse or practical nurse licensure and have currently completed at least one nursing
1727 course that includes clinical experience involving direct client care;

1728 5. Have satisfactorily passed a competency evaluation program that meets the criteria of
1729 ~~42 CFR 484.36 (b)~~ 42 CFR 484.80(c). Home attendants of personal care services need
1730 only be evaluated on the tasks subjects in ~~42 CFR 484.36 (b)~~ 42 CFR 484.80(c) as
1731 those tasks subjects relate to the personal care services to be provided; or

1732 6. Have satisfactorily completed training using the "Personal Care Aide Training
1733 Curriculum," 2003 edition, of the Department of Medical Assistance Services provided by
1734 an HCO that meets the requirements of subsection B. However, this training is
1735 permissible for home attendants and volunteers of personal care services only.

1736 B. An HCO may develop a 40-hour training program for home attendants and volunteers of
1737 personal care services that shall:

1738 1. Include education addressing:

1739 a. Goals of personal care;

1740 b. Personal care and rehabilitative services;

1741 c. Observation, reporting and documentation of patient status and the care or service
1742 furnished;

- 1743 d. Documentation requirements for Medicaid individuals
- 1744 e. Reading and recording temperature, pulse, and respiration;
- 1745 f. Prevention of skin breakdown, including recognizing and reporting changes in skin
- 1746 condition such as pressure ulcers;
- 1747 g. Physical and biological aspects of aging;
- 1748 h. Orientation to types of physical disabilities;
- 1749 i. The physical, emotional, and developmental needs of and ways to work with the
- 1750 populations served including the need for respect for the client or patient, his or her
- 1751 privacy and his or her property
- 1752 j. Body mechanics, including normal range of motion and positioning;
- 1753 k. Basic elements of body functioning and changes in body function that must be
- 1754 reported to a home attendant's or volunteer's supervisor
- 1755 l. Home management, including maintenance of a clean, safe, and healthy
- 1756 environment;
- 1757 m. Basic infection control policies and procedures
- 1758 n. Safety and accident prevention in the home, including safe transfer techniques
- 1759 and ambulation;
- 1760 o. Policies and procedures regarding accidents or injuries;
- 1761 p. Recognizing emergencies and knowledge of emergency policies and procedures
- 1762 q. Food, nutrition, and meal preparation, including adequate nutrition and fluid intake;
- 1763 r. Special considerations in preparation of special diets;
- 1764 s. Appropriate and safe techniques in personal hygiene and grooming that include
- 1765 nail and skin care, oral hygiene, toileting and elimination, and bathing and hair care
- 1766 of clients and patients with limited mobility;
- 1767 t. Care of the home and personal belongings.
- 1768 2. Be conducted by a registered nurse who meets the requirements in 18VAC90-26-30.
- 1769 3. Issue and maintain certificates of completion containing:
- 1770 a. The instructor's printed name and signature;
- 1771 b. The participant's printed name; and
- 1772 c. The date of completion of the program.

1773 **Statutory Authority**

1774 §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.

1775 **Historical Notes**

1776 Derived from Virginia Register Volume 22, Issue 3, eff. January 1, 2006.

1777 **12VAC5-381-300. Skilled services.**

Part III

Skilled Services and Personal Care Services

- 1780 A. ~~The organization~~ An HCO shall ~~may~~ provide a program of home health skilled services
- 1781 that ~~shall include~~ includes ~~one or more of the following:~~
- 1782 1. Nursing services;
- 1783 2. Physical therapy services;
- 1784 3. Occupational therapy services;
- 1785 4. Speech ~~therapy~~ language pathology services;

1786 5. Respiratory therapy services; or
1787 6. Medical social services; or
1788 7. Pharmaceutical services.

1789 B. An HCO shall ensure that All all skilled services delivered shall be are prescribed in a
1790 medical plan of care that contains at least the following information includes:

1791 1. Diagnosis and prognosis;
1792 2. Functional limitations;
1793 3. Orders for all skilled services, including:
1794 (i) a. specific Specific procedures;
1795 (ii) b. treatment Treatment modalities; and
1796 (iii) c. frequency Frequency and duration of the services ordered;
1797 4. Orders for medications, when applicable; and
1798 5. Orders for special dietary or nutritional needs, when applicable.

1799 An HCO shall ensure The the medical plan of care shall be is approved and signed by the
1800 client's primary care patient's physician.

1801 C. An HCO shall ensure Verbal oral orders shall be are:

1802 1. documented Documented within no more than 24 consecutive hours in the client's
1803 clinical record by the actively licensed health care professional practitioner receiving the
1804 order; and

1805 2. shall be countersigned Countersigned by the prescribing person actively licensed
1806 health care practitioner.

1807 D. An HCO shall immediately notify a patient's The primary care physician shall be notified
1808 immediately of any changes in the client's patient's condition that indicates a need to alter the
1809 medical plan of care.

1810 E. An HCO shall ensure The the medical plan of care shall be is reviewed, approved, and
1811 signed by the patient's primary care physician at least every 60 calendar days.

1812 F. An HCO shall appoint in writing There shall be a director of skilled services, who shall:

1813 1. be Be a physician actively licensed by the Virginia Board of Medicine or a registered
1814 nurse actively licensed by the Virginia Board of Nursing;

1815 2. Be responsible for the overall direction and management of skilled services including
1816 the availability of services, the quality of services and appropriate staffing; and

1817 3. The individual shall have Have the appropriate experience for the scope of services
1818 provided by the organization HCO.

1819 G. The organization shall develop and implement policies and procedures for the handling of
1820 drugs and biologicals, including procurement, storage, administration, self-administration, and
1821 disposal of drugs and shall allow clients to procure their medications from a pharmacy of their
1822 choice.

1823 H. All prescription drugs shall be prescribed and properly dispensed to clients according to
1824 the provisions of Chapters 33 (§ 54.1-3300 et seq.) and 34 (§ 54.1-3400 et seq.) of Title 54.1 of
1825 the Code of Virginia and the regulations of the Virginia Board of Pharmacy, except for
1826 prescription drugs authorized by § 54.1-3408 of the Drug Control Act, such as epinephrine for
1827 emergency administration, normal saline and heparin flushes for the maintenance of IV lines,
1828 and adult immunizations, which may be given by a nurse pursuant to established protocol.

1829 **Statutory Authority**

1830 §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.

1831 **Historical Notes**

1832 Derived from Virginia Register Volume 22, Issue 3, eff. January 1, 2006.

1833 **12VAC5-381-310. Nursing services.**

1834 A. An HCO shall ensure that All all nursing services shall be are:

1835 1. ~~directly~~ Directly provided by an actively licensed and appropriately qualified registered
1836 nurse or licensed practical nurse; ~~;~~ or

1837 2. By a person to whom ~~except for those~~ nursing tasks ~~that may be~~ are delegated by a
1838 registered nurse ~~according to~~ in accordance with 18VAC90-20-420 through 18VAC90-
1839 20-460 ~~of the regulations of the Virginia Board of Nursing Part VI (18VAC90-19-240 et~~
1840 seq.) of the Regulations Governing the Practice of Nursing and with a plan developed
1841 and implemented by the ~~organization~~ HCO.

1842 B. An HCO shall ensure that nursing services are supervised in person in the patient's
1843 residence ~~Supervision of services shall be provided as often as necessary, but not less often~~
1844 than every 60 calendar days, as determined by:

1845 1. ~~the~~ The ~~client's~~ patient's needs; ~~;~~

1846 2. ~~the~~ The assessment by the registered nurse; ~~;~~ and

1847 3. ~~the~~ The organization's HCO's written policies ~~not to exceed 90 days.~~

1848 **Statutory Authority**

1849 §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.

1850 **Historical Notes**

1851 Derived from Virginia Register Volume 22, Issue 3, eff. January 1, 2006.

1852 **12VAC5-381-320. Therapy services.**

1853 A. An HCO shall ensure that ~~Physical~~ physical therapy, occupational therapy, speech
1854 ~~therapy~~ language pathology, or respiratory therapy services ~~shall be~~ are provided according to
1855 the medical plan of care by or under the direction of an appropriately qualified therapist ~~currently~~
1856 actively licensed in Virginia and ~~may~~ shall include, ~~but are not limited to:~~

1857 1. Assessing ~~client~~ the patient's needs or admission for service as appropriate;

1858 2. Implementing a medical plan of care and revising as necessary;

1859 3. Initiating appropriate preventive, therapeutic, and rehabilitative techniques according
1860 to the medical plan of care;

1861 4. Educating the ~~client~~ patient and family regarding treatment modalities and use of
1862 equipment and devices;

1863 5. Providing consultation to other actively licensed health care ~~professionals~~
1864 practitioners, as applicable;

1865 6. Communicating with the physician and other actively licensed health care
1866 ~~professionals~~ practitioners regarding changes in the ~~client's~~ patient's needs;

1867 7. Supervising therapy assistants and home attendants as appropriate; and

1868 8. Preparing clinical notes.

1869 B. An HCO may employ or contract with ~~Therapy~~ therapy assistants ~~may be used to provide~~
1870 therapy services. An HCO shall ensure that:

1871 1. ~~The~~ An occupational therapy assistant ~~shall be~~ is ~~currently~~ actively certified by the
1872 National Board for Certification in Occupational Therapy and ~~shall practice~~ practices
1873 under the supervision of a an actively licensed occupational therapist; ~~and~~

1874 2. The ~~A~~ physical therapy assistant shall be ~~is~~ currently actively licensed by the Virginia
1875 Board of Physical Therapy and shall ~~practice~~ practices under the supervision of a an
1876 actively licensed physical therapist.

1877 ~~G. Duties of therapy assistants shall be within their scope of practice and may include, but~~
1878 ~~are not limited to:~~

1879 1. ~~Performing services planned, delegated, and supervised by the appropriately licensed~~
1880 ~~therapist; and~~

1881 2. ~~Preparing clinical notes.~~

1882 ~~D. C. An HCO shall ensure that therapy services are supervised in-person in the patient's~~
1883 ~~residence. Supervision of services shall be provided as often as necessary, but not less often~~
1884 ~~than prescribed by the applicable therapy licensing board, as determined by:~~

1885 1. ~~the~~ The ~~client's~~ patient's needs;;

1886 2. ~~the~~ The assessment of the actively licensed therapist; and

1887 3. ~~the~~ The organization's HCO's written policies ~~not to exceed 90 days.~~

1888 **Statutory Authority**

1889 §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.

1890 **Historical Notes**

1891 Derived from Virginia Register Volume 22, Issue 3, eff. January 1, 2006.

1892 **12VAC5-381-330. Home attendants assisting with skilled services.**

1893 A. An HCO that employs or contracts with Home home attendants assisting to assist with
1894 providing skilled services may permit home attendants, consistent with the medical plan of care,
1895 to:

1896 1. Assist ~~clients~~ patients with (i) activities of daily living, (ii) ambulation, and ~~prescribed~~
1897 restorative exercise, and (iii) ~~other special duties with appropriate training and~~
1898 demonstrated competency;

1899 2. Administer normally self-administered drugs as allowed by § 54.1-3408 of the Virginia
1900 Drug Control Act (~~Chapter 34 (§ 54.1-3400 et seq.)~~ (§ 54.1-3400 et seq. of Title 54.1 of
1901 the Code of Virginia);

1902 3. Measure and record fluid intake and output;

1903 4. Take and record blood pressure, pulse and respiration;

1904 5. Record and report to the appropriate actively licensed health care ~~professional~~
1905 practitioner changes in the ~~client's~~ patient's condition;

1906 6. Document services and observations in the ~~client's~~ clinical record; and

1907 7. Perform any other duties that the attendant is qualified to do by additional training and
1908 demonstrated competency as allowed by state or federal guidelines.

1909 B. Prior to the initial delivery of services, an HCO shall ensure that the home attendant shall
1910 receive receives specific written instructions for the ~~client's~~ patient's care from the appropriate
1911 actively licensed health care ~~professional~~ practitioner responsible for the care.

1912 C. An HCO shall ensure that a Home attendants home attendant:

1913 1. ~~shall work~~ Works under the supervision of the appropriate actively licensed health
1914 ~~care professional~~ practitioner responsible for the ~~client's~~ patient's care, with supervision
1915 being conducted in-person at least once every 60 calendar days; and

1916 ~~D. Relevant in-service education or training for home attendants shall consist of at least~~

1917 2. Completes no less than 12 hours annually of in-service education or training, which-
1918 In-service training may be in conjunction with on-site supervision.

1919 **Statutory Authority**

1920 §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.

1921 **Historical Notes**

1922 Derived from Virginia Register Volume 22, Issue 3, eff. January 1, 2006; amended, Virginia
1923 Register Volume 27, Issue 26, eff. September 29, 2011.

1924 **12VAC5-381-340. Medical social services.**

1925 A. An HCO shall ensure that ~~Medical~~ medical social services ~~shall be~~ are provided
1926 according to the medical plan of care by or under the direction of ~~a qualified~~ an actively licensed
1927 clinical social worker or an individual who has master's degree in social work from a school
1928 accredited by the Council on Social Work Education, both of which shall have ~~who holds,~~ at a
1929 minimum, a bachelor's degree with major studies in social work, sociology, or psychology from a
1930 four-year college or university accredited by the Council on Social Work Education and has at
1931 least two years one year's experience in case work or counseling in a health care or social
1932 services delivery system.

1933 ~~The organization shall have one year from January 1, 2006, to ensure the designated~~
1934 ~~individual meets the qualifications of this standard.~~

1935 B. An HCO may assign ~~The duties of~~ to a social worker, including ~~may include, but are not~~
1936 ~~limited to:~~

- 1937 1. Assessing the ~~client's~~ patient's psychological status;
- 1938 2. Implementing a medical plan of care ~~and revising, as necessary;~~
- 1939 3. Providing social work services including ~~(i)~~ short-term individual counseling, ~~(ii)~~
1940 community resource planning, and ~~(iii)~~ crisis intervention;
- 1941 4. Providing consultation with the ~~patient's primary care~~ physician and other actively
1942 licensed health care ~~professionals~~ practitioners regarding changes in the ~~client's~~
1943 patient's needs;
- 1944 5. Preparing notes on the care or services provided; and
- 1945 6. Participating in discharge planning.

1946 **Statutory Authority**

1947 §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.

1948 **Historical Notes**

1949 Derived from Virginia Register Volume 22, Issue 3, eff. January 1, 2006.

1950 **12VAC5-381-350. Pharmacy Pharmaceutical services.**

1951 **Part IV**
1952 **Pharmaceutical Services**

1953 A. An HCO shall ensure that ~~All~~ all prescription drugs ~~shall be~~ are prescribed and properly
1954 dispensed to the ~~client~~ patient according to the provisions of the Chapters 33 (§ 54.1-3300 et
1955 seq.) and 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia and the regulations of the
1956 Virginia Board of Pharmacy, except for prescription drugs authorized by § 54.1-3408 of the Drug
1957 Control Act, ~~such as epinephrine for emergency administration, normal saline and heparin~~
1958 ~~flushes for the maintenance of IV lines, and adult immunizations, which may be given by a~~
1959 ~~nurse pursuant to established protocol.~~

1960 B. An HCO may permit ~~Home~~ home attendants ~~may to~~ to administer normally self-
1961 administered drugs as allowed by § 54.1-3408 of the Virginia Drug Control Act (~~Chapter 34 (§~~
1962 ~~54.1-3400 et seq.)~~ (§ 54.1-3400 et seq. of Title 54.1 of the Code of Virginia). ~~Any other drug~~
1963 ~~shall be administered only by a licensed nurse or physician assistant.~~

1964 C. ~~The organization shall develop written policies and procedures for the administration of~~
1965 ~~home infusion therapy medications that include, but are not limited to:~~

- 1966 1. ~~Developing a plan of care or service;~~
- 1967 2. ~~Initiation of medication administration based on a prescriber's order and monitoring of~~
1968 ~~the client for response to the treatment and any adverse reactions or side effects;~~
- 1969 3. ~~Assessment of any factors related to the home environment that may affect the~~
1970 ~~prescriber's decisions for initiating, modifying, or discontinuing medications;~~
- 1971 4. ~~Communication with the prescriber concerning assessment of the client's response to~~
1972 ~~therapy, any other client specific needs, and any significant change in the client's~~
1973 ~~condition;~~
- 1974 5. ~~Communication with the client's provider pharmacy concerning problems or needed~~
1975 ~~changes in a client's medication;~~
- 1976 6. ~~Maintaining a complete and accurate record of medications prescribed, medication~~
1977 ~~administration data, client assessments, any laboratory tests ordered to monitor~~
1978 ~~response to drug therapy and results, and communications with the prescriber and~~
1979 ~~pharmacy provider;~~
- 1980 7. ~~Educating or instructing the client, family members, or other caregivers involved in the~~
1981 ~~administration of infusion therapy in the proper storage of medication, in the proper~~
1982 ~~handling of supplies and equipment, in any applicable safety precautions, in recognizing~~
1983 ~~potential problems with the client, and actions to take in an emergency; and~~
- 1984 8. ~~Initial and retraining of all organization staff providing infusion therapy.~~

1985 D. ~~C.~~ An HCO shall employ a registered nurse, who has completed
1986 training in infusion therapy, and has the knowledge, skills, and competencies to safely
1987 administer infusion therapy, to:

- 1988 1. ~~supervise~~ Supervise medication administration by staff employees consistent with the
1989 type of medication being administered;
- 1990 2. ~~This person shall be responsible for ensuring~~ Ensure employee compliance with
1991 applicable laws and regulations;
- 1992 3. Ensure adherence to the policies and procedures related to administration of
1993 medications; and
- 1994 4. ~~conducting~~ Conduct periodic annual assessments of staff employee competency in
1995 performing infusion therapy.

1996 **Statutory Authority**

1997 §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.

1998 **Historical Notes**

1999 Derived from Virginia Register Volume 22, Issue 3, eff. January 1, 2006; amended, Virginia
2000 Register Volume 27, Issue 26, eff. September 29, 2011.

2001 **DOCUMENTS INCORPORATED BY REFERENCE (12VAC5-381)(Repealed)**

2002 Personal Care Aide Training Curriculum, 2003 Edition, Virginia Department of Medical
2003 Assistance Services.



COMMONWEALTH of VIRGINIA

Department of Health
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RICHMOND, VA 23218

M. NORMAN OLIVER, MD, MA
STATE HEALTH COMMISSIONER

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

MEMORANDUM

DATE: November 9, 2021

TO: Virginia State Board of Health

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

SUBJECT: *Proposed Stage for Regulations Governing COVID-19 Reporting*

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. In 2019, VDH submitted a Fast-Track action to bring this chapter of the regulations into compliance with recent changes in the field of communicable disease detection and control and to allow greater flexibility with respect to reporting requirements in light of rapidly changing laboratory technologies and the emergence of new pathogens that are of public health concern. The Fast-Track received more than 10 comments objecting to the use of a Fast-Track.

Consistent with the Fast-Track, this amendment removes, edits, and adds definitions as necessary to reflect current public health definitions and needs; removes the requirement to report weekly counts of influenza diagnoses; modifies the timelines for laboratories to submit isolates or specimens for further public health laboratory testing to improve the viability of material available for testing; replaces reporting by use of the Epi-1 form with reporting via an online web portal. The list of isolates or specimens that must be forwarded for further public health testing has been removed from 12VAC5-90-90 in this action because it is being added to 12VAC5-90-80 in a separate exempt regulatory action. The section on select agent reporting has been modified to clarify that VDH requires an annual report and an immediate report of a loss, theft, or release. Other, minor changes are listed in the Detail of Changes. In addition to the Fast-Track amendments, this Proposed Stage action requires ethnicity to be reported for all reportable diseases and updates the name of a reportable disease.

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



townhall.virginia.gov

Proposed Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-90
VAC Chapter title(s)	Disease Reporting and Control Regulations
Action title	Amendment to comply with changes in public health practice
Date this document prepared	11/4/2021

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

Brief Summary

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

The Regulations for Disease Reporting and Control provide information about the process and procedures for reporting diseases to the Virginia Department of Health (VDH), including what diseases must be reported, who must report them and other details related to reporting and disease control. VDH is proposing an amendment to the regulations to bring them into compliance with recent changes in the field of communicable disease detection and control and to allow greater flexibility with respect to reporting requirements in light of rapidly changing laboratory technologies and the emergence of new pathogens that are of public health concern.

This amendment removes, edits, and adds definitions as necessary to reflect current public health definitions and needs; removes the requirement to report weekly counts of influenza diagnoses; modifies the timelines for laboratories to submit isolates or specimens for further public health laboratory testing to improve the viability of material available for testing; replaces reporting by use of the Epi-1 form with reporting via an online web portal. The list of isolates or specimens that must be forwarded for further

public health testing has been removed from 12VAC5-90-90 in this action because it was added to 12VAC5-90-80 in a separate exempt regulatory action. The section on select agent reporting has been modified to clarify that VDH requires an annual report and an immediate report of a loss, theft, or release. Other, minor changes are listed below under Detail of Changes.

This action was originally submitted as a Fast Track in 2019 that received more than 10 comments objecting to the use of the Fast Track action. The majority of commenters objected to the Virginia Department of Health receiving reports, which include personal information, of their influenza data. This action does not add any influenza reporting requirements. Instead, this amendment will strike "influenza should be reported by number of cases only (and type of influenza, if available)" to clarify that only confirmed influenza cases are required to be reported.

Acronyms and Definitions

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

No acronyms are used that are not defined in context.

Mandate and Impetus

Identify the mandate for this regulatory change and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, or board decision). For purposes of executive branch review, "mandate" has the same meaning as defined in Executive Order 14 (as amended, July 16, 2018), "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

The impetus for this regulatory action is a board decision to bring the regulations into compliance with recent changes in the field of communicable disease detection and control, and to provide greater flexibility with respect to reporting requirements. The proposed changes will assure timelier reporting of diseases while at the same time reducing the overall burden of disease reporting.

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, contains 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.

Further, § 32.1-42 of the Code of Virginia authorizes the Board of Health to promulgate regulations and orders to prevent a potential emergency caused by a disease dangerous to public health. The Board of Health is empowered to adopt such regulations as are necessary to carry out provisions of laws of the Commonwealth administered by the state health commissioner by § 32.1-12 of the Code of Virginia.

Purpose

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

The proposed changes are essential to protect the health and safety of citizens because they will improve the ability of VDH to conduct surveillance and implement disease control for conditions of public health concern. 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:

- Add, remove, and update definitions to enhance clarity;
- Specify new timelines for submission of isolates or specimens for state public health laboratory testing;
- Remove the list of isolates or specimens that must be forwarded for public health laboratory testing from 12VAC5-90-90 in this amendment because the list was added to 12VAC5-90-80 in another regulatory action;
- Remove the requirement that physicians and directors of medical care facilities submit weekly counts of cases of influenza;
- Replace reporting by way of the Epi-1 form with reporting through the VDH's online morbidity reporting portal;
- Add language that states that if a laboratory ascertains that the reference laboratory that tests a specimen reports to VDH electronically, then those reference laboratory findings do not need to be reported by the laboratory of origin;
- Add language that clarifies that if a facility director reports on behalf of the laboratory, the laboratory is still responsible for submitting isolates or specimens for public health testing "unless the laboratory has submitted an exemption request that has been approved by the department", thereby providing a process for opting out of the specimen forwarding requirement;
- Remove language referencing the commissioner's role in enforcement of isolation and quarantine because it has been removed from the Code of Virginia;
- Modify language to refer only to medications that are available in the United States for the treatment of ophthalmia neonatorum;
- Clarify that confirmatory testing is not required for blood lead levels that are below the CDC reference range on screening test;
- Limit the reporting of select agents to only an annual report and those scenarios in which such agents are released, lost, or stolen;
- Require that health care facilities share with VDH any data they supply to CDC as a result of a requirement of the Centers for Medicare and Medicaid Services and not limited to the Hospital Inpatient Quality Reporting Program of that agency

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 as well as removing the requirement to report weekly influenza counts or to report routine, non-emergency changes in select agent inventory. No disadvantages have been identified.

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

Requirements More Restrictive than Federal

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

None of these requirements is more restrictive than federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

Identify any other state agencies, localities, or other entities particularly affected by the regulatory change. "Particularly affected" are those that are likely to bear any identified disproportionate material impact which would not be experienced by other agencies, localities, or entities. "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulation or regulatory change are most likely to occur. If no agency, locality, or entity is particularly affected, include a specific statement to that effect.

Other State Agencies Particularly Affected

DCLS will receive isolates or specimens from other laboratories in a more timely fashion.

Localities Particularly Affected

The impact of these changes is anticipated to be the same for all localities.

Other Entities Particularly Affected

All healthcare providers and medical care facilities who are subject to these regulations would be equally impacted by these amendments.

Economic Impact

Pursuant to § 2.2-4007.04 of the Code of Virginia, identify all specific economic impacts (costs and/or benefits), anticipated to result from the regulatory change. When describing a particular economic impact,

specify which new requirement or change in requirement creates the anticipated economic impact. Keep in mind that this is change versus the status quo.

Impact on State Agencies

<p><i>For your agency:</i> projected costs, savings, fees or revenues resulting from the regulatory change, including: a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources</p>	<p>Cost to the state will be related to communicating the changed requirements to the regulated community. Disease reporting requirements are usually summarized on posters and distributed to laboratories, infection preventionists, and others involved in disease reporting. The cost was \$4,500 when the regulations were last amended: (1) \$1800 to print 600 copies of the Regulations for Disease Reporting and Control, (2) \$200 to print 600 posters of Conditions Reportable by Directors of Laboratories in Virginia, and (3) \$2500 to print 20,000 posters of the Virginia Reportable Disease List. This cost will be paid by existing funds available at the time the regulations are finalized.</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>No additional expenditures anticipated by any other state agency.</p>	
<p><i>For all agencies:</i> Benefits the regulatory change is designed to produce.</p>	<p>Benefits include more complete reporting of diseases of public health importance to VDH so that actions can be taken to minimize the spread of diseases in Virginia's communities and a better understanding of the magnitude of these health problems in Virginia will be gained.</p>	

Impact on Localities

<p>Projected costs, savings, fees or revenues resulting from the regulatory change.</p>	<p>The proposed changes should not incur a cost to local governments. Local health department staff are already engaged in the duties relative to emerging infections and tracking reported cases of disease.</p>	
<p>Benefits the regulatory change is designed to produce.</p>	<p>Benefits include more complete reporting of diseases of public health importance to VDH so that actions can be taken to minimize the spread of diseases in Virginia's communities and a better understanding of the magnitude of these health problems in Virginia will be gained.</p>	

Impact on Other Entities

<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 regulations pertain to physicians, laboratory directors, medical facility directors and directors of other settings where disease outbreaks may occur. The proposed amendments apply to each of those entities; however, the removal of the requirement that physicians and directors of medical care facilities submit weekly counts of</p>	
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	cases of influenza, and limiting the reporting of select agents to only the Code-required annual report plus those scenarios in which such agents are released, lost, or stolen, and adding the requirement for morbidity reporting to be done through VDH's online morbidity reporting portal should reduce the burden of reporting among these entities.	
Agency's best estimate of the number of such entities that will be affected. Include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.	20,000 physicians 125 laboratories 100 hospitals 250 nursing homes Some of these may be small businesses.	
All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Be specific and include all costs including, but not limited to: a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change; c) fees; d) purchases of equipment or services; and e) time required to comply with the requirements.	No additional costs are expected based on changes proposed to the existing regulations.	
Benefits the regulatory change is designed to produce.	Benefits include more complete reporting of diseases of public health importance to VDH so that actions can be taken to minimize the spread of diseases in Virginia's communities and a better understanding of the magnitude of these health problems in Virginia will be gained.	

Alternatives to Regulation

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

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

Regulatory Flexibility Analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the

objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) establishing less stringent compliance or reporting requirements; 2) establishing less stringent schedules or deadlines for compliance or reporting requirements; 3) consolidation or simplification of compliance or reporting requirements; 4) establishing performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the regulatory change.

VDH has assessed the requirements of the regulatory requirements and has not identified alternative methods of achieving the goals of this regulatory action. Reporting requirements have been removed when possible, such as for weekly counts of influenza diagnoses and routine reporting of select agent transfers, and the replacement of reporting by paper with reporting by way of an electronic portal should be less cumbersome for the regulated community. Complete and timely reporting is necessary to prevent and control the spread of communicable diseases, leaving few alternatives to exempt any healthcare providers from their responsibility to report disease to VDH.

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

If you are using this form to report the result of a periodic review/small business impact review that is being conducted as part of this regulatory action, and was announced during the NOIRA stage, indicate whether the regulatory change meets the criteria set out in Executive Order 14 (as amended, July 16, 2018), e.g., is necessary for the protection of public health, safety, and welfare; minimizes the economic impact on small businesses consistent with the stated objectives of applicable law; and is clearly written and easily understandable.

In addition, as required by § 2.2-4007.1 E and F of the Code of Virginia, discuss the agency’s consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation; (3) the complexity of the regulation; (4) the extent to which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation. Also, discuss why the agency’s decision, consistent with applicable law, will minimize the economic impact of regulations on small businesses.

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

The agency has assessed the need for the Disease Reporting and Control regulations and has found that they are critical to containing and mitigating communicable disease spread throughout the Commonwealth.

VDH received 588 comments regarding this regulation in a 2019 Fast Track action; many concerned over their privacy and the reporting of individual influenza data from clinicians to the VDH. That action was not increasing data reported to VDH, but rather decreasing reporting requirements. Still, the information required to be reported is necessary to better allow VDH to protect the health and well-being of Virginians.

Public Comment

Summarize all comments received during the public comment period following the publication of the previous stage, and provide the agency response. Include all comments submitted: including those

received on Town Hall, in a public hearing, or submitted directly to the agency. If no comment was received, enter a specific statement to that effect.

The following table summarizes comments received during the public comment period following the publication of the Fast-Track Regulatory Action, for which commenters did not propose specific amendments to the regulation. VDH received a total of 588 comments, 521 of which were from unique IP addresses. Some commenters are counted in multiple categories, which is why the total below is greater than 588.

Commenter	Comment	Agency response
519 people via Virginia Regulatory Town Hall, including the National Vaccine Information Center and The Family Foundation of Virginia	Object to reporting of private health information related to influenza to VDH	<p>Influenza is a serious public health threat. The virus is constantly mutating and has the potential to cause severe pandemics. It has been a reportable condition since 1980, when the <i>Regulations for Disease Reporting and Control (Regulations)</i> were first enacted.</p> <p>Laboratory directors are required to report laboratory confirmed cases of influenza. Tracking this information allows public health to identify circulating viruses and is critical in identifying new strains that emerge.</p> <p>In addition to laboratory directors reporting, before 2018, healthcare providers were required to report the number of influenza cases they diagnosed, regardless of the method of diagnosis. In clinical practice, many influenza cases are diagnosed clinically (without testing) or using a point-of-care rapid test.</p> <p>Tracking the number of cases allows VDH to understand the timing and magnitude of an influenza outbreak. In 2018, VDH determined it could now track this through its syndromic surveillance system, Essence. VDH amended the <i>Regulations</i> for healthcare providers to report only laboratory-confirmed influenza cases. This change would reduce the reporting burden on providers.</p> <p>However, the language "influenza should be reported by number of cases only (and type of influenza, if available)" was not changed in two other sections of the <i>Regulations</i>, so providers are still reporting the number of cases regardless of the method of diagnosis.</p> <p>The intention of this language is to strike "influenza should be reported by number of cases only (and type of influenza, if available)" to clarify that only confirmed influenza cases are required to be reported.</p>

<p>104 people via Virginia Regulatory Town Hall, including the National Vaccine Information Center and The Family Foundation of Virginia</p>	<p>Object to the use of a Fast-Track action</p>	<p>In 2018, VDH amended these Regulations to only require reporting of laboratory confirmed cases of influenza. Prior to that amendment, influenza was required to be reported regardless of the method of diagnosis (i.e. point-of-care rapid tests and laboratory confirmed tests). In making that change, we failed to also amend sections that stated "influenza should be reported by number of cases only (and type of influenza, if available)." This led to confusion and providers continued reporting all influenza diagnosis to VDH, which VDH no longer needed due to other surveillance systems in place. VDH used a Fast-Track action as we saw this as an amendment to clarify a change already put in place.</p>
<p>2 people via Virginia Regulatory Town Hall</p>	<p>Object to the Virginia Department of Health's authority to pass laws</p>	<p>Chapter 2 of Title 32.1 of the Code of Virginia, §§ 32.1-12 and 32.1-35 through 32.1-73, contains 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.</p> <p>Further, § 32.1-42 of the Code of Virginia authorizes the Board of Health to promulgate regulations and orders to prevent a potential emergency caused by a disease dangerous to public health. The Board of Health is empowered to adopt such regulations as are necessary to carry out provisions of laws of the Commonwealth administered by the state health commissioner by § 32.1-12 of the Code of Virginia.</p>

Public Participation

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

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

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall web site

at: <https://townhall.virginia.gov>. Comments may also be submitted by mail, email or fax to Kristin Collins, 109 Governor St., Richmond, VA 23119, 804-864-7298, Kristin.Collins@vdh.virginia.gov. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

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

Detail of Changes

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

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

Table 1: Changes to Existing VAC Chapter(s)

Current section number	New section number, if applicable	Current requirement	Change, intent, rationale, and likely impact of new requirements
12VAC5-90-10		Definitions	<ul style="list-style-type: none"> • Healthcare-associated infection (also known as nosocomial infection) –Replaced the term “hospital” with “medical care facility” to reflect infections that may occur in hospitals or nursing homes. • Hepatitis C, acute – Remove definition. This definition was needed when this infection was newly defined, but now the disease is better recognized and understood. • Hepatitis C, chronic – Remove definition. The infection is well understood in the regulated community so the definition is no longer needed. • Influenza A, novel virus – Modify definition to indicate that genetic reassortment of human and animal influenza viruses represent novel virus. Helps more clearly define what is meant by influenza A novel virus. • Lead, reportable levels – Remove definition. The proposed amendment requires all lead

			<p>results to be reported, so the definition of a lead, reportable levels is no longer relevant.</p> <ul style="list-style-type: none"> • Tubercle bacilli – Modify definition to include Mycobacterium bovis, Mycobacterium canetti, Mycobacterium microti, and Mycobacterium caprae as additional species included in the Mycobacterium tuberculosis complex. More clearly defines the tubercle bacilli of interest. • Tuberculin skin test (TST) – Remove definition. No longer needed because reporting is based on a positive result from any test. • Tuberculosis – Remove definition. This definition is not needed because more specific definitions for TB active disease and infection are already included in the regulations. • Tuberculosis, active disease – In the definition, change from “disease” to “communicable disease” to indicated that TB is spread from person to person. • Tuberculosis infection in children age <4 years – Modify definition name to Tuberculosis infection to account for the change being made in a separate regulatory action to require reporting of tuberculosis infection among all ages, not just persons <4 years of age. Also change “tuberculin skin testing” to “positive result from a test for tuberculosis infection” to reflect a broader range of acceptable diagnostic test types.
12VAC5-90-80		Directors of laboratories	<ul style="list-style-type: none"> • Change from submitting the isolate or clinical specimen within seven days to the Division of Consolidated Laboratory or other specified public health laboratory to submitting the isolate within five days and the clinical specimen within two days of a positive result.
12VAC5-90-80		Submission of initial isolate or other specimen for further public health testing.	<ul style="list-style-type: none"> • Change Enterobacteriaceae to Enterobacterales

<p>12VAC5-90-90</p>		<p>Physicians</p>	<ul style="list-style-type: none"> • Adds ethnicity as a required field • Clarify that the list of elements to be reported on a case (e.g., name, address) represent the minimum reporting requirements. • Remove language stating that influenza should be reported by number of cases only. This is no longer required under this proposal. • Language added to reflect morbidity reporting through VDH's online morbidity reporting portal. • Add language referring to "disease-specific" surveillance form instead of surveillance form. • Modify language to reflect that reporting timeframes are as established in 12VAC5-90-80 rather than listing them again in this subsection.
<p>12VAC5-90-90</p>		<p>Directors of laboratories</p>	<ul style="list-style-type: none"> • Adds ethnicity as a required field • Language added that if a laboratory ascertains that the reference laboratory that tests a specimen reports to VDH electronically, then those reference laboratory findings do not need to be reported by the laboratory of origin. • Language added to reflect morbidity reporting through VDH's online morbidity reporting portal. • Modify language to reflect that reporting timeframes are as established in 12VAC5-90-80 rather than listing them again in this subsection. • Language in subsection B pertaining to the submission of an initial isolate or other initial specimen to DCLS has been stricken because it has been updated and moved to 12VAC5-90-80 in a separate exempt regulatory action. • Add language that clarifies that if a facility director reports on behalf of the laboratory, the laboratory is still responsible for submitting isolates or specimens for public health testing "unless the laboratory has submitted an

			exemption request that has been approved by the department”.
12VAC5-90-90		Persons in charge of a medical facility	<ul style="list-style-type: none"> • Adds ethnicity as a required field • Remove language stating that influenza should be reported by number of cases only. This is no longer required under this proposed amendment. • Modify language to reflect that reporting timeframes are as established in 12VAC5-90-80 rather than listing them again in this subsection. • Add language to reflect morbidity reporting through VDH’s online morbidity reporting portal. • Add language referring to “disease-specific” surveillance forms instead of surveillance forms.
12VAC5-90-90		Persons in charge of hospitals, nursing facilities or nursing homes, assisted living facilities, and correctional facilities	<ul style="list-style-type: none"> • List reportable organisms next to disease names so the reportable disease lists are equally meaningful to practicing clinicians and laboratorians.
12VAC5-90-103		Isolation for communicable disease of public health threat.	<ul style="list-style-type: none"> • Remove language referencing the commissioner’s role in enforcement. This is no longer contained in the Code of Virginia.
12VAC5-90-107		Quarantine	<ul style="list-style-type: none"> • Remove language referencing the commissioner’s role in enforcement. This is no longer contained in the Code of Virginia.
12VAC5-90-140		Procedure for preventing ophthalmia neonatorum	<ul style="list-style-type: none"> • Modify language to refer only to medications that are available in the United States.
12VAC5-90-215		Schedule and criteria for and confirmation of blood lead testing and information to be provided	<ul style="list-style-type: none"> • Change language “built before 1960” to “built before 1950”. • Add language stating that confirmatory testing is not required if the result of the capillary test is below CDC’s reference value. Reflects current national guidance on confirmatory testing. • Changed numbering under, “D. Confirmation of blood lead levels” to reflect the addition of language noted above.
12VAC5-90-225		Additional data to be reported related to persons with active tuberculosis	<ul style="list-style-type: none"> • Replace “tuberculin skin test (TST)” with “tests for tuberculosis infection” to reflect the availability of other test for infection.

			<ul style="list-style-type: none"> • Remove the examples provided for Mycobacterium tuberculosis complex. Not needed because this is defined earlier in the regulations. • Replaced “tubercle bacilli” with “M. tuberculosis complex” • Add language that laboratories are required to submit results of tests for tuberculosis infection. • Changed numbering under, “B. Laboratories are required to submit the following” to reflect the addition of language noted above.
<p>12VAC5-90-280</p>		<p>Reporting of dangerous microbes and pathogens</p>	<ul style="list-style-type: none"> • Removed the definitions for “Biologic agent”, “CDC”, “Diagnosis”, “Proficiency testing”, “Responsible official”, “Toxin”, and “Verification” because they are no longer needed. • Clarified that “dangerous microbes and pathogens” are “select agents and toxins”. • Removed subsections on Administration, Reportable agents, Those required to report, and Exemption from reporting as they are no longer necessary. This section of the regulations is being streamlined to require annual reporting as specified in the Code of Virginia and reporting of instances in which agency response would be necessary. • Section D. Items to report. Renumbered to Section B. Removed the requirement that a report shall be made on a form determined by VDH, contain information on the objectives of the work with the agent, location (including building and room) where each select agent is stored or used, identification information of persons with access to each agent, identification information of the person in charge of the agents, or that the laboratory has to report that it is registered with the CDC Select Agent Program. These requirements are no longer needed. Added that the

			<p>name and address of the laboratory must be reported.</p> <ul style="list-style-type: none"> • Section E. Renumbered to Section C. Timing of reports. Language has been modified to define who at a laboratory submits the required reports annually and in instances involving a release, loss, or theft of a select agent of toxin, to whom at VDH and when. Language pertaining to reports that will no longer be required has been removed. • Section H. Release of reported information. Renumbered to Section D and the statement about exemptions from liability has been moved to this subsection.
12VAC5-90-370		Reporting of healthcare-associated infections	<ul style="list-style-type: none"> • The term “facilities” has been replaced with the term “health care facilities” to comply with the language in the Code of Virginia. The data that health care facilities share with VDH will be any they supply to CDC as a result of a requirement of the Centers for Medicare and Medicaid Services and not limited to the Hospital Inpatient Quality Reporting Program of that agency.
12VAC5-90-9998		FORMS	Removed reference to the following forms; Confidential Morbidity Report, Epi1 (rev. 10/2011), and the Virginia Cancer Registry Reporting Form (rev. 1/1998). These forms are no longer used by VDH.

1 **Project 5795 - Fast-Track**

2 **Department Of Health**

3 **Amendment to comply with changes in public health practice**

4 **12VAC5-90-10. 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 "Affected area" means any part or the whole of the Commonwealth, which has been identified
8 as where persons reside, or may be located, who are known to have been exposed to or infected
9 with, or who are reasonably suspected to have been exposed to or infected with, a communicable
10 disease of public health threat. "Affected area" shall include, but not be limited to, cities, counties,
11 towns, and subsections of such areas, public and private property, buildings, and other structures.

12 "Arboviral infection" means a viral illness that is transmitted by a mosquito, tick, or other
13 arthropod. This includes, but is not limited to, chikungunya (CHIK), dengue, eastern equine
14 encephalitis (EEE), LaCrosse encephalitis (LAC), also known as California encephalitis, St. Louis
15 encephalitis (SLE), West Nile virus (WNV), and Zika virus (Zika) infection.

16 "Board" means the State Board of Health.

17 "Cancer" means all carcinomas, sarcomas, melanomas, leukemias, and lymphomas
18 excluding localized basal and squamous cell carcinomas of the skin, except for lesions of the
19 mucous membranes.

20 "CDC" means the Centers for Disease Control and Prevention of the U.S. Department of
21 Health and Human Services.

22 "Child care center" means a child day center, child day program, family day home, family day
23 system, or registered family day home as defined by § 63.2-100 of the Code of Virginia, or a
24 similar place providing day care of children by such other name as may be applied.

25 "Clinic" means any facility, freestanding or associated with a hospital, that provides preventive,
26 diagnostic, therapeutic, rehabilitative, or palliative care or services to outpatients.

27 "Commissioner" means the State Health Commissioner or his duly designated officer or agent,
28 unless stated in a provision of this chapter that it applies to the State Health Commissioner in his
29 sole discretion.

30 "Communicable disease" means an illness due to an infectious agent or its toxic products
31 which is transmitted, directly or indirectly, to a susceptible host from an infected person, animal,
32 or arthropod or through the agency of an intermediate host or a vector or through the inanimate
33 environment.

34 "Communicable disease of public health significance" means an illness caused by a specific
35 or suspected infectious agent that may be transmitted directly or indirectly from one individual to
36 another. This includes but is not limited to infections caused by human immunodeficiency viruses,
37 bloodborne pathogens, and tubercle bacillus. The State Health Commissioner may determine that
38 diseases caused by other pathogens constitute communicable diseases of public health
39 significance.

40 "Communicable disease of public health threat" means an illness of public health significance,
41 as determined by the State Health Commissioner in accordance with this chapter, caused by a
42 specific or suspected infectious agent that may be reasonably expected or is known to be readily
43 transmitted directly or indirectly from one individual to another and has been found to create a
44 risk of death or significant injury or impairment; this definition shall not, however, be construed to

45 include human immunodeficiency viruses or the tubercle bacilli, unless used as a bioterrorism
46 weapon.

47 "Companion animal" means, consistent with the provisions of § 3.2-6500 of the Code of
48 Virginia, any domestic or feral dog, domestic or feral cat, nonhuman primate, guinea pig, hamster,
49 rabbit not raised for human food or fiber, exotic or native animal, reptile, exotic or native bird, or
50 any feral animal or any animal under the care, custody, or ownership of a person or any animal
51 that is bought, sold, traded, or bartered by any person. Agricultural animals, game species, or any
52 animals regulated under federal law as research animals shall not be considered companion
53 animals for the purpose of this chapter.

54 "Condition" means any adverse health event, such as a disease, an infection, a syndrome, or
55 as indicated by a procedure (including but not limited to the results of a physical exam, laboratory
56 test, or imaging interpretation) suggesting that an exposure of public health importance has
57 occurred.

58 "Contact" means a person or animal known to have been in such association with an infected
59 person or animal as to have had an opportunity of acquiring the infection.

60 "Contact services" means a broad array of services that are offered to persons with infectious
61 diseases and their contacts. Contact services include contact tracing, providing information about
62 current infections, developing risk reduction plans to reduce the chances of future infections, and
63 connecting to appropriate medical care and other services.

64 "Contact tracing" means the process by which an infected person or health department
65 employee notifies others that they may have been exposed to the infected person in a manner
66 known to transmit the infectious agent in question.

67 "Coronavirus infection, severe" means suspected or confirmed infection with severe acute
68 respiratory syndrome (SARS)-associated coronavirus (SARS-CoV), Middle East respiratory
69 syndrome (MERS)-associated coronavirus (MERS-CoV), or another coronavirus causing a
70 severe acute illness.

71 "Decontamination" means the use of physical or chemical means to remove, inactivate, or
72 destroy hazardous substances or organisms from a person, surface, or item to the point that such
73 substances or organisms are no longer capable of causing adverse health effects and the surface
74 or item is rendered safe for handling, use, or disposal.

75 "Department" means the State Department of Health, also referred to as the Virginia
76 Department of Health (VDH).

77 "Designee" or "designated officer or agent" means any person, or group of persons,
78 designated by the State Health Commissioner, to act on behalf of the commissioner or the board.

79 "Ehrlichiosis/Anaplasmosis" means human infections caused by *Ehrlichia chaffeensis*
80 (formerly included in the category "human monocytic ehrlichiosis" or "HME"), *Ehrlichia ewingii* or
81 *Anaplasma phagocytophilum* (formerly included in the category "human granulocytic ehrlichiosis"
82 or "HGE").

83 "Epidemic" means the occurrence in a community or region of cases of an illness clearly in
84 excess of normal expectancy.

85 "Essential needs" means basic human needs for sustenance including but not limited to food,
86 water, clothing, and health care (e.g., medications, therapies, testing, and durable medical
87 equipment).

88 "Exceptional circumstances" means the presence, as determined by the commissioner in his
89 sole discretion, of one or more factors that may affect the ability of the department to effectively
90 control a communicable disease of public health threat. Factors to be considered include but are
91 not limited to: (i) characteristics or suspected characteristics of the disease-causing organism or
92 suspected disease-causing organism such as virulence, routes of transmission, minimum

93 infectious dose, rapidity of disease spread, the potential for extensive disease spread, and the
94 existence and availability of demonstrated effective treatment; (ii) known or suspected risk factors
95 for infection; (iii) the potential magnitude of the effect of the disease on the health and welfare of
96 the public; and (iv) the extent of voluntary compliance with public health recommendations. The
97 determination of exceptional circumstances by the commissioner may take into account the
98 experience or results of investigation in Virginia, another state, or another country.

99 "Foodborne outbreak" means two or more cases of a similar illness acquired through the
100 consumption of food contaminated with chemicals or an infectious agent or its toxic products.
101 Such illnesses include but are not limited to heavy metal intoxication, staphylococcal food
102 poisoning, botulism, salmonellosis, shigellosis, Clostridium perfringens food poisoning, hepatitis
103 A, and Shiga toxin-producing Escherichia coli infection.

104 "Healthcare-associated infection" (also known as nosocomial infection) means a localized or
105 systemic condition resulting from an adverse reaction to the presence of an infectious agent or
106 agents or its toxin or toxins that (i) occurs in a patient in a health care ~~setting~~ facility (e.g., a
107 ~~hospital~~ medical care facility or outpatient clinic), and (ii) was not found to be present or incubating
108 at the time of admission unless the infection was related to a previous admission to the same
109 setting, ~~and (iii) if the setting is a hospital, meets the criteria for a specific infection site as defined~~
110 ~~by CDC.~~

111 "~~Hepatitis C, acute~~" means ~~the following clinical characteristics are met: (i) discrete onset of~~
112 ~~symptoms indicative of viral hepatitis and (ii) jaundice or elevated serum aminotransferase levels~~
113 ~~and the following laboratory criteria are met: (a) serum alanine aminotransferase levels (ALT)~~
114 ~~greater than 200 IU/L; (b) IgM anti-HAV negative (if done); (c) IgM anti-HBc negative (if done);~~
115 ~~and (d) hepatitis C virus antibody (anti-HCV) positive, HCV antigen positive, or HCV RNA positive~~
116 ~~by nucleic acid test.~~

117 "~~Hepatitis C, chronic~~" means ~~that the laboratory criteria specified in clauses (b), (c) and (d)~~
118 ~~listed above for an acute case are met but clinical signs or symptoms of acute viral hepatitis are~~
119 ~~not present and serum alanine aminotransferase (ALT) levels do not exceed 200 IU/L. This~~
120 ~~category will include cases that may be acutely infected but not symptomatic.~~

121 "Immunization" means a procedure that increases the protective response of an individual's
122 immune system to specified pathogens.

123 "Independent pathology laboratory" means a nonhospital or a hospital laboratory performing
124 surgical pathology, including fine needle aspiration biopsy and bone marrow specimen
125 examination services, which reports the results of such tests directly to physician offices, without
126 reporting to a hospital or accessioning the information into a hospital tumor registry.

127 "Individual" means a person or companion animal. When the context requires it, "person or
128 persons" shall be deemed to include any individual.

129 "Infection" means the entry and multiplication or persistence of a disease-causing organism
130 (prion, virus, bacteria, fungus, parasite, or ectoparasite) in the body of an individual. An infection
131 may be inapparent (i.e., without recognizable signs or symptoms but identifiable by laboratory
132 means) or manifest (clinically apparent).

133 "Influenza A, novel virus" means infection of a human with an influenza A virus subtype that
134 is different from currently circulating human influenza H1 and H3 viruses. Novel subtypes include
135 H2, H5, H7, and H9 subtypes or influenza H1 and H3 subtypes originating from a nonhuman
136 species or from genetic reassortment of human and animal influenza viruses.

137 "Invasive" means the organism is affecting a normally sterile site, including but not limited to
138 blood or cerebrospinal fluid.

139 "Investigation" means an inquiry into the incidence, prevalence, extent, source, mode of
140 transmission, causation of, and other information pertinent to a disease occurrence.

141 "Isolation" means the physical separation, including confinement or restriction of movement,
142 of an individual or individuals who are infected with, or are reasonably suspected to be infected
143 with, a communicable disease in order to prevent or limit the transmission of the communicable
144 disease to uninfected and unexposed individuals.

145 "Isolation, complete" means the full-time confinement or restriction of movement of an
146 individual or individuals infected with, or reasonably suspected to be infected with, a
147 communicable disease in order to prevent or limit the transmission of the communicable disease
148 to uninfected and unexposed individuals.

149 "Isolation, modified" means a selective, partial limitation of freedom of movement or actions
150 of an individual or individuals infected with, or reasonably suspected to be infected with, a
151 communicable disease. Modified isolation is designed to meet particular situations and includes
152 but is not limited to the exclusion of children from school, the prohibition or restriction from
153 engaging in a particular occupation or using public or mass transportation, or requirements for
154 the use of devices or procedures intended to limit disease transmission.

155 "Isolation, protective" means the physical separation of a susceptible individual or individuals
156 not infected with, or not reasonably suspected to be infected with, a communicable disease from
157 an environment where transmission is occurring, or is reasonably suspected to be occurring, in
158 order to prevent the individual or individuals from acquiring the communicable disease.

159 "Laboratory" means a clinical laboratory that examines materials derived from the human body
160 for the purpose of providing information on the diagnosis, prevention, or treatment of disease.

161 "Laboratory director" means any person in charge of supervising a laboratory conducting
162 business in the Commonwealth of Virginia.

163 "Law-enforcement agency" means any sheriff's office, police department, adult or youth
164 correctional officer, or other agency or department that employs persons who have law-
165 enforcement authority that is under the direction and control of the Commonwealth or any local
166 governing body. "Law-enforcement agency" shall include, by order of the Governor, the Virginia
167 National Guard.

168 ~~"Lead, reportable levels" means any detectable blood lead level in children 15 years of age~~
169 ~~and younger and levels greater than or equal to 5 µg/dL in a person older than 15 years of age.~~

170 "Least restrictive" means the minimal limitation of the freedom of movement and
171 communication of an individual while under an order of isolation or an order of quarantine that
172 also effectively protects unexposed and susceptible individuals from disease transmission.

173 "Medical care facility" means any hospital or nursing home licensed in the Commonwealth, or
174 any hospital operated by or contracted to operate by an entity of the United States government
175 or the Commonwealth of Virginia.

176 "Midwife" means any person who is licensed as a nurse midwife by the Virginia Boards of
177 Nursing and Medicine or who is licensed by the Board of Medicine as a certified professional
178 midwife.

179 "National Healthcare Safety Network" or "NHSN" means a surveillance system created by the
180 CDC for accumulating, exchanging, and integrating relevant information on infectious adverse
181 events associated with health care delivery.

182 "Nucleic acid detection" means laboratory testing of a clinical specimen to determine the
183 presence of deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) specific for an infectious agent
184 using any method, including hybridization, sequencing, or amplification such as polymerase chain
185 reaction.

186 "Nurse" means any person licensed as a professional nurse or as a licensed practical nurse
187 by the Virginia Board of Nursing.

188 "Occupational outbreak" means a cluster of illness or disease that is indicative of a work-
189 related exposure. Such conditions include but are not limited to silicosis, asbestosis, byssinosis,
190 pneumoconiosis, and tuberculosis.

191 "Outbreak" means the occurrence of more cases of a disease than expected.

192 "Period of communicability" means the time or times during which the etiologic agent may be
193 transferred directly or indirectly from an infected person to another person, or from an infected
194 animal to a person.

195 "Physician" means any person licensed to practice medicine or osteopathy by the Virginia
196 Board of Medicine.

197 "Quarantine" means the physical separation, including confinement or restriction of
198 movement, of an individual or individuals who are present within an affected area or who are
199 known to have been exposed, or may reasonably be suspected to have been exposed, to a
200 communicable disease and who do not yet show signs or symptoms of infection with the
201 communicable disease in order to prevent or limit the transmission of the communicable disease
202 of public health threat to unexposed and uninfected individuals.

203 "Quarantine, complete" means the full-time confinement or restriction of movement of an
204 individual or individuals who do not have signs or symptoms of infection but may have been
205 exposed, or may reasonably be suspected to have been exposed, to a communicable disease of
206 public health threat in order to prevent the transmission of the communicable disease of public
207 health threat to uninfected individuals.

208 "Quarantine, modified" means a selective, partial limitation of freedom of movement or actions
209 of an individual or individuals who do not have signs or symptoms of the infection but have been
210 exposed to, or are reasonably suspected to have been exposed to, a communicable disease of
211 public health threat. Modified quarantine may be designed to meet particular situations and
212 includes but is not limited to limiting movement to the home, work, or one or more other locations,
213 the prohibition or restriction from using public or mass transportation, or requirements for the use
214 of devices or procedures intended to limit disease transmission.

215 "Reportable disease" means an illness due to a specific toxic substance, occupational
216 exposure, or infectious agent, which affects a susceptible individual, either directly, as from an
217 infected animal or person, or indirectly through an intermediate host, vector, or the environment,
218 as determined by the board.

219 "School" means (i) any public school from kindergarten through grade 12 operated under the
220 authority of any locality within the Commonwealth, (ii) any private or religious school that offers
221 instruction at any level or grade from kindergarten through grade 12; and (iii) any private or
222 religious nursery school or preschool, or any private or religious child care center required to be
223 licensed by the Commonwealth.

224 "Serology" means the testing of blood, serum, or other body fluids for the presence of
225 antibodies or other markers of an infection or disease process.

226 "Surveillance" means the ongoing systematic collection, analysis, and interpretation of
227 outcome-specific data for use in the planning, implementation, and evaluation of public health
228 practice. A surveillance system includes the functional capacity for data analysis as well as the
229 timely dissemination of these data to persons who can undertake effective prevention and control
230 activities.

231 "Susceptible individual" means a person or animal who is vulnerable to or potentially able to
232 contract a disease or condition. Factors that affect an individual's susceptibility include but are not
233 limited to physical characteristics, genetics, previous or chronic exposures, chronic conditions or
234 infections, immunization history, or use of medications.

235 "Toxic substance" means any substance, including any raw materials, intermediate products,
236 catalysts, final products, or by-products of any manufacturing operation conducted in a
237 commercial establishment, that has the capacity, through its physical, chemical or biological
238 properties, to pose a substantial risk of death or impairment either immediately or over time, to
239 the normal functions of humans, aquatic organisms, or any other animal but not including any
240 pharmaceutical preparation which deliberately or inadvertently is consumed in such a way as to
241 result in a drug overdose.

242 ~~"Tubercle bacilli" means disease-causing organisms belonging to the Mycobacterium~~
243 ~~tuberculosis complex and includes Mycobacterium tuberculosis, Mycobacterium bovis, and~~
244 ~~Mycobacterium africanum or other members as may be established by the commissioner.~~

245 "Tubercle bacilli" means disease-causing organisms belonging to the Mycobacterium
246 tuberculosis complex and includes Mycobacterium tuberculosis, Mycobacterium africanum,
247 Mycobacterium bovis, Mycobacterium canetti, Mycobacterium microti, Mycobacterium caprae or
248 other members as may be established by the commissioner.

249 ~~"Tuberculin skin test (TST)" means a test for demonstrating infection with tubercle bacilli,~~
250 ~~performed according to the Mantoux method, in which 0.1 ml of 5 TU strength tuberculin purified~~
251 ~~protein derivative (PPD) is injected intradermally on the volar surface of the arm. Any reaction is~~
252 ~~observed 48-72 hours after placement and palpable induration is measured across the diameter~~
253 ~~transverse to the long axis of the arm. The measurement of the indurated area is recorded in~~
254 ~~millimeters and the significance of the measured induration is based on existing national and~~
255 ~~department guidelines.~~

256 ~~"Tuberculosis" means a disease caused by tubercle bacilli.~~

257 "Tuberculosis, active disease" (also "active tuberculosis disease" and "active TB disease"),
258 as defined by § 32.1-49.1 of the Code of Virginia, means a communicable disease caused by an
259 airborne microorganism and characterized by the presence of either (i) a specimen of sputum or
260 other bodily fluid or tissue that has been found to contain tubercle bacilli as evidenced by culture
261 or nucleic acid amplification, including preliminary identification by rapid methodologies; (ii) a
262 specimen of sputum or other bodily fluid or tissue that is suspected to contain tubercle bacilli as
263 evidenced by smear, and where sufficient clinical and radiographic evidence of active tuberculosis
264 disease is present as determined by a physician licensed to practice medicine in Virginia; or (iii)
265 sufficient clinical and radiographic evidence of active tuberculosis disease as determined by the
266 commissioner is present, but a specimen of sputum or other bodily fluid or tissue containing, or
267 suspected of containing, tubercle bacilli is unobtainable.

268 ~~"Tuberculosis infection in children age <4 years" means a significant reaction resulting from a~~
269 ~~tuberculin skin test (TST) or other approved test for latent infection without positive result from a~~
270 ~~test for tuberculosis infection without clinical or radiographic other evidence of active tuberculosis~~
271 ~~disease, in children from birth up to their fourth birthday.~~

272 "Vaccinia, disease or adverse event" means vaccinia infection or serious or unexpected
273 events in persons who received the smallpox vaccine or their contacts, including but not limited
274 to bacterial infections, eczema vaccinatum, erythema multiforme, generalized vaccinia,
275 progressive vaccinia, inadvertent inoculation, post-vaccinial encephalopathy or
276 encephalomyelitis, ocular vaccinia, and fetal vaccinia.

277 "Waterborne outbreak" means two or more cases of a similar illness acquired through the
278 ingestion of or other exposure to water contaminated with chemicals or an infectious agent or its
279 toxic products. Such illnesses include but are not limited to giardiasis, viral gastroenteritis,
280 cryptosporidiosis, hepatitis A, cholera, and shigellosis. A single case of laboratory-confirmed
281 primary amebic meningoencephalitis or of waterborne chemical poisoning is considered an
282 outbreak.

283 **12VAC5-90-80. List of diseases that shall be reported.**

284 A. Reportable disease list. The board declares suspected or confirmed cases of the following
285 named diseases, toxic effects, and conditions to be reportable by the persons enumerated in
286 12VAC5-90-90. Conditions identified by an asterisk (*) require immediate communication to the
287 local health department by the most rapid means available upon suspicion or confirmation, as
288 defined in subsection C of this section. Other conditions should be reported within three days of
289 suspected or confirmed diagnosis, unless otherwise specified in this section. Neonatal Abstinence
290 Syndrome shall be reported as specified in subsection E of this section.

- 291 Amebiasis (*Entamoeba histolytica*)
- 292 *Anthrax (*Bacillus anthracis*)
- 293 Arboviral infections (e.g., CHIK, dengue, EEE, LAC, SLE, WNV, Zika)
- 294 Babesiosis (*Babesia* spp.)
- 295 *Botulism (*Clostridium botulinum*)
- 296 *Brucellosis (*Brucella* spp.)
- 297 Campylobacteriosis (*Campylobacter* spp.)
- 298 *Candida auris*, infection or colonization
- 299 Carbapenemase-producing organism, infection or colonization
- 300 Chancroid (*Haemophilus ducreyi*)
- 301 Chickenpox (*Varicella* virus)
- 302 Chlamydia trachomatis infection
- 303 *Cholera (*Vibrio cholerae* O1 or O139)
- 304 *Coronavirus infection, severe
- 305 Cryptosporidiosis (*Cryptosporidium* spp.)
- 306 Cyclosporiasis (*Cyclospora* spp.)
- 307 *Diphtheria (*Corynebacterium diphtheriae*)
- 308 *Disease caused by an agent that may have been used as a weapon
- 309 Ehrlichiosis/Anaplasmosis (*Ehrlichia* spp., *Anaplasma phagocytophilum*)
- 310 Giardiasis (*Giardia* spp.)
- 311 Gonorrhea (*Neisseria gonorrhoeae*)
- 312 Granuloma inguinale (*Calymmatobacterium granulomatis*)
- 313 **Haemophilus influenzae* infection, invasive
- 314 Hantavirus pulmonary syndrome
- 315 Hemolytic uremic syndrome (HUS)
- 316 *Hepatitis A
- 317 Hepatitis B (acute and chronic)
- 318 Hepatitis C (acute and chronic)
- 319 Hepatitis, other acute viral
- 320 Human immunodeficiency virus (HIV) infection
- 321 Influenza, confirmed
- 322 *Influenza-associated deaths if younger than 18 years of age
- 323 Lead, blood levels
- 324 Legionellosis (*Legionella* spp.)

325 Leprosy (Hansen's disease) (*Mycobacterium leprae*)
326 Leptospirosis (*Leptospira interrogans*)
327 Listeriosis (*Listeria monocytogenes*)
328 Lyme disease (*Borrelia* spp.)
329 Lymphogranuloma venereum (*Chlamydia trachomatis*)
330 Malaria (*Plasmodium* spp.)
331 *Measles (Rubeola)
332 *Meningococcal disease (*Neisseria meningitidis*)
333 Mumps
334 Neonatal abstinence syndrome (NAS)
335 Ophthalmia neonatorum
336 *Outbreaks, all (including foodborne, health care-associated, occupational, toxic
337 substance-related, waterborne, and any other outbreak)
338 *Pertussis (*Bordetella pertussis*)
339 *Plague (*Yersinia pestis*)
340 *Poliovirus infection, including poliomyelitis
341 *Psittacosis (*Chlamydophila psittaci*)
342 *Q fever (*Coxiella burnetii*)
343 *Rabies, human and animal
344 Rabies treatment, post-exposure
345 *Rubella, including congenital rubella syndrome
346 Salmonellosis (*Salmonella* spp.)
347 Shiga toxin-producing *Escherichia coli* infection
348 Shigellosis (*Shigella* spp.)
349 *Smallpox (*Variola virus*)
350 Spotted fever rickettsiosis (*Rickettsia* spp.)
351 Streptococcal disease, Group A, invasive or toxic shock
352 Streptococcus pneumoniae infection, invasive if younger than five years of age
353 Syphilis (*Treponema pallidum*) report *congenital, *primary, *secondary, and other
354 Tetanus (*Clostridium tetani*)
355 Toxic substance-related illness
356 Trichinosis (Trichinellosis) (*Trichinella spiralis*)
357 *Tuberculosis, active disease (*Mycobacterium tuberculosis* complex)
358 Tuberculosis infection
359 *Tularemia (*Francisella tularensis*)
360 *Typhoid/Paratyphoid infection (*Salmonella Typhi*, *Salmonella Paratyphi*)
361 *Unusual occurrence of disease of public health concern
362 *Vaccinia, disease or adverse event
363 Vancomycin-intermediate or vancomycin-resistant *Staphylococcus aureus* infection
364 *Vibriosis (*Vibrio* spp.)
365 *Viral hemorrhagic fever

366 *Yellow fever
367 Yersiniosis (*Yersinia* spp.)
368 B. Conditions reportable by directors of laboratories. Laboratories shall report all test results
369 indicative of and specific for the diseases, infections, microorganisms, conditions, and toxic
370 effects specified in this subsection for humans. Such tests include microbiological culture,
371 isolation, or identification; assays for specific antibodies; and identification of specific antigens,
372 toxins, or nucleic acid sequences. Additional condition-specific requirements are noted in this
373 subsection and subsection D of this section. Conditions identified by an asterisk (*) require
374 immediate communication to the local health department by the most rapid means available upon
375 suspicion or confirmation, as defined in subsection C of this section. Other conditions should be
376 reported within three days of suspected or confirmed diagnosis.
377 Amebiasis (*Entamoeba histolytica*)
378 *Anthrax (*Bacillus anthracis*)
379 Arboviral infection, for example, CHIK, dengue, EEE, LAC, SLE, WNV, or Zika
380 Babesiosis (*Babesia* spp.)
381 *Botulism (*Clostridium botulinum*)
382 *Brucellosis (*Brucella* spp.)
383 Campylobacteriosis (*Campylobacter* spp.)
384 *Candida auris* - Include available antimicrobial susceptibility findings in report.
385 Carbapenemase-producing organism - Include available antimicrobial susceptibility
386 findings in report.
387 Chancroid (*Haemophilus ducreyi*)
388 Chickenpox (*Varicella* virus)
389 Chlamydia trachomatis infection
390 *Cholera (*Vibrio cholerae* O1 or O139)
391 *Coronavirus infection, severe (e.g., SARS-CoV, MERS-CoV)
392 Cryptosporidiosis (*Cryptosporidium* spp.)
393 Cyclosporiasis (*Cyclospora* spp.)
394 *Diphtheria (*Corynebacterium diphtheriae*)
395 Ehrlichiosis/Anaplasmosis (*Ehrlichia* spp., *Anaplasma phagocytophilum*)
396 Giardiasis (*Giardia* spp.)
397 Gonorrhea (*Neisseria gonorrhoeae*) - Include available antimicrobial susceptibility findings
398 in report.
399 **Haemophilus influenzae* infection, invasive
400 Hantavirus pulmonary syndrome
401 *Hepatitis A
402 Hepatitis B (acute and chronic) - For All hepatitis B patients, also report available results
403 of serum alanine aminotransferase (ALT) and all available results from the hepatitis panel.
404 Hepatitis C (acute and chronic) - For all patients with any positive HCV test, also report all
405 results of HCV viral load tests, including undetectable viral loads and report available
406 results of serum alanine aminotransferase (ALT) and all available results from the hepatitis
407 panel.

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

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

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

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

422 Legionellosis (*Legionella* spp.)

423 Leptospirosis (*Leptospira interrogans*)

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

426 Lyme disease (*Borrelia* spp.)

427 Malaria (*Plasmodium* spp.)

428 *Measles (Rubeola)

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

431 Mumps

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

433 1. Acid fast bacilli;

434 2. *M. tuberculosis* complex or any other mycobacteria;

435 3. Antimicrobial susceptibility results for *M. tuberculosis* complex.

436 *Pertussis (*Bordetella pertussis*)

437 *Plague (*Yersinia pestis*)

438 *Poliovirus infection

439 *Psittacosis (*Chlamydophila psittaci*)

440 *Q fever (*Coxiella burnetii*)

441 *Rabies, human and animal

442 *Rubella

443 Salmonellosis (*Salmonella* spp.)

444 Shiga toxin-producing *Escherichia coli* infection

445 Shigellosis (*Shigella* spp.)

446 *Smallpox (*Variola virus*)

447 Spotted fever rickettsiosis (*Rickettsia* spp.)

448 Streptococcal disease, Group A, invasive or toxic shock

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

450 *Syphilis (*Treponema pallidum*)

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

455 Trichinosis (Trichinellosis) (*Trichinella spiralis*)

456 Tuberculosis infection

457 *Tularemia (*Francisella tularensis*)

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

460 *Vaccinia, disease or adverse event

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

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

465 *Viral hemorrhagic fever

466 *Yellow fever

467 Yersiniosis (*Yersinia* spp.)

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

475 Anthrax (*Bacillus anthracis*)

476 Botulism (*Clostridium botulinum*)

477 Brucellosis (*Brucella* spp.)

478 Cholera (*Vibrio cholerae* O1 or O139)

479 Coronavirus infection, severe

480 Diphtheria (*Corynebacterium diphtheriae*)

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

482 *Haemophilus influenzae* infection, invasive

483 Hepatitis A

484 Influenza-associated deaths if younger than 18 years of age

485 Influenza A, novel virus

486 Measles (*Rubeola virus*)

487 Meningococcal disease (*Neisseria meningitidis*)

488 Outbreaks, all

489 Pertussis (*Bordetella pertussis*)

490 Plague (*Yersinia pestis*)

491 Poliovirus infection, including poliomyelitis

492 Psittacosis (*Chlamydophila psittaci*)

493 Q fever (*Coxiella burnetii*)

- 494 Rabies, human and animal
- 495 Rubella, including congenital rubella syndrome
- 496 Smallpox (Variola virus)
- 497 Syphilis, congenital, primary, and secondary (*Treponema pallidum*)
- 498 Tuberculosis, active disease (*Mycobacterium tuberculosis* complex)
- 499 Tularemia (*Francisella tularensis*)
- 500 Typhoid/Paratyphoid infection (*Salmonella* Typhi, *Salmonella* Paratyphi (all types))
- 501 Unusual occurrence of disease of public health concern
- 502 Vaccinia, disease or adverse event
- 503 Vibriosis (*Vibrio* spp., *Photobacterium damsela*, *Grimontia hollisae*), other than toxigenic
- 504 *Vibrio cholerae* O1 or O139, which are reportable as cholera
- 505 Viral hemorrhagic fever
- 506 Yellow fever

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

- 515 Anthrax (*Bacillus anthracis*)
- 516 Botulism (*Clostridium botulinum*)
- 517 Brucellosis (*Brucella* sp.)
- 518 *Candida auris*
- 519 *Candida haemulonii*
- 520 Carbapenem-resistant ~~Enterobacteriaceae~~ Enterobacterales
- 521 Carbapenem-resistant *Pseudomonas aeruginosa*
- 522 Cholera (*Vibrio cholerae* O1 or O139)
- 523 Coronavirus infection, severe (e.g., SARS-CoV, MERS-CoV)
- 524 Diphtheria (*Corynebacterium diphtheriae*)
- 525 *Haemophilus influenzae* infection, invasive
- 526 Influenza, unsubtypeable
- 527 Listeriosis (*Listeria monocytogenes*)
- 528 Meningococcal disease (*Neisseria meningitidis*)
- 529 Plague (*Yersinia pestis*)
- 530 Poliovirus infection
- 531 Q fever (*Coxiella burnetii*)
- 532 Salmonellosis (*Salmonella* spp.)
- 533 Shiga toxin-producing *E. coli* infection (Laboratories that identify a Shiga toxin but do not
 534 perform simultaneous culture for Shiga toxin-producing *E. coli* should forward all positive
 535 stool specimens or positive enrichment broths to the Division of Consolidated Laboratory
 536 Services for confirmation and further characterization.)

537 Shigellosis (*Shigella* spp.)
538 Streptococcal disease, Group A, invasive
539 Tuberculosis (A laboratory identifying *Mycobacterium tuberculosis* complex (see 12VAC5-
540 90-225) shall submit a representative and viable sample of the initial culture to the Division
541 of Consolidated Laboratory Services or other laboratory designated by the board to
542 receive such specimen.)
543 Tularemia (*Francisella tularensis*)
544 Typhoid/Paratyphoid infection (*Salmonella Typhi*, *Salmonella Paratyphi* (all types))
545 Vancomycin-intermediate or vancomycin-resistant *Staphylococcus aureus* infection
546 Vibriosis (*Vibrio* spp., *Photobacterium damsela*, *Grimontia hollisae*)
547 Yersiniosis (*Yersinia* spp.)

548 Other diseases as may be requested by the health department.

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

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

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

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

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

574 **12VAC5-90-90. Those required to report.**

575 A. Physicians. Each physician who treats or examines any person who is suffering from or
576 who is suspected of having a reportable disease or condition shall report at a minimum, that
577 person's name, address, age, date of birth, race, ethnicity, sex, and pregnancy status for females;
578 name of disease diagnosed or suspected; the date of onset of illness; available laboratory tests
579 and results; and the name, address, and telephone number of the physician and medical facility
580 where the examination was made, ~~except that influenza should be reported by number of cases~~
581 ~~only (and type of influenza, if available)~~. Reports are to be made to the local health department
582 serving the jurisdiction where the physician practices. A physician may designate someone to
583 report on his behalf, but the physician remains responsible for ensuring that the appropriate report

584 is made. Any physician, designee, or organization making such report as authorized herein shall
585 be immune from liability as provided by § 32.1-38 of the Code of Virginia.

586 Such reports shall be made within the timeframes specified in 12VAC5-90-80 to the local
587 health department serving the jurisdiction in which the facility is located. Reports shall be made
588 on a Form Epi-1, a computer generated printout containing the data items requested on Form
589 Epi-1, via the Department of Health's online Confidential Morbidity Report portal
590 (<http://www.vdh.virginia.gov/clinicians>) or a CDC or VDH disease-specific surveillance form.~~that~~
591 ~~provides the same information and shall be made within three days of the suspicion or~~
592 ~~confirmation of disease except that those identified in 12VAC5-90-80 C shall be reported~~
593 ~~immediately by the most rapid means available, preferably by telephone, to the local health~~
594 ~~department serving the jurisdiction in which the facility is located. Reporting may be done by~~
595 ~~means of secure electronic transmission upon agreement of the physician and the department.~~

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

599 B. Directors of laboratories. Laboratory directors shall report any laboratory examination of
600 any clinical specimen, ~~whether performed in-house or referred to an out-of-state laboratory,~~ which
601 yields evidence, ~~by the laboratory method(s) indicated or any other confirmatory test,~~ of a disease
602 listed in 12VAC5-90-80 B. Laboratory directors shall report results that are performed in-house or
603 referred to a reference laboratory, with the following exception: if the laboratory director ascertains
604 that the reference laboratory that tests a specimen reports to the department electronically, then
605 those reference laboratory findings do not need to be reported by the laboratory of origin.

606 Each report shall give the source of the specimen and the laboratory method and result; the
607 name, address, age, date of birth, race, ethnicity, sex, and pregnancy status for females (if known)
608 of the person from whom the specimen was obtained; and the name, address, and telephone
609 number of the physician at whose request and medical facility at which the examination was
610 made. When the influenza virus is isolated, the type should be reported, if available. Reports shall
611 be made ~~within three days of identification of evidence of disease, except that those identified in~~
612 ~~12VAC5-90-80 C shall be reported immediately by the most rapid means available, preferably by~~
613 ~~telephone, the timeframes specified in 12VAC5-90-80 to the local health department serving the~~
614 ~~jurisdiction in which the laboratory is located. Reports shall be made on Form Epi-1 via the~~
615 Department's online Confidential Morbidity Report portal or on the laboratory's own form if it
616 includes the required information. Computer generated reports containing the required
617 information may be submitted. Reporting may be done by means of secure electronic
618 transmission upon agreement of the laboratory director and the department. Reports of HIV
619 genetic nucleotide sequence data associated with HIV drug resistance tests must be submitted
620 electronically. Any person making such report as authorized herein shall be immune from liability
621 as provided by § 32.1-38 of the Code of Virginia.

622 A laboratory identifying evidence of any of the following conditions shall notify the local health
623 department of the positive culture or other positive test result ~~within the timeframes specified in~~
624 ~~12VAC5-90-80 and submit the initial isolate or other initial specimen to the Division of~~
625 ~~Consolidated Laboratory Services within seven days of identification. All specimens must be~~
626 ~~identified with the patient and physician information required in this subsection.~~

- 627 Anthrax
- 628 Botulism
- 629 Brucellosis
- 630 Cholera
- 631 Diphtheria

- 632 ~~E. coli infection, Shiga toxin-producing. (Laboratories that use a Shiga toxin EIA~~
633 ~~methodology but do not perform simultaneous culture for Shiga toxin-producing E. coli~~
634 ~~should forward all positive stool specimens or positive enrichment broths to the Division~~
635 ~~of Consolidated Laboratory Services for confirmation and further characterization.)~~
636 ~~Haemophilus influenzae infection, invasive~~
637 ~~Influenza A, novel virus~~
638 ~~Listeriosis~~
639 ~~Meningococcal disease~~
640 ~~Pertussis~~
641 ~~Plague~~
642 ~~Poliovirus infection~~
643 ~~Q fever~~
644 ~~Salmonellosis~~
645 ~~Shigellosis~~
646 ~~Streptococcal disease, Group A, invasive~~
647 ~~Tuberculosis (A laboratory identifying Mycobacterium tuberculosis complex (see 12VAC5-~~
648 ~~90-225) shall submit a representative and viable sample of the initial culture to the Division~~
649 ~~of Consolidated Laboratory Services or other laboratory designated by the board to~~
650 ~~receive such specimen.)~~
651 ~~Tularemia~~
652 ~~Typhoid/Paratyphoid fever~~
653 ~~Vancomycin-intermediate or vancomycin-resistant Staphylococcus aureus infection~~
654 ~~Vibrio infection, including infections due to Photobacterium damsela and Grimontia~~
655 ~~hollisae~~
656 ~~Yersiniosis~~
657 ~~Other diseases as may be requested by the health department~~

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

664 Laboratories operating within a medical care facility shall be considered to be in compliance
665 with the requirement to notify the local health department when the director of that medical care
666 facility assumes the reporting responsibility; however, laboratories are still required to submit
667 isolates to the Division of Consolidated Laboratory Services or other designated laboratory as
668 noted in ~~this subsection~~ 12VAC5-90-80 D unless the laboratory has submitted an exemption
669 request that has been approved by the department.

670 C. Persons in charge of a medical care facility. Any person in charge of a medical care facility
671 shall make a report to the local health department serving the jurisdiction where the facility is
672 located of the occurrence in or admission to the facility of a patient with a reportable disease listed
673 in 12VAC5-90-80 A unless he has evidence that the occurrence has been reported by a physician.
674 Any person making such report as authorized herein shall be immune from liability as provided
675 by § 32.1-38 of the Code of Virginia. The requirement to report shall include all inpatient,
676 outpatient, and emergency care departments within the medical care facility. Such report shall
677 contain the patient's name, address, age, date of birth, race, ethnicity, sex, and pregnancy status

678 for females; name of disease being reported; available laboratory tests and results; the date of
679 admission; hospital chart number; date expired (when applicable); and attending physician.
680 Influenza should be reported by number of cases only (and type of influenza, if available). Reports
681 shall be made within three days of the suspicion or confirmation of disease except that those
682 identified in 12VAC5-90-80 C shall be reported immediately by the most rapid means available,
683 preferably by telephone, the timeframes specified in 12VAC5-90-80 to the local health department
684 serving the jurisdiction in which the facility is located. Reports shall be made on Form Epi-1, a
685 computer generated printout containing the data items requested on Form Epi-1, via the
686 Department of Health's online Confidential Morbidity Report portal
687 (<http://www.vdh.virginia.gov/clinicians>), or a CDC or VDH disease-specific surveillance form that
688 provides the same information. Reporting may be done by means of secure electronic
689 transmission upon agreement of the medical care facility and the department.

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

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

704 E. Local health directors. The local health director shall forward any report of a disease or
705 report of evidence of a disease which has been made on a resident of his jurisdiction to the Office
706 of Epidemiology within three days of receipt. This report shall be submitted immediately by the
707 most rapid means available if the disease is one requiring rapid communication, as required in
708 12VAC5-90-80 C. All such rapid reporting shall be confirmed in writing and submitted to the Office
709 of Epidemiology, by either a paper report or entry into a shared secure electronic disease
710 surveillance system, within three days. Furthermore, the local health director shall immediately
711 forward to the appropriate local health director any disease reports on individuals residing in the
712 latter's jurisdiction or to the Office of Epidemiology on individuals residing outside Virginia. The
713 Office of Epidemiology shall be responsible for notifying other state health departments of
714 reported illnesses in their residents and for notifying CDC as necessary and appropriate.

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

- 722 Creutzfeldt-Jakob disease
- 723 Human immunodeficiency virus (HIV) infection
- 724 Hepatitis B (acute and chronic)
- 725 Hepatitis C (acute and chronic)
- 726 Rabies

- 727 Smallpox (Variola virus)
- 728 Syphilis, infectious (Treponema pallidum)
- 729 Tuberculosis, active disease (Mycobacterium tuberculosis complex)
- 730 Vaccinia, disease or adverse event
- 731 Viral hemorrhagic fever

732 G. Employees, conditional employees, and persons in charge of food establishments.
733 12VAC5-421-80 of the Food Regulations requires a food employee or conditional employee to
734 notify the person in charge of the food establishment when diagnosed with certain diseases that
735 are transmissible through food and requires the person in charge of the food establishment to
736 notify the regulatory authority. Refer to 12VAC5-421-80 for further guidance and clarification
737 regarding these reporting requirements.

738 **12VAC5-90-103. Isolation for communicable disease of public health threat.**

739 A. Application. The commissioner, in his sole discretion, may invoke the provisions of Article
740 3.02 (§ 32.1-48.05 et seq.) of Chapter 2 of Title 32.1 of the Code of Virginia and may declare the
741 isolation of any individual or individuals upon a determination that:

- 742 1. Such individual or individuals are known to have been infected with or are reasonably
743 suspected to have been infected with a communicable disease of public health threat;
- 744 2. Exceptional circumstances render the procedures of Article 3.01 (§ 32.1-48.01 et seq.)
745 of Chapter 2 of Title 32.1 of the Code of Virginia to be insufficient, or the individual or
746 individuals have failed or refused to comply voluntarily with the control measures directed
747 by the commissioner in response to a communicable disease of public health threat; and
- 748 3. Isolation is the necessary means to contain a communicable disease of public health
749 threat, to ensure that such isolated individual or individuals receive appropriate medical
750 treatment subject to the provisions of § 32.1-44 of the Code of Virginia, or to protect health
751 care providers and others who may come into contact with such infected individual or
752 individuals.

753 The commissioner, in his sole discretion, may also order the isolation of an affected area if, in
754 addition to the above, the Governor has declared a state of emergency for such affected area of
755 the Commonwealth.

756 B. Documentation. For isolation for a communicable disease of public health threat,
757 information about the infection or suspected infection, the individual, individuals, and/or affected
758 area, and the nature or suspected nature of the exposure shall be duly recorded by the local
759 health department in consultation with the Office of Epidemiology. This information shall be
760 sufficient to enable documenting a record of findings and to enable the commissioner to prepare
761 the order of isolation, including the information required in § 32.1-48.12 of the Code of Virginia. In
762 addition, sufficient information on individuals shall be maintained by the local health department
763 to enable appropriate follow-up of individuals for health status evaluation and treatment as well
764 as compliance with the order of isolation.

765 The commissioner shall ensure that the protected health information of any individual or
766 individuals subject to the order of isolation is disclosed only in compliance with state and federal
767 law.

768 C. Means of isolation. The local health department shall assess the situation, and in
769 consultation with the Office of Epidemiology, identify the least restrictive means of isolation that
770 effectively protects unexposed and susceptible individuals. The place of isolation selected shall
771 allow the most freedom of movement and communication with family members and other contacts
772 without allowing disease transmission to other individuals and shall allow the appropriate level of
773 medical care needed by isolated individuals to the extent practicable. The commissioner, in his

774 sole discretion, may order the isolated individual or individuals to remain in their residences, to
775 remain in another place where they are present, or to report to a place or places designated by
776 the commissioner for the duration of their isolation.

777 The commissioner's order of isolation shall be for a duration consistent with the known period
778 of communicability of the communicable disease of public health threat or, if the course of the
779 disease is unknown or uncertain, for a period anticipated as being consistent with the period of
780 communicability of other similar infectious agents. In the situation where an area is under
781 isolation, the duration of isolation shall take into account the transmission characteristics and
782 known or suspected period of communicability.

783 D. Delivery. The local health department shall deliver the order of isolation, or ensure its
784 delivery by an appropriate party such as a law-enforcement officer or health department
785 employee, to the affected individual or individuals in person to the extent practicable. If, in the
786 opinion of the commissioner, the scope of the notification would exceed the capacity of the local
787 health department to ensure individual notification in a timely manner, then print, radio, television,
788 Internet, and/or other available means shall be used to inform those affected.

789 E. Enforcement. ~~Upon finding that there is probable cause to believe that any individual or~~
790 ~~individuals who are subject to an order of isolation may fail or refuse to comply with such order,~~
791 ~~the commissioner in his sole discretion may include in the order a requirement that such individual~~
792 ~~or individuals are to be taken immediately into custody by law enforcement agencies and detained~~
793 ~~for the duration of the order of isolation or until the commissioner determines that the risk of~~
794 ~~noncompliance is no longer present.~~ For any individual or individuals identified as, or for whom
795 probable cause exists that he may be, in violation of any order of isolation, or for whom probable
796 cause exists that he may fail or refuse to comply with any such order, the enforcement authority
797 directed by the commissioner to law-enforcement agencies shall include but need not be limited
798 to the power to detain or arrest.

799 Any individual or individuals so detained shall be held in the least restrictive environment that
800 can provide any required health care or other services for such individual. The commissioner shall
801 ensure that law-enforcement personnel responsible for enforcing an order or orders of isolation
802 are informed of appropriate measures to take to protect themselves from contracting the disease
803 of public health threat.

804 F. Health status monitoring. The local health department shall monitor the health of those
805 under isolation either by regular telephone calls, visits, self-reports, or by reports of caregivers or
806 healthcare providers or by other means.

807 G. Essential needs. Upon issuance of an order of isolation to an individual or individuals by
808 the commissioner, the local health department shall manage the isolation, in conjunction with local
809 emergency management resources, such that individual essential needs can be met to the extent
810 practicable. Upon issuance of an order of isolation by the commissioner for an affected area,
811 existing emergency protocols pursuant to Chapter 3.2 (§ 44-146.13 et seq.) of Title 44 of the Code
812 of Virginia shall be utilized for mobilizing appropriate resources to ensure essential needs are
813 met.

814 H. Appeals. Any individual or individuals subject to an order of isolation or a court-ordered
815 confirmation or extension of any such order may file an appeal of the order of isolation in
816 accordance with the provisions of § 32.1-48.13 of the Code of Virginia. An appeal shall not stay
817 any order of isolation.

818 I. Release from isolation. Once the commissioner determines that an individual or individuals
819 no longer pose a threat to the public health, the order of isolation has expired, or the order of
820 isolation has been vacated by the court, the individual or individuals under the order of isolation
821 shall be released immediately. If the risk of an infected individual transmitting the communicable

822 disease of public health threat to other individuals continues to exist, an order of isolation may be
823 developed to extend the restriction prior to release from isolation.

824 J. Affected area. If the criteria in subsection A of this section are met and an area is known or
825 suspected to have been affected, then the commissioner shall notify the Governor of the situation
826 and the need to order isolation for the affected area during the known or suspected time of
827 exposure. In order for an affected area to be isolated, the Governor must declare a state of
828 emergency for the affected area.

829 If an order of isolation is issued for an affected area during the known or suspected time of
830 exposure, the commissioner shall cause the order of isolation to be communicated to the
831 individuals residing or located in the affected area. The use of multiple forms of communication,
832 including but not limited to radio, television, internet, and/or other available means, may be
833 required in order to reach the individuals who were in the affected area during the known or
834 suspected time of exposure.

835 The provisions for documentation, means of isolation, enforcement, health status monitoring,
836 essential needs, and release from isolation described above will apply to the isolation of affected
837 areas. Appropriate management of a disease of public health threat for an affected area may
838 require the coordinated use of local, regional, state, and national resources. In specifying one or
839 more affected areas to be placed under isolation, the objective will be to protect as many people
840 as possible using the least restrictive means. As a result, defining the precise boundaries and
841 time frame of the exposure may not be possible, or may change as additional information
842 becomes available. When this occurs, the commissioner shall ensure that the description of the
843 affected area is in congruence with the Governor's declaration of emergency and shall ensure
844 that the latest information is communicated to those in or exposed to the affected area.

845 **12VAC5-90-107. Quarantine.**

846 A. Application. The commissioner, in his sole discretion, may invoke the provisions of Article
847 3.02 (§ 32.1-48.05 et seq.) of Chapter 2 of Title 32.1 of the Code of Virginia and may order a
848 complete or modified quarantine of any individual or individuals upon a determination that:

- 849 1. Such individual or individuals are known to have been exposed to or are reasonably
850 suspected to have been exposed to a communicable disease of public health threat;
- 851 2. Exceptional circumstances render the procedures of Article 3.01 (§ 32.1-48.01 et seq.)
852 of Chapter 2 of Title 32.1 of the Code of Virginia to be insufficient, or the individual or
853 individuals have failed or refused to comply voluntarily with the control measures directed
854 by the commissioner in response to a communicable disease of public health threat; and
- 855 3. Quarantine is the necessary means to contain a communicable disease of public health
856 threat to which an individual or individuals have been or may have been exposed and thus
857 may become infected.

858 The commissioner, in his sole discretion, may also order the quarantine of an affected area if,
859 in addition to the above, the Governor has declared a state of emergency for such affected area
860 of the Commonwealth.

861 B. Documentation. For quarantine for a communicable disease of public health threat,
862 information about the infection or suspected infection; the individual, individuals, and/or affected
863 area; and the nature or suspected nature of the exposure shall be duly recorded by the local
864 health department, in consultation with the Office of Epidemiology. This information shall be
865 sufficient to enable documenting a record of findings and enable the commissioner to prepare a
866 written order of quarantine, including the information required in § 32.1-48.09 of the Code of
867 Virginia. In addition, sufficient information on individuals shall be maintained by the local health
868 department to enable appropriate follow-up of individuals for health status evaluation and
869 treatment as well as compliance with the order of quarantine.

870 The commissioner shall ensure that the protected health information of any individual or
871 individuals subject to the order of quarantine is disclosed only in compliance with state and federal
872 law.

873 C. Means of quarantine. The local health department shall assess the situation, and in
874 consultation with the Office of Epidemiology, shall recommend to the commissioner the least
875 restrictive means of quarantine that effectively protects unexposed and susceptible individuals.
876 The place of quarantine selected shall allow the most freedom of movement and communication
877 with family members and other contacts without allowing disease transmission to others.

878 The commissioner, in his sole discretion, may order the quarantined individual or individuals
879 to remain in their residences, to remain in another place where they are present, or to report to a
880 place or places designated by the commissioner for the duration of their quarantine.

881 The commissioner's order of quarantine shall be for a duration consistent with the known
882 incubation period of the communicable disease of public health threat or, if the incubation period
883 is unknown or uncertain, for a period anticipated as being consistent with the incubation period
884 for other similar infectious agents. In the situation where an area is under quarantine, the duration
885 of quarantine shall take into account the transmission characteristics and known or suspected
886 incubation period.

887 D. Delivery. The local health department shall deliver the order of quarantine, or ensure its
888 delivery by an appropriate party such as a law-enforcement officer or health department
889 employee, to the affected individual or individuals in person to the extent practicable. If, in the
890 opinion of the commissioner, the scope of the notification would exceed the capacity of the local
891 health department to ensure notification in a timely manner, then print, radio, television, Internet,
892 and/or other available means shall be used to inform those affected.

893 E. Enforcement. ~~Upon finding that there is probable cause to believe that any individual or~~
894 ~~individuals who are subject to an order of quarantine may fail or refuse to comply with such order,~~
895 ~~the commissioner in his sole discretion may include in the order a requirement that such individual~~
896 ~~or individuals are to be taken immediately into custody by law-enforcement agencies and detained~~
897 ~~for the duration of the order of quarantine or until the commissioner determines that the risk of~~
898 ~~and from noncompliance is no longer present.~~ For any individual or individuals identified as, or for
899 whom probable cause exists that he may be, in violation of any order of quarantine, or for whom
900 probable cause exists that he may fail or refuse to comply with any such order, the enforcement
901 authority directed by the commissioner to law-enforcement agencies shall include but need not
902 be limited to the power to detain or arrest.

903 Any individual or individuals so detained shall be held in the least restrictive environment that
904 can provide any required health care or other services for such individual. The commissioner shall
905 ensure that law-enforcement personnel responsible for enforcing an order or orders of quarantine
906 are informed of appropriate measures to take to protect themselves from contracting the disease
907 of public health threat.

908 F. Health status monitoring. The local health department shall monitor the health of those
909 under quarantine either by regular telephone calls, visits, self-reports, or by reports of caregivers
910 or healthcare providers or by other means. If an individual or individuals develop symptoms
911 compatible with the communicable disease of public health threat, then 12VAC5-90-103 would
912 apply to the individual or individuals.

913 G. Essential needs. Upon issuance of an order of quarantine to an individual or individuals by
914 the commissioner, the local health department shall manage the quarantine, in conjunction with
915 local emergency management resources, such that individual essential needs can be met to the
916 extent practicable. Upon issuance of an order of quarantine by the commissioner for an affected
917 area, existing emergency protocols pursuant to Chapter 3.2 (§ 44-146.13 et seq.) of Title 44 of

918 the Code of Virginia shall be utilized for mobilizing appropriate resources to ensure essential
919 needs are met.

920 H. Appeals. Any individual or individuals subject to an order of quarantine or a court-ordered
921 confirmation or extension of any such order may file an appeal of the order of quarantine in
922 accordance with the provisions of § 32.1-48.10 of the Code of Virginia. An appeal shall not stay
923 any order of quarantine.

924 I. Release from quarantine. Once the commissioner determines that an individual or
925 individuals are no longer at risk of becoming infected and pose no risk of transmitting the
926 communicable disease of public health threat to other individuals, the order of quarantine has
927 expired, or the order of quarantine has been vacated by the court, the individuals under the order
928 of quarantine shall be released immediately. If the risk of an individual becoming infected and
929 transmitting the communicable disease of public health threat to other individuals continues to
930 exist, an order of quarantine may be developed to extend the restriction prior to release from
931 quarantine.

932 J. Affected area. If the criteria in subsection A of this section are met and an area is known or
933 suspected to have been affected, then the commissioner shall notify the Governor of the situation
934 and the need to order quarantine for the affected area. In order for an affected area to be
935 quarantined, the Governor must declare a state of emergency for the affected area.

936 If an order of quarantine is issued for an affected area, the commissioner shall cause the order
937 of quarantine to be communicated to the individuals residing or located in the affected area. The
938 use of multiple forms of communication, including but not limited to radio, television, Internet,
939 and/or other available means, may be required in order to reach the individuals who were in the
940 affected area during the known or suspected time of exposure.

941 The provisions for documentation, means of quarantine, enforcement, health status
942 monitoring, essential needs, and release from quarantine described above will apply to the
943 quarantine of affected areas. Appropriate management of a disease of public health threat for an
944 affected area may require the coordinated use of local, regional, state, and national resources. In
945 specifying one or more affected areas to be placed under quarantine, the objective will be to
946 protect as many people as possible using the least restrictive means. As a result, defining the
947 precise boundaries and time frame of the exposure may not be possible, or may change as
948 additional information becomes available. When this occurs, the commissioner shall ensure that
949 the description of the affected area is in congruence with the Governor's declaration of emergency
950 and shall ensure that the latest information is communicated to those in or exposed to the affected
951 area.

952 **12VAC5-90-140. Procedure for preventing ophthalmia neonatorum.**

953 The physician, nurse, or midwife in charge of the infant's care after delivery of a baby shall
954 ensure that ~~one of the following is administered in each eye of that newborn baby as soon as
955 possible after birth: (i) two drops of a 1.0% silver nitrate solution; (ii) a 1-cm ribbon of 1.0%
956 tetracycline ophthalmic ointment; or (iii) a 1-cm ribbon of 0.5% erythromycin ophthalmic ointment~~
957 is administered in each eye of that newborn baby as soon as possible. This treatment shall be
958 recorded in the medical record of the infant.

959 **12VAC5-90-215. Schedule and criteria for and confirmation of blood lead testing and
960 information to be provided.**

961 A. Schedule for testing. Every child shall be tested to determine the blood lead level at 12
962 months and 24 months of age if the health care provider determines that the child meets any of
963 the criteria listed in subsection B of this section. Children 25 months through 72 months of age
964 who present for medical care and meet any of criteria of subsection B of this section shall also be
965 tested if they have either not previously been tested for blood lead level or were previously tested

966 but experienced a change since testing that has resulted in an increased risk of lead exposure
967 based on the criteria listed in subsection B of this section.

968 B. Criteria for testing.

- 969 1. The child is eligible for or receiving benefits from Medicaid or the Special Supplemental
970 Nutrition Program for Women, Infants and Children (WIC);
- 971 2. The child is living in or regularly visiting a house, apartment, dwelling, structure, or child
972 care facility built before ~~1960~~1950;
- 973 3. The child is living in or regularly visiting a house, apartment, dwelling, structure, or child
974 care facility built before 1978 that has (i) peeling or chipping paint or (ii) recent (within the
975 last six months) ongoing or planned renovations;
- 976 4. The child is living in or regularly visiting a house, apartment, dwelling, or other structure
977 in which one or more persons have blood lead testing yielding evidence of lead exposure;
- 978 5. The child is living with an adult whose job, hobby, or other activity involves exposure to
979 lead;
- 980 6. The child is living near an active lead smelter, battery recycling plant, or other industry
981 likely to release lead;
- 982 7. The child's parent, guardian, or other person standing in loco parentis requests the
983 child's blood be tested due to any suspected exposure; or
- 984 8. The child is a recent refugee or immigrant or is adopted from outside of the United
985 States.

986 C. Exceptions. A child who does not meet any of the schedule or criteria provided in
987 subsection A or B of this section is considered to be at low risk, and testing is not required but
988 may be conducted at the discretion of the health care provider. The testing requirement shall be
989 waived if the parent, guardian, or other person standing in loco parentis of a child objects to the
990 testing on the basis that the procedure conflicts with his religious tenets or practices.

991 D. Confirmation of blood lead levels. Blood lead level testing shall be performed on venous or
992 capillary blood. Tests of venous blood performed by a laboratory certified by the federal Centers
993 for Medicare & Medicaid Services in accordance with 42 USC § 263a, the Clinical Laboratory
994 Improvement Amendment of 1988 (CLIA-certified), are considered confirmatory. Tests of venous
995 blood performed by any other laboratory and tests of capillary blood shall be confirmed by a repeat
996 blood test, preferably venous, performed by a CLIA-certified laboratory. Such confirmatory testing
997 shall be performed in accordance with the following schedule:

- 998 1. Confirmatory testing is not required if the result of the capillary test is below CDC's
999 reference value.
- 1000 ~~1-2.~~ Within one to three months if the result of the capillary test is at or above the CDC's
1001 reference value and up to 9 micrograms of lead per deciliter of whole blood (µg/dL).
- 1002 ~~2-3.~~ Within one week to one month if the result of the capillary test is 10-44 µg/dL. The
1003 higher this test result, the more urgent the need for a confirmatory test.
- 1004 ~~3-4.~~ Within 48 hours if the result of the capillary test is 45-59 µg/dL.
- 1005 ~~4-5.~~ Within 24 hours if the result of the capillary test is 60-69 µg/dL.
- 1006 ~~5-6.~~ Immediately as an emergency laboratory test if the result of the capillary test is 70
1007 µg/dL or higher.

1008 E. Information to be provided. As part of regular well-check visits for all children, the health
1009 care provider shall make available to parents, guardians, or other persons standing in loco
1010 parentis information on the dangers of lead poisoning, potential sources of lead and ways to
1011 prevent exposure, and a list of available lead-related resources. When blood lead level testing is

1012 performed, the health care provider shall share the child's blood lead level test result with the
1013 child's parent, guardian, or other person standing in loco parentis and report to the local health
1014 department in accordance with the requirements of 12VAC5-90-80.

1015 **12VAC5-90-225. Additional data to be reported related to persons with active tuberculosis**
1016 **disease (confirmed or suspected).**

1017 A. Physicians and directors of medical care facilities are required to submit all of the following:

1018 1. An initial report to be completed when there are reasonable grounds to suspect that a
1019 person has active TB disease, but no later than when antituberculosis drug therapy is
1020 initiated. The reports must include the following: the affected person's name; age; date of
1021 birth; gender; address; pertinent clinical, radiographic, microbiologic and pathologic
1022 reports, whether pending or final; such other information as may be needed to locate the
1023 patient for follow-up; and name, address, and telephone number of the treating physician.

1024 2. A secondary report to be completed simultaneously or within one to two weeks following
1025 the initial report. The report must include: the date, method, and results of ~~tuberculin skin~~
1026 ~~test (TST)~~ tests for tuberculosis infection; the date and results of the initial and any follow-
1027 up chest radiographs; the dates and results of bacteriologic or pathologic testing, the
1028 antituberculosis drug regimen, including names of the drugs, dosages and frequencies of
1029 administration, and start date; the date and results of drug susceptibility testing; HIV
1030 status; contact screening information; and name, address, and telephone number of
1031 treating physician.

1032 3. Subsequent reports are to be made when updated information is available. Subsequent
1033 reports are required when: clinical status changes, the treatment regimen changes;
1034 treatment ceases for any reason; or there are any updates to laboratory results, treatment
1035 adherence, name, address, and telephone number of current provider, patient location or
1036 contact information, or other additional clinical information.

1037 4. Physicians and/or directors of medical care facilities responsible for the care of a patient
1038 with active tuberculosis disease are required to develop and maintain a written treatment
1039 plan. This plan must be in place no later than the time when antituberculosis drug therapy
1040 is initiated. Patient adherence to this treatment plan must be documented. The treatment
1041 plan and adherence record are subject to review by the local health director or his
1042 designee at any time during the course of treatment.

1043 5. The treatment plan for the following categories of patients must be submitted to the
1044 local health director or his designee for approval no later than the time when
1045 antituberculosis drug therapy is started or modified:

1046 a. For individuals who are inpatients or incarcerated, the responsible provider or facility
1047 must submit the treatment plan for approval prior to discharge or transfer.

1048 b. Individuals, whether inpatient, incarcerated, or outpatient, who also have one of the
1049 following conditions:

1050 (1) HIV infection.

1051 (2) Known or suspected active TB disease resistant to rifampin, rifabutin, rifapentine
1052 or other rifamycin with or without resistance to any other drug.

1053 (3) A history of prior treated or untreated active TB disease, or a history of relapsed
1054 active TB disease.

1055 (4) A demonstrated history of nonadherence to any medical treatment regimen.

1056 B. Laboratories are required to submit the following:

1057 1. Results of smears that are positive for acid fast bacilli.

- 1058 2. Results of cultures positive for any member of the Mycobacterium tuberculosis complex
1059 (i.e., *M. tuberculosis*, *M. bovis*, *M. africanum*) or any other mycobacteria.
- 1060 3. Results of rapid methodologies, including acid hybridization or nucleic acid
1061 amplification, which are indicative of *M. tuberculosis* complex or any other mycobacteria.
- 1062 4. Results of tests for antimicrobial susceptibility performed on cultures positive for
1063 ~~tubercle bacilli~~ *M. tuberculosis* complex.
- 1064 5. Results of tests for tuberculosis infection.
- 1065 ~~5.6.~~ Laboratories, whether testing is done in-house or referred to an out-of-state
1066 laboratory, shall submit a representative and viable sample of the initial culture positive
1067 for any member of the *M. tuberculosis* complex to the Virginia Division of Consolidated
1068 Laboratory Services or other laboratory designated by the board to receive such
1069 specimen.

1070 **12VAC5-90-280. Reporting of dangerous microbes and pathogens.**

1071 A. Definitions. The following words and terms when used in this part shall have the following
1072 meanings unless the context clearly indicates otherwise:

1073 "~~Biologic agent~~" means ~~any microorganism (including, but not limited to, bacteria, viruses,~~
1074 ~~fungi, rickettsiae, or protozoa), or infectious substance, or any naturally occurring, bioengineered,~~
1075 ~~or synthesized component of any such microorganism or infectious substance, capable of causing~~
1076 ~~death, disease, or other biological malfunction in a human, an animal, a plant, or other living~~
1077 ~~organism; deterioration of food, water, equipment, supplies, or material of any kind; or deleterious~~
1078 ~~alteration of the environment.~~

1079 "~~CDC~~" means ~~the Centers for Disease Control and Prevention of the U.S. Department of~~
1080 ~~Health and Human Services.~~

1081 "~~Diagnosis~~" means ~~the analysis of specimens for the purpose of identifying or confirming the~~
1082 ~~presence or characteristics of a select agent or toxin, provided that such analysis is directly related~~
1083 ~~to protecting the public health or safety.~~

1084 "~~Proficiency testing~~" means ~~a sponsored, time-limited analytical trial whereby one or more~~
1085 ~~analytes, previously confirmed by the sponsor, are submitted to the testing laboratory for analysis~~
1086 ~~and where final results are graded, scores are recorded and provided to participants, and scores~~
1087 ~~for participants are evaluated.~~

1088 "~~Responsible official~~" means ~~any person in charge of directing or supervising a laboratory~~
1089 ~~conducting business in the Commonwealth of Virginia. At colleges and universities, the~~
1090 ~~responsible official shall be the president of the college or university or his designee. At private,~~
1091 ~~state, or federal organizations, the responsible official shall be the laboratory director or a chief~~
1092 ~~officer of the organization or his designee.~~

1093 "~~Select agent or toxin~~" or "~~select agent and toxin~~" means all those biological agents or toxins
1094 as defined by federal regulations in 42 CFR Part 73, including Health and Human Services select
1095 agents and toxins and overlap select agents and toxins. "Dangerous microbes and pathogens"
1096 will be known as "select agents and toxins".

1097 "~~Toxin~~" means ~~the toxic material or product of plants, animals, microorganisms (including but~~
1098 ~~not limited to bacteria, viruses, fungi, rickettsiae, or protozoa); or infectious substances; or a~~
1099 ~~recombinant or synthesized molecule, whatever the origin and method of production; and includes~~
1100 ~~any poisonous substance or biological product that may be engineered as a result of~~
1101 ~~biotechnology or produced by a living organism; or any poisonous isomer or biological product,~~
1102 ~~homolog, or derivative of such a substance.~~

1103 "~~Verification~~" means ~~the process required to assure the accuracy, precision, and the analytical~~
1104 ~~sensitivity and specificity of any procedure used for diagnosis.~~

1105 ~~B. Administration. The dangerous microbes and pathogens will be known as "select agents~~
1106 ~~and toxins." The select agent and toxin registry will be maintained by the Virginia Department of~~
1107 ~~Health, Office of Epidemiology, Division of Surveillance and Investigation.~~

1108 ~~C. Reportable agents. The board declares the select agents and toxins and overlap select~~
1109 ~~agents and toxins outlined in 42 CFR Part 73 to be reportable and adopts it herein by reference~~
1110 ~~including subsequent amendments and editions. The select agents and toxins are to be reportable~~
1111 ~~by the persons enumerated in subsection F of this section.~~

1112 ~~D.B. Items to report. Each report shall be made on a form determined by the department and~~
1113 ~~shall contain the following: name, source and characterization information on select agents and~~
1114 ~~toxins and quantities held; objectives of the work with the agent; location (including building and~~
1115 ~~room) where each select agent or toxin is stored or used; identification information of persons~~
1116 ~~with access to each agent; identification information of the person in charge of each of the agents;~~
1117 ~~and the name and address of the laboratory and the name, position and identification information~~
1118 ~~of one responsible official as a single point of contact for the organization. The report shall also~~
1119 ~~indicate whether the laboratory is registered with the CDC Select Agent Program and may contain~~
1120 ~~additional information as required by 42 CFR Part 73 or the department.~~

1121 ~~E.C. Timing of reports. Reports shall be made to the department within seven calendar days~~
1122 ~~of submission of an application to the CDC Select Agent Program. By January 31 of every year,~~
1123 ~~laboratoriesthe responsible official at a laboratory as designated by the federal select agent~~
1124 ~~program shall provide a written update to the department, which shall include a copy of the federal~~
1125 ~~registration certificate received through the CDC Select Agent ProgramDivision of Surveillance~~
1126 ~~and Investigation in the Office of Epidemiology containing the information specified in subsection~~
1127 ~~B.~~

1128 ~~In the event that a select agent or toxin that has previously been reported to the department~~
1129 ~~is destroyed, a copy of federal forms addressing the destruction of the select agent or toxin must~~
1130 ~~be submitted to the department within seven calendar days of submission to the CDC Select~~
1131 ~~Agent Program.~~

1132 ~~In the event that a select agent or toxin, or a specimen or isolate from a specimen containing~~
1133 ~~a select agent or toxin, has previously been reported to the department and is subsequently~~
1134 ~~transferred to a facility eligible for receiving the items, a copy of federal forms addressing the~~
1135 ~~transfer of the select agent or toxin must be submitted to the department within seven calendar~~
1136 ~~days of submission to the CDC Select Agent Program.~~

1137 ~~In the event of a suspected release, loss, or theft of any select agent or toxin, the responsible~~
1138 ~~official at a laboratory as designated by the federal select agent program shall make a report to~~
1139 ~~the department immediately by the most rapid means available, preferably by telephone. The~~
1140 ~~report shall be submitted to the Division of Surveillance and Investigation in the Office of~~
1141 ~~Epidemiology. The rapid report shall be followed up by a written report within seven calendar days~~
1142 ~~and shall include the following information:~~

- 1143 1. The name of the biologic agent and any identifying information (e.g., strain or other
1144 characterization information);
- 1145 2. An estimate of the quantity released, lost, or stolen;
- 1146 3. An estimate of the time during which the release, loss, or theft occurred; and
- 1147 4. The location (building, room) from or in which the release, loss, or theft occurred. The
1148 report may contain additional information as required by 42 CFR Part 73 or the
1149 department.

1150 ~~If a release has occurred, the report shall also include the nature, environment, and location~~
1151 ~~of the release; number, names, and position of exposed individuals; and actions taken as a result~~
1152 ~~of the release.~~

1153 The department shall be notified in writing of any change to information previously submitted
1154 to the department. If a new application or an amendment to an existing application is filed with
1155 the CDC Select Agent Program, a copy of the application or amendment shall be submitted to the
1156 department within seven calendar days of submission to the CDC Select Agent Program.

1157 ~~F. These required to report. The laboratory director shall be responsible for annual reporting~~
1158 ~~of select agents and toxins to the Virginia Department of Health and for the reporting of any~~
1159 ~~changes within the time periods as specified within these regulations. Such reports shall be made~~
1160 ~~on forms to be determined by the department. Any person making such reports as authorized~~
1161 ~~herein shall be immune from liability as provided by § 32.1-38 of the Code of Virginia.~~

1162 ~~G. Exemption from reporting. A person who detects a select agent or toxin for the purpose of~~
1163 ~~diagnosing a disease, verification, or proficiency testing and either transfers the specimens or~~
1164 ~~isolates containing the select agent or toxin to a facility eligible for receiving them or destroys~~
1165 ~~them on site is not required to make a report except as required by 12VAC5-90-80 and 12VAC5-~~
1166 ~~90-90. Proper destruction of the agent shall take place through autoclaving, incineration, or by a~~
1167 ~~sterilization or neutralization process sufficient to cause inactivation. The transfer or destruction~~
1168 ~~shall occur within seven calendar days after identification of a select agent or toxin used for~~
1169 ~~diagnosis or testing and within 90 calendar days after receipt for proficiency testing.~~

1170 ~~Any additional exemptions from reporting under 42 CFR Part 73, including subsequent~~
1171 ~~amendments and editions, are also exempt from reporting under this regulation; however, the~~
1172 ~~department shall be notified of the exemption by submitting a copy of federal forms addressing~~
1173 ~~the exemption within seven calendar days of submission to the CDC Select Agent Program.~~

1174 ~~H.D. Release of reported information. Reports submitted to the select agent and toxin registry~~
1175 ~~shall be confidential and shall not be a public record pursuant to the Freedom of Information Act,~~
1176 ~~regardless of submitter. Release of information on select agents or toxins shall be made only by~~
1177 ~~order of the State Health Commissioner to the CDC and state and federal law-enforcement~~
1178 ~~agencies in any investigation involving the release, theft, or loss of a select agent or toxin required~~
1179 ~~to be reported to the department under this regulation. Any person making such reports as~~
1180 ~~authorized herein shall be immune from liability as provided by § 32.1-38 of the Code of Virginia.~~

1181 **12VAC5-90-370. Reporting of healthcare-associated infections.**

1182 ~~A. Reportable infections. Facilities Health care facilities that report data into the Centers for~~
1183 ~~Disease Control and Prevention's National Healthcare Safety Network (NHSN) for as a~~
1184 ~~requirement of the Centers for Medicare and Medicaid Services Hospital Inpatient Quality~~
1185 ~~Reporting Program shall share the data, through the NHSN, with the department.~~

1186 ~~B. Liability protection and data release. Any person making such report as authorized herein~~
1187 ~~shall be immune from liability as provided by § 32.1-38 of the Code of Virginia. Infection rate data~~
1188 ~~may be released to the public by the department upon request. Data shall be aggregated to~~
1189 ~~ensure that no individual patient may be identified.~~

1190 FORMS (12VAC5-90)

1191 FORMS (12VAC5-90)

1192 [Confidential Morbidity Report, Epi-1 \(rev. 10/2011\)](#)

1193 [Virginia Cancer Registry Reporting Form \(rev. 1/1998\)](#)



COMMONWEALTH of VIRGINIA

Department of Health

P O BOX 2448

RICHMOND, VA 23218

M. NORMAN OLIVER, MD, MA
STATE HEALTH COMMISSIONER

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

MEMORANDUM

DATE: November 3, 2021

TO: Virginia State Board of Health

FROM: Julie Henderson, Office of Environmental Health Services

SUBJECT: Fast Track Revision - Sewage Handling and Disposal Regulations 12VAC5-610

The Sewage Handling and Disposal Regulations (the Regulations) establish the minimum site evaluation, design, and construction requirements for onsite sewage (septic) systems installed in the Commonwealth. The Board of Health (the Board) has not made significant revisions to the Regulations since 2000. On December 16, 2020, the Virginia Department of Health (the Department) began a process to make several non-controversial updates to the Regulations. Since that time, the Department has developed six draft versions of the proposed fast-track amendments. Each version was shared with the Sewage Handling and Disposal Advisory Committee (SHADAC) and Department staff for feedback, with draft proposals and feedback received from stakeholders being shared in SHADAC meeting minutes and on the agency website.

The intent of this planned regulatory action is to establish minimum design and installation criteria for conveyance pump stations and dispersal areas utilizing treated effluent (TL-2 and TL-3). Historically, the criteria were addressed via agency Guidance Memorandum and Policies (GMP). These types of designs were addressed piecemeal through product specific approvals beginning in 1995 and culminated in a comprehensive policy in 2009, GMP 147, which established procedures for treatment units to receive general approval, hydraulic loading rates for alternative onsite sewage systems, and design and installation criteria for the dispersal areas through a series of blanket variances to 12VAC5-610.

Upon approval by the Board of Health, the proposed fast-track 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 public comment period. The regulations will become effective 15 days after the close of the public comment period. If 10 or more members of the public comment, then the fast-track regulation will serve as the Notice of Intended Regulatory Action and the standard rulemaking process is followed to promulgate the regulations.



townhall.virginia.gov

Fast-Track Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-610
VAC Chapter title(s)	Sewage Handling and Disposal Regulations
Action title	Addition of Design Elements for Treated Effluent - Fast Track
Date this document prepared	11 03 2021

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

Brief Summary

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

The purpose of this fast track amendment to the Sewage Handling and Disposal Regulations is to establish minimum design and installation criteria for conveyance pump stations and dispersal areas utilizing treated effluent (TL-2 and TL-3). Historically, the criteria were addressed via agency Guidance Memorandum and Policies (GMP). These types of designs were addressed piecemeal through product specific approvals beginning in 1995 and culminated in a comprehensive policy in 2009, GMP 147, which established procedures for treatment units to receive general approval, hydraulic loading rates for alternative onsite sewage systems, and design and installation criteria for the dispersal areas through a series of blanket variances to 12VAC5-610.

GMP 147 was rescinded following promulgation of the Regulations for Alternative Onsite Sewage Systems (12VAC5-613 AOSS Regulations). However, those regulations are performance regulations and therefore did not include the specific design and installation criteria found in GMP 147. To address this gap, the Virginia Department of Health (VDH) issued GMP 2016-03, noted that designers could continue to use design guidance from rescinded GMP 147 which would be in compliance with the AOSS Regulations. Parts of the rescinded GMP are superseded by 12VAC5-613 so there is conflicting and extraneous information that makes it confusing as a definitive reference. In working to resolve the confusion, VDH determined that moving the policy into regulation was necessary to resolve the discrepancies and confusion and also to provide clear design instruction and authority to licensed professionals in Virginia.

The proposed fast track amendments seek to incorporate the design elements from GMP 147, with appropriate revisions based on discussion with stakeholders. The fast track includes necessary definitions and modifies procedural requirements for these designs to conform with those allowed under GMP 147 and to recognize authorizations allowed to licensed individuals through §§54.1-402.A.11. Relevant design criteria for the various dispersal methods using TL-2 and TL-3 effluent are provided. These criteria provide relief from certain provisions in the existing 12VAC5-610 in recognition of the higher quality effluent. The amendments also include updates stakeholders agreed would be noncontroversial, including updates to pump designs to include pumps integral to a treatment system, wording to define how to characterize a seasonal water table, and the physical location of control panels.

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.

"GMP" means Guidance Memorandum and Policies

"Effluent" means treated wastewater

"Onsite Soil Evaluator" is a designer licensed by the Department of Professional and Occupation Regulation to design onsite sewage systems within the limits of the license for size complexity of the system.

"TL-2" means treatment level 2 which is equivalent to a final effluent quality of less than or equal to 30 mg/l 5 Day Biochemical Oxygen Demand and 30 mg/l Total Suspended Solids

"TL-3" means treatment level 3 which is equivalent to a final effluent quality of less than or equal to 10 mg/l 5 Day Biochemical Oxygen Demand and 10 mg/l Total Suspended Solids

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.

- 1) December 10, 2021.
- 2) Virginia Department of Health.
- 3) Addition of Design Elements for Treated Effluent Fast Track – Sewage Handling and Disposal Regulations.

Mandate and Impetus

Identify the mandate for this regulatory change and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, or board decision). For purposes of executive branch review, “mandate” has the same meaning as defined in Executive Order 14 (as amended, July 16, 2018), “a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part.”

As required by Virginia Code § 2.2-4012.1, also explain why this rulemaking is expected to be noncontroversial and therefore appropriate for the fast-track process.

There are two classes of designers licensed in Virginia to design onsite wastewater treatment systems: onsite soil evaluators and professional engineers. Onsite soil evaluators (OSEs) are limited by Virginia Code §§54.1-402.A.11 to certain size and types of designs. One limitation is that OSEs can only use “packaged equipment, such as equipment of catalogued standard design that has been coordinated and tested by the manufacturer, and complies with all applicable codes...” By moving these design criteria into regulation, OSEs can clearly access the regulation for the design and eliminate any potential conflict that may exist with the referenced Code section. Currently, OSEs use “packaged equipment” approved via agency policy.

VDH presented a first draft of the amendments to the Sewage Handling and Disposal Regulation Advisory Committee (SHADAC) in December 2020. Since then VDH has produced six (6) additional drafts and presented them to the SHADAC. Comments were collected from SHADAC, VDH staff, and the public throughout the process. The drafts and comments are posted on the VDH [website here](#). Presentations were also made to VDH staff and to the Virginia Onsite Wastewater Recycling Association. VDH has worked with the SHADAC to create a regulation that has stakeholder support.

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.

- (1) Virginia Department of Health
- (2) Title 32.1 of the Code of Virginia, and specifically §§ 32.1-12 and 32.1-164, provide that the State Board of Health has supervision and control over the safe and sanitary collection, conveyance, transportation, treatment, and disposal of sewage by onsite sewage systems and alternative discharging sewage systems, and treatment works as they

affect the public health and welfare. Pursuant to §2.2-4012.1 of the Code of Virginia, rules that are expected to be noncontroversial may be promulgated or repealed in accordance with the process set out in that section.

Purpose

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

The purpose of this fast track amendment to the Sewage Handling and Disposal Regulations is to establish minimum design and installation criteria for dispersal areas receiving treated wastewater. The Virginia Department of Health (VDH) and stakeholders have used design criteria contained in policy to ensure designs are protective of public health and the environment. While this process has allowed for permitting and design of such systems, incorporation of these criteria into the regulations is necessary to ensure clarity of design and installation criteria. VDH worked closely with the SHADAC to review existing guidance for these designs to ensure previous guidance was still appropriate, and to make improvements where necessary for inclusion in the proposed fast track. The SHADAC includes representation from a wide range of program stakeholders, and based on feedback from the SHADAC, VDH believes the proposed revisions will be noncontroversial.

The proposed changes are essential to protect the public health because there is no clear design criteria in the Regulations, and the original guidance are superseded by the Regulations for Alternative Onsite Sewage Systems (12VAC5-613). The confusion can lead to conflicts over designs submitted at a minimum and, more importantly, designs that are not as protective of public health being installed due to the ambiguity.

The proposed changes address design ambiguity and design authority by clearly spelling out the design requirements for systems utilizing TL-2 and TL-3 effluent.

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 proposed amendments modify the formal plan requirements for designs that meet the authorization limits for OSE designs under §§54.1-402.A.11. New definitions are added for wastewater treatment levels and others related to the addition of the new dispersal area requirements. Of primary importance are modifications to trench and elevated sand mound design criteria when treated wastewater is applied as well as the addition of a new dispersal method, pads, which are not currently in the regulations. The amendments also include revisions to the section on pumps to clarify different standards for pumps integral to treatment systems and conveyance pumps for TL-2 or TL-3 effluent systems as compared to pumps dispersing septic tank wastewater from conventional systems.

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 the proposed amendments provide for homeowners, onsite sewage system designers, onsite sewage system installers and VDH is that they provide clarity of design and installation criteria for dispersal systems receiving TL-2 and TL-3 by shifting them from policy to regulations. Moving the design criteria into regulation maintains the authority of OSEs to utilize such designs as allowed by their licensure under §§54.1-402.A.11 and maintains the cost effective nature of an owner to hire an OSE rather than the professional engineer for routine standard designs. This does create a disadvantage to the agency and stakeholders in that future changes deemed necessary cannot be expedited quickly by agreed upon updates to guidance documents. The proposed amendments also provide an advantage for designers and system manufacturers by establishing clear criteria for pumps integral to treatment. This will help reduce any confusion with pump requirements contained in the regulations that were intended for pumps moving raw or minimally treated wastewater for dispersal, which is a different purpose and has different minimum requirements.

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 federal requirements, other than non-enforceable general guidance, addressing the design and construction of onsite sewage systems.

Agencies, Localities, and Other Entities Particularly Affected

Identify any other state agencies, localities, or other entities particularly affected by the regulatory change. "Particularly affected" are those that are likely to bear any identified disproportionate material impact which would not be experienced by other agencies, localities, or entities. "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulation or regulatory change are most likely to occur. If no agency, locality, or entity is particularly affected, include a specific statement to that effect.

Other State Agencies Particularly Affected

Department of Environmental Quality, Department of Professional and Occupational Regulations, Department of Housing and Community Development.

Localities Particularly Affected

The regulations apply equally in all localities throughout the Commonwealth.

Other Entities Particularly Affected

Onsite sewage system owners, onsite soil evaluators, professional engineers, onsite sewage system installers, onsite sewage system operators, system manufacturers, home builders, and realtors.

Economic Impact

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

Impact on State Agencies

<p><i>For your agency:</i> projected costs, savings, fees or revenues resulting from the regulatory change, including: a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources</p>	<p>VDH does not anticipate any significant additional costs or savings as a result of the proposed amendments. The amendments do not affect fees or revenues, as those are addressed in the Regulations Governing Application Fees for Construction Permits for Onsite Sewage Disposal Systems and Private Wells (12VAC5-620).</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>VDH does not anticipate any additional costs or savings for other state agencies.</p>
<p><i>For all agencies:</i> Benefits the regulatory change is designed to produce.</p>	<p>The benefit of the regulations is that it improves clarity of design criteria. This is not anticipated to impact agency cost or savings.</p>

Impact on Localities

<p>Projected costs, savings, fees or revenues resulting from the regulatory change.</p>	<p>VDH does not anticipate any additional costs or savings for localities.</p>
<p>Benefits the regulatory change is designed to produce.</p>	<p>The designs permitted by the proposed amendments can be permitted today via agency policy. Therefore, VDH does not anticipate any economic benefit to localities.</p>

Impact on Other Entities

<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>System owners, onsite soil evaluators, professional engineers, onsite sewage system installers, and onsite sewage system operators all currently rely upon agency policy for these alternative onsite sewage systems dispersal area designs, and would thus rely on the proposed amendments moving forward.</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>VDH receives approximately 1,200 designs each year for alternative systems. Those systems are designed by onsite soil evaluators and professional engineers. Over the past year 197 onsite soil evaluators, and 90 professional engineers have submitted onsite sewage system designs to VDH. There are approximately 354 alternative onsite sewage system installers in the Commonwealth, that could potentially install alternative systems, and 244 alternative onsite sewage system operators that could potentially maintain alternative systems.</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>The designs permitted by the proposed amendments can be permitted today via agency policy. The goal of moving the policy into regulation is to maintain the ability for designers to continue to utilize such designs by eliminating any ambiguity as to the authority for the designs. Therefore, there is no anticipated increase in the cost of reporting, recordkeeping, or other administrative cost for small businesses. One modification from current agency policy to the proposed amendments is an increase in the depth of cover over dispersal systems receiving treated wastewater from 4 inches to 6 inches of cover. This is anticipated to have an average increased development cost of less than \$500 for alternative system designs that require soil cover be brought in. However, most designers already utilize 6 inches or more of cover, meaning the amendments would not impact those designs. The proposed amendments are not anticipated to have an impact on the purchase of equipment or services, or time to comply with requirements, and will not impact fees.</p>
<p>Benefits the regulatory change is designed to produce.</p>	<p>The proposed amendments are intended to provide clarity to the requirements for the design and installation of TL-2 and TL-3 dispersal systems, with the goal of reducing the need for designers to amend design plans or VDH to deny permit applications. The proposed amendments include updates to pump designs to include pumps integral to treatment units, creation of a new dispersal category of pads, clarification of the distinction between pads and sand mounds, and minimum design criteria for trenches receiving treated effluent, which should also reduce design changes and denials.</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.

The original GMP 147 has been superseded in part by 12VAC5-613 which created performance requirements for alternative onsite sewage systems. 12VAC5-613 did not include the specific design criteria for alternative onsite sewage systems found in the GMP. The Agency and private sector have been relying on a rescinded policy. The language in the policy is somewhat confusing and it relied on blanket variances to the Sewage Handling and Disposal Regulations. Moving the pertinent parts of the policy into regulation will codify the requirements, eliminate confusion, and provide a firm design basis for both professional engineers and OSEs. There is no alternative to a regulatory amendment.

Regulatory Flexibility Analysis

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

The intent of the Fast Track action is to maintain flexibility for designs and reduce confusion for owners, designers, manufacturers, installers, operators, and VDH. This will help to streamline application review times and reduce denials saving owners time and money.

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.

As required by § 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 Virginia Department of Health is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal 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 Marcia Degen, VDH – 5th floor, 109 Governor St., Richmond VA 23219; phone 804-387-1883; fax 804-864-7454; or email Marcia.degen@vdh.virginia.gov. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

Detail of Changes

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

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

Table 1: Changes to Existing VAC Chapter(s)

Current chapter-section number	New chapter-section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
12VAC5-610-120		Definitions	Adding 5 definitions. Three are being copied from 12VAC5-613 for Treatment Level 2 effluent, Treatment Level 3 effluent, and Treatment unit or Treatment system. Two new definitions are added for infiltrative surface and working volume. The new definitions provide clarity and ready reference for the proposed amendments.
12VAC5-610-250		Formal plans and specifications are required for certain complexity and size of system.	Formal plans and specifications are waived for designs less than or equal to 1000 gallons per day that are exempt from license requirements for professional engineers under §§54.1-402.A.11. OSEs are provided design

			authority for defined systems. For those systems that OSEs are allowed to design, formal plans and specifications are not required. This has been allowed through a rescinded policy. Moving this into regulation will allow this cost saving practice to continue.
12VAC5-610-880.B		Design standards for pumps, pump stations, and force mains pumping raw or septic tank effluent are defined.	880.B.6 allows for vertical turbine and suction lift pumps to be used. 880.B.7 is modified to require that control panels be located to allow for working access. Stakeholders agree that vertical turbine and suction lift pumps are viable alternatives to the current centrifugal pumps. Stakeholders requested that control panel access be addressed.
	12VAC5-880.C	None	Provides criteria for pumps and pump stations that move treated wastewater to a dispersal system. Because these are dealing with water with very little solids, some of the criteria for raw sewage pump stations do not apply. This section allows a reduction in force main velocity and allows for emergency storage volume to be provided in a treatment tank which will provide greater design flexibility. It clarifies that standards for alarms, valves, access, controls, etc. are maintained.
	12VAC5-610-880.D.	None	Recognizes that pumps that are integral to treatment systems (units) cannot be held to the same design criteria as a raw sewage pump station. This will avoid confusion by staff and designers of trying to apply inappropriate criteria to these pumps.
12VAC5-610-950.C & C1		C. States that a perched water table is indicated by free standing water, gray mottling or coloration C1 states that a lateral groundwater interceptor shall extend a distance of 10 feet on either side of the soil absorption area.	C. The science of identifying perched water tables through soil coloration has advanced and this statement has been updated to use current soil science terminology of 'free standing water, gray mottlings, or redoximorphic features'. This will lead to more accurately defining perched water tables leading to better designs that are more protective of public health. C1 has created confusion and is clarified by saying 'shall extend for a distance of 10 feet on <u>both</u> sides of the absorption area'.

			The minor changes are supported by stakeholders as correcting outdated or confusing language in the regulation.
12VAC5-610-950.D & Table 5.4		Contains loading rates for absorption trenches	When this section was written, loading rates were only supplied for septic tank effluent but it was not stated as such. The section tag and the title of Table 5.4 have been modified to clarify that this section and table applies to systems receiving septic tank effluent.
	12VAC5-610-950.K	None	<p>Provides installation criteria for trenches receiving TL-2 and TL-3. This section provides relief from the current regulation in that it reduces the amount of soil cover required from 12 inches to 6 inches; eliminates the increase in trench depth with slope; and clarifies the sidewall depth requirement for trenches. This section maintains the minimum soil dispersal area of 400 square feet for a single family residential dwelling.</p> <p>The reduction in soil cover is a saving from the original regulation, however GMP 147 had reduced that requirement to 4 inches. After discussions with stakeholders, most designers are using at least 6 inches and only one commenter objected to the change from 4 to 6 inches.</p>
	12VAC5-610-950 Table 5.5	None	<p>Creates soil loading rates for TL-2 and TL-3 effluent for various dispersal systems.</p> <p>The increased rates have been used since approximately 2009 when GMP 147 was issued. 12VAC5-613 incorporated a very minimal loading rate chart as it was intended to be a performance regulation utilized primarily by engineers. The expanded Table 5.5 gives clear direction to OSEs and engineers on loading rates for various types of dispersal systems. Engineers can still design under 12VAC5-613 and are not required to follow Table 5.5.</p>
12VAC5-610-960		This section sets standards for elevated sand mounds receiving septic tank effluent. It references an outdated design manual.	The revisions update the design reference for mounds receiving septic tank effluent; eliminates a recordation requirement; eliminates the statement that formal plans are required as that is covered in section 250; eliminates the requirement that VDH be notified of work start including delivery of materials; reiterates the minimum size of 400 square feet for any single family

			<p>residential system. A statement is added to clarify the distinction between a pad and a mound.</p> <p>These changes eliminate items that cost money and time and that add no value to a project from a public health standpoint.</p>
	12VAC5-610-960.E.	None	<p>This new language provides design criteria for mounds receiving TL-2 or TL-3 effluent including referencing Table 5.5 for loading rates; setting a minimum sand depth of 6 inches (reduced from 12 inches for septic tank effluent); the soil cover is reduced to 6 inches; and allows for manufacturer supported designs that deviate from the requirement for pressure dosing.</p> <p>The addition of the design criteria will create clarity. The policy used the term pad and mound interchangeably to some degree and it was unclear which requirements applied to which type of system. This language clearly spells out what is required for a mound system.</p>
	12VAC5-610-966	None	<p>This new section provides design criteria for pads. Pads do not currently exist in the regulation and were only found in policy. In reviewing the policy, stakeholders found that some of the requirements were arbitrary. The new section here removes the arbitrary limits of a maximum size for a pad and allows for mixing of pads and trenches. It clarifies that all pads must be dosed due to the nature of the level bottom of the pad. Language was added to explain that pads are oriented parallel to the natural surface topographic contours and a tolerance for 'level' was added.</p> <p>The policy suggested that pads could be put on the surface of the ground. That was not the intention and in practice it does not work and breakouts of sewage can occur. The new language clarifies the minimum sidewall depth for a pad (8 inches) and provides a minimum center to center spacing for piping. There is an allowance for deviations from some criteria for manufacturer supported designs that have been tested and approved.</p>

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

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

New chapter-section number	New requirements	Other regulations and law that apply	Intent and likely impact of new requirements

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

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

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

1 **Project 6961 - Fast-Track**

2 **Department Of Health**

3 **Fast Track 12VAC5-610 - Update of the Sewage Handling and Disposal Regs to**
4 **incorporate design elements of GMP 147**

5 **12VAC5-610-120. Definitions.**

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

8 "Agent" means a legally authorized representative of the owner.

9 "Alluvial soil" means a soil developing from recently deposited alluvium and exhibiting
10 essentially no horizon development or modification of the recently deposited materials.

11 "Alluvium" means mineral materials, either weathered or unweathered, that are transported
12 by flowing water and deposited or redeposited in a flood-plain or marine terrace.

13 "Aquifer" means water-bearing portion of a geologic formation that transmits water.

14 "Biochemical oxygen demand, five-day" or "BOD₅" means the quantitative measure of the
15 amount of oxygen consumed by bacteria while stabilizing, digesting, or treating biodegradable
16 organic matter under aerobic conditions over a five-day incubation period; BOD₅ is expressed in
17 milligrams per liter (mg/l).

18 "Certification letter" means a letter issued by the commissioner, in lieu of a construction
19 permit, which identifies a specific site and recognizes the appropriateness of the site for an
20 onsite wastewater disposal system.

21 "Colluvial soil" means a soil developing from recently deposited colluvium and exhibiting
22 essentially no horizon development or modification of the recently deposited materials.

23 "Colluvium" means an accumulation of soil material, or a mixture of stone fragments and soil
24 material, deposited at the base of slopes or in depressional areas, primarily by gravity.

25 "Commissioner" means the State Health Commissioner or his subordinate who has been
26 delegated powers in accordance with subdivision 2 of 12VAC5-610-40.

27 "Cr horizon" means weathered or soft bedrock and is used to indicate root restrictive layers
28 or bedrock or saprolite.

29 "Dilution area" means the land immediately adjacent to and down gradient, in the direction of
30 ground water flow, from a mass sewage disposal system, which is provided for the purpose of
31 diluting nitrogen, or other nutrients occurring in wastewater, with ambient ground water, in order
32 to assure compliance with nutrient standards contained in this chapter.

33 "District health department" means a consolidation of local health departments as authorized
34 in § 32.1-31 C of the Code of Virginia.

35 "Division" means the Division of Onsite Sewage and Water Services, Office of
36 Environmental Health Services, State Health Department or its administrative successor.

37 "Existing construction" (with failing sewage disposal systems) means an existing structure
38 where the sewage disposal system serving the structure has failed or is currently in violation of
39 state law or regulations and requires correction.

40 "General approval" means approval granted to systems which are proven and tested in
41 accordance with Article 2 (12VAC5-610-441 et seq.) of Part II of this chapter.

42 "Grandfathered lot" means:

43 1. Any lot upon which no permit has been issued and which is in a subdivision approved by
44 the department prior to July 1, 2000, in accordance with a local subdivision ordinance. Individual
45 lots may or may not have been evaluated; or

46 2. Any lot, parcel, or portion thereof with a previously issued permit or a specific written
47 approval (not including a certification letter) from the department.

48 "Gray color" means a chroma-2 or less on the Munsell Color Chart.

49 "Impervious strata" means soil or soil materials with an estimated or measured percolation
50 rate in excess of 120 minutes per inch.

51 "Infiltrative surface" means the designated interface where effluent moves from distribution
52 pipng, media, and fill to natural soil.

53 "Local health department" means a branch of the State Health Department established in
54 each city and county in accordance with § 32.1-30 of the Code of Virginia.

55 "Mass sewage disposal system" means a sewage disposal system or systems which will
56 discharge effluent to a single absorption area or multiple absorption areas with or without
57 combined flows, such that the loading rate applied to any acre, as determined by the
58 department, exceeds 1,200 gallons per day.

59 "Mineral soil" means a soil consisting predominantly of, and having its properties determined
60 predominantly by, mineral matter. A mineral soil usually contains less than 20% organic matter,
61 but it may contain an organic surface layer up to 12 inches thick.

62 "New construction" means construction of a building for which a building permit is required.

63 "Office" means the Office of Environmental Health Services, State Health Department.

64 "Owner" means the Commonwealth or any of its political subdivisions, including sanitary
65 districts, sanitation district commissions and authorities, any individual, any group of individuals
66 acting individually or as a group, or any public or private institution, corporation, company,
67 partnership, firm or association which owns or proposes to own a sewerage system or treatment
68 works.

69 "Person" means an individual, corporation, partnership, association or any other legal entity.

70 "Previously issued permit" means any permit issued prior to July 1, 2000, and in accordance
71 with the regulations in effect at the time the permit was issued. There is no distinction between
72 an expired permit and one that has been continually renewed.

73 "Pump and haul" means any unusual circumstance wherein sewage is permitted to be
74 transported by vehicle to a point of disposal. The term "pump and haul" includes all facilities and
75 appurtenances necessary to collect and store the sewage for handling by a contractor having a
76 valid sewage handling permit.

77 "Rock" or "bedrock" means continuous, coherent, lithologic material that has relative
78 hardness depending on the degree of weathering. Bedrock has characteristics such as strike,
79 dip, jointing, and lithological compositions. Structure and water movement are rock controlled.
80 Bedrock grinds with an auger, and mechanical penetration is more difficult or prevented as the
81 material gets harder.

82 "Saprolite" means material weathered from igneous or metamorphic rock, without soil
83 structure, and with remnant structure and fabric of the parent rock which is soft in place and can
84 be penetrated easily with an auger.

85 "Secondary effluent" means effluent treated to reduce five-day biochemical oxygen demand
86 to 30 mg/l or less, total suspended solids to 30 mg/l or less, and fats, oils, and grease to less
87 than 5 mg/l.

88 "Septic tank effluent" means effluent characterized by a five-day biochemical oxygen
89 demand between 120 and 200 mg/l; total suspended solids between 70 and 150 mg/l; fats, oils,

90 and grease of 30 mg/l or less; and having no other toxic, hazardous, or constituents not
91 routinely found in residential wastewater flows.

92 "Septage" means the mat of grease and scum on the surface of septic tanks, the
93 accumulated sludge at the bottom of tanks and the sewage present at the time of pumping.

94 "Sewage" means water-carried and nonwater-carried human excrement, kitchen, laundry,
95 shower, bath or lavatory wastes separately or together with such underground, surface, storm or
96 other water and liquid industrial wastes as may be present from residences, buildings, vehicles,
97 industrial establishments or other places.

98 "Sewage disposal system" means a sewerage system or treatment works designed not to
99 result in a point source discharge.

100 "Sewage handler" means any person who removes or contracts to remove and transports by
101 vehicle the contents of any septic tank, sewage treatment plant, privy, holding tank, portable
102 toilet or any sewage, septage or sewage sludges which have been processed to meet
103 acceptable treatment standards as defined in this chapter or the Sewage Regulations (12VAC5-
104 580-10 et seq.).

105 "Sewage handling" means the vehicular conveyance of sewage (See "Transportation" in §
106 32.1-163 of the Code of Virginia).

107 "Sewerage system" means pipe lines or conduits, pumping stations and force mains and all
108 other construction, devices and appliances appurtenant thereto, used for the collection and
109 conveyance of sewage to a treatment works or point of ultimate disposal.

110 "Shrink-swell soils" means soils with horizons that contain montmorillonite and other clays
111 that excessively shrink upon drying and swell upon wetting.

112 "Sink hole" means a depression in the topography without a surface outlet for drainage from
113 the low point. Sink holes are common in areas containing limestone and generally result from
114 the collapse of solution cavities.

115 "Soil" means the weathered mineral and organic fraction of the earth's regolith, which is less
116 than or equal to 2.0 mm in size as observed in place. Soil comprises sands, silts or clays or
117 combinations of these textured components and may contain larger aggregate materials such
118 as gravel, cobbles, stones or channers or precipitates from aqueous solution. Soil includes the
119 A, O, B, C, and E horizons.

120 "Soil horizon" means a layer of soil or soil material approximately parallel to the land surface
121 and different from adjacent genetically related layers in physical, chemical, and biological
122 properties or characteristics such as color, structure, texture, consistency, kinds and numbers of
123 organisms present, degree of acidity or alkalinity, etc.

124 "Subdivision" means multiple building lots derived from a parcel or parcels of land.

125 "Subsurface soil absorption" means a process which utilizes the soil to treat and dispose of
126 effluent from a treatment works. (Also see "Subsurface drainfield" in § 32.1-163 of the Code of
127 Virginia).

128 "Total suspended solids" or "TSS" means a measure of the mass of all suspended solids in
129 a sample typically measured in milligrams per liter (mg/l).

130 "Treatment level 2 effluent" or "TL-2 effluent" means secondary effluent as defined in
131 12VAC5-610-120 that has been treated to produce BOD₅ and TSS concentrations equal to or
132 less than 30 mg/l each.

133 "Treatment level 3 effluent" or "TL-3 effluent" means effluent that has been treated to
134 produce BOD₅ and TSS concentrations equal to or less than 10 mg/l each.

135 "Treatment unit" or "treatment system" means a method, technique, equipment, or process
136 other than a septic tank or septic tanks used to treat sewage to produce effluent of a specified
137 quality before the effluent is dispersed to a soil treatment area.

138 "Treatment works" means any device or system used in the storage, treatment, disposal or
139 reclamation of sewage or combinations of sewage and industrial wastes, including but not
140 limited to pumping, power and other equipment and appurtenances, septic tanks and any works,
141 including land, that are or will be (i) an integral part of the treatment process or (ii) used for
142 ultimate disposal of residues or effluent resulting from such treatment.

143 "Working volume" means the volume in a pump tank between the pump off level and the
144 high water alarm level.

145 Part II

146 Procedural Regulations

147 Article 1

148 Procedures

149 **12VAC5-610-250. Procedures for obtaining a construction permit for a sewage disposal**
150 **system.**

151 Construction permits are issued by the commissioner but all requests for a sewage disposal
152 construction permit shall be directed initially to the district or local health department. For
153 construction permits with design flows less than 1,000 gallons per day that are exempt from the
154 license requirements for professional engineers under § 54.1-402.A.11, the requirement for
155 formal plans and specifications is waived.

156 A. Type I. A Type I sewage disposal system is an individual sewage disposal system
157 incorporating a septic tank and subsurface soil absorption (septic tank-subsurface drainfield)
158 serving a single residence. The submission of an application is all that is normally necessary to
159 initiate procedure for obtaining a permit under this subsection. If after a site investigation, it is
160 determined that pumping, enhanced flow distribution (see 12VAC5-610-930 A) or low pressure
161 distribution (see 12VAC5-610-940) is necessary, the system shall be considered a Type II
162 system.

163 B. Type II. A Type II sewage disposal system is a sewage disposal system incorporating a
164 septic tank and subsurface soil absorption system which serves a commercial or other
165 establishment, more than a single family dwelling unit, or where pumping, enhanced flow
166 distribution (see 12VAC5-610-930 A) or low pressure distribution (see 12VAC5-610-940) is
167 necessary. The procedure for obtaining a permit includes the following steps:

- 168 1. The submission of an application;
169 2. A preliminary conference as necessary; and
170 3. The submission of informal plans, specifications, design criteria, and other data, as may
171 be required by the district or local health department. Depending on the size and complexity of
172 the system, the submission of formal plans and specifications may be required.

173 C. Type III. A Type III sewage disposal system includes sewage disposal systems other than
174 a septic tank subsurface soil absorption system, and subsurface soil absorption systems,
175 regardless of design, with design flows greater than 1,000 gpd. The procedure for obtaining a
176 permit under this subsection includes the following steps:

- 177 1. The submission of an application;

178 2. A preliminary conference; and
179 3. The submission of formal plans, specifications and design criteria. Other supporting data
180 may be required on a case-by-case basis.

181 When high strength wastes are proposed for subsurface disposal, the treatment
182 methodology shall comply with the requirements found in 12VAC5-580-10 et seq. of the
183 Sewage Regulations.

184 D. Type IV-Privies. The submission of an application is all that is normally necessary to
185 initiate the procedure for obtaining a permit under this section.

186 E. Application. All applications for any type sewage disposal system shall be made on an
187 application form provided by the district or local health department and approved by the
188 department.

189 F. Preliminary conference. A preliminary conference with the district or local health
190 department is held for Type II and Type III systems. When a Type III system for septage
191 disposal is planned, the conference shall be with the department. At such conference the owner
192 and/or his agent shall be prepared to set forth the sewage disposal problems and the proposed
193 solution in such a manner to support his conclusions and recommendations.

194 G. Formal plans.

195 1. All formal plans for sewage disposal systems shall bear a suitable title showing the name
196 of the owner and shall show the scale in feet, a graphical scale, the north point, date, and the
197 name of the licensed professional engineer by or under whom prepared. The cover sheet and
198 each plan sheet shall bear the same general title identifying the overall sewage disposal project
199 and each shall be numbered. Appropriate subtitles should be included on the individual sheets.

200 The plans shall be clear and legible. They shall be drawn to a scale which will permit all
201 necessary information to be plainly shown. The size of the plans should be no larger than 30
202 inches by 48 inches. Data used should be indicated. Location, when made, shall be shown on
203 the plans. Logs of test borings shall be given either on plans or in the specifications.

204 Detailed plans shall consist of plan views, elevations, sections, and supplementary views
205 which together with the specifications and general layouts provide the working information for
206 the contract and construction of the work, including dimensions and relative elevations of
207 structures, the location and outline form of equipment, the location and size of piping, water
208 levels, ground elevations, and erosion control abatement facilities.

209 2. Geographical and other features. Topography, elevations (contour lines), existing or
210 proposed streets and all bodies of water, ditches, buildings, springs, cisterns and wells within
211 100 feet horizontally of the proposed sewage disposal system site and/or well, a water
212 mounding analysis showing the impact of the proposed sewage system on ground water and all
213 property lines shall be clearly shown.

214 3. General layout. The general layout shall show the following:

- 215 a. Test borings, ground water elevation (if observed), and soil profiles;
- 216 b. Size and location of sewage disposal systems;
- 217 c. Schematic flow diagram showing the flow through the various disposal system
218 units;
- 219 d. Piping; and
- 220 e. Hydraulic profile showing the flow of sewage.

221 4. Detailed plans. Detailed plans shall show the following:

- 222 a. Location, dimensions and elevations of existing or proposed system facilities;

223 b. Pertinent data concerning the rated capacity of pumps, blowers, motors and other
224 mechanical devices. All or part of such data may be included in the specifications by
225 suitable reference on the plans;

226 c. Average and maximum hydraulic flow in profile; and

227 d. Adequate description of any features not otherwise covered by the specifications.

228 H. Formal specifications. Complete technical specifications for the construction of the
229 sewage disposal system and all appurtenances shall accompany the plans. The specifications
230 accompanying construction drawings shall include, but not be limited to, all construction
231 information not shown on the drawings, which is necessary to inform the builder in detail of the
232 design requirements as to the quality of material workmanship and fabrication of the project,
233 type, size, strength, operating characteristics, and rating of equipment; allowable infiltration,
234 machinery, valves, piping, and jointing of pipe, electrical apparatus, wiring and meters;
235 operating tools and construction materials; special filter materials such as stone, sand, gravel or
236 slag; miscellaneous appurtenances; chemicals when used; instructions for testing materials and
237 equipment as necessary to meet design standards and operating test for the complete works
238 and component units.

239 I. Special requirements for certain sewage disposal systems. A construction permit for a
240 single sewage disposal system proposed to serve a dwelling unit with multiple living units,
241 multiple dwelling units or multiple lots with dwelling units shall be issued only to a single owner.
242 The owner shall provide legal documentation to assure operation and the maintenance of the
243 system for the expected life of the living units or dwellings.

244 J. Construction permit with conditions.

245 1. Definition: "Conditional construction permit" means a permit authorizing the installation of
246 a septic tank subsurface soil absorption system which does not fully conform to the criteria in
247 Part V (12VAC5-610-660 et seq.) of this chapter pertaining to septic tank size, subsurface soil
248 absorption system size and certain ground water table conditions as indicated by soil
249 evaluation, but which, under the conditions to which the permit is subject, can be reasonably
250 expected to function without danger to public health.

251 2. The purpose of this section is to allow for the issuance of conditional construction permits.
252 Procedures for obtaining a conditional construction permit are the same as those contained in
253 subsections A, B, C and D of this section.

254 3. Conditional construction permits may be issued for any one or more of the following use
255 conditions when satisfactory substantiation is provided by the applicant:

256 a. Reduced water flow based on permanent water saving plumbing devices;

257 b. Limitations on the number of persons occupying the dwelling or using the facility
258 served by the proposed septic tank system;

259 c. Intermittent or seasonal use of the dwelling or facility served by the septic tank
260 system; and

261 d. Temporary use of the septic tank system for a specified time period not to exceed
262 one year. Such permits may be renewable when the commissioner determines there
263 is a good cause for renewal.

264 4. Criteria.

265 a. The septic tank and/or drainfield size may be reduced based on the use conditions
266 contained in subdivision 3 a, b, c, or d of this subsection.

267 b. In areas with seasonal fluctuating water table(s), where the seasonally high water
268 table would cause failure if the system were to be used continuously, septic tank
269 systems may be installed when the period of use of the septic tank system coincides

270 with the period when the ground water table, as indicated by free water, is at its
271 lowest level. Acceptable separation distances to free standing ground water are the
272 same as those found in Tables 4.3 and 4.4 of this chapter.

273 c. Because of the increased risk of failure, a conditional permit shall not be issued, in
274 an area with a seasonally fluctuating water table if the proposed absorption area is
275 within 200 feet of a shellfish growing area, recreational waters or a public water
276 supply impoundment.

277 5. The district or local health department shall affix to the conditional construction permit a
278 clear and concise statement relating the conditions and circumstances which formed the basis
279 for issuing the conditional permit as well as the owner's obligations under the permit.

280 6. The holder of any conditional construction permit shall have the permit recorded and
281 indexed in the grantor index under the holder's name in the land records of the clerk of the
282 circuit court having jurisdiction over the site of the septic tank system. District or local health
283 departments shall be provided with certification that the conditional septic tank system permit
284 has been recorded in the land records of the circuit court. The conditional permit shall become
285 effective one day after the district or local health department receives notification of recordation.
286 The district or local health department shall advise the local building official that conditional
287 septic tank system permits are not valid without certification that the permits have been properly
288 recorded as required and shall forthwith notify the local building official when the conditional
289 permit becomes effective. Final approval of the construction of the septic tank subsurface soil
290 absorption system shall not be given until or unless the system is constructed in accordance
291 with the conditions of the permit. The operation permit will be issued in accordance with
292 12VAC5-610-340.

293 7. As per § 32.1-164.1 of the Code of Virginia, the holder of the permit and any subsequent
294 holders of the permit shall be bound by the conditions stated in the permit unless the holder or
295 subsequent holder obtains an additional permit for modification or alteration of the septic tank
296 system to meet any new use conditions.

297 **12VAC5-610-880. Pumping.**

298 A. Force mains. General.

299 1. Velocity. At pumping capacity, a minimum self-scouring velocity of two feet per second
300 shall be maintained. A velocity of eight feet per second should not be exceeded.

301 2. Air relief valve. Air relief valves shall be placed at high points in the force main, as
302 necessary, to relieve air locking.

303 3. Bedding. All force mains shall be bedded to supply uniform support along their length.

304 4. Protection against freezing. Force mains shall be placed deep enough to prevent
305 freezing.

306 5. Location. Force mains shall not pass closer than 50 feet to any drinking water source
307 unless pressure tested in place at pump shut-off head. Under no circumstances shall a force
308 main come within 10 feet of a nonpublic drinking water source.

309 6. Materials of construction. All pipe used for force mains shall be of the pressure type with
310 pressure type joints.

311 7. Anchors. Force mains shall be sufficiently anchored within the pump station and
312 throughout the line length. The number of bends shall be as few as possible. Thrust blocks,
313 restrained joints and/or tie rods shall be provided where restraint is needed.

314 8. Backfilling and tamping. Force main trenches shall be backfilled and tamped as soon as
315 possible after the installation of the force main has been approved. Material for backfilling shall
316 be free of large stones and debris.

317 B. Pumping station and pumps. General.

318 1. Sizing. Pumping station wet wells shall provide at least one quarter (1/4) day storage
319 above the high level alarm set point. Actual volume between high and low level limits is
320 determined on a case-by-case basis depending on the objective of pumping: (i) when low
321 pressure dosing is utilized see 12VAC5-610-940 A for sizing requirements; (ii) when pumping to
322 a gravity distribution box the wet well shall be sized to provide a working volume between 1/4
323 the daily flow and the daily flow; (iii) when pumping for the purpose of enhancing flow
324 distribution (see 12VAC5-610-930 A) the working volume of the wet ~~wall~~ well shall be 0.6 of the
325 volume of the percolation piping.

326 2. Materials. Materials for construction of pumping stations are the same as for septic tanks
327 (see 12VAC5-610-810). All materials and equipment utilized in pumping stations shall be
328 unaffected by the corrosive action of sewage.

329 3. Access. An access manhole terminating above the ground surface shall be provided. The
330 manhole shall have a minimum width dimension of 24 inches and shall be provided with a shoe
331 box type cover adequately secured.

332 4. Construction. Pumping stations constructed of precast or poured in place concrete shall
333 conform with the construction requirements contained in 12VAC5-610-815 E. When precast
334 concrete pipe is utilized for a pumping station, the pipe shall be placed on and bonded to a
335 concrete pad at least six inches thick and having a width at least one foot greater than the
336 diameter of the pipe. All pumping stations shall be watertight. All conduits entering or leaving the
337 pumping stations shall be provided with a water stop. The influent pipe shall enter the pumping
338 station at an elevation at least one inch higher than the maximum water level in the wet well
339 (total usable volume).

340 5. Installation. Placement of pumping stations shall conform to the requirements for
341 placement of septic tanks contained in 12VAC5-610-815 F.

342 6. Pumps. All pumps utilized shall be of the open face centrifugal, vertical turbine, or suction
343 lift type designed to pump sewage. Pumps utilized for the sole purpose of pumping effluent to a
344 higher elevation shall have a capacity approximately 2.5 times the average daily flow in gallons
345 per minute but not less than five gallons per minute at the system head. Pumps utilized for the
346 purpose of enhancing flow distribution (See 12VAC5-610-930 A) shall have a minimum capacity
347 of 36 gallons per minute at system head per 1200 linear feet of percolation piping. Pumps
348 discharging to a low pressure distribution system shall be sized in accordance with 12VAC5-
349 610-940 A. Dual alternating pumps are required on systems 1800 linear feet or greater in
350 accordance with 12VAC5-610-930 B. Pumps shall be so placed that under normal start
351 conditions it shall be subjected to a positive suction head. When multiple pumps are used, each
352 pump shall have its own separate suction line. Suitable shutoff valves shall be provided on the
353 discharge line and suction line (if provided) for normal pump isolation. A check valve shall be
354 placed in the discharge line between the pump and shutoff valve. When the pump discharge is
355 at a lower elevation than the high liquid level in the pump station, an antisiphon device shall be
356 provided on the pump discharge. Pumps shall be piped so that they can be removed for
357 servicing without having to dewater the wet well.

358 7. Controls. Each pumping station shall be provided with controls for automatically starting
359 and stopping the pumps ~~based on water level~~. When float type controls are utilized, they shall
360 be placed so as to be unaffected by the flow entering the wet well. Provisions shall be made for
361 automatically alternating the pumps. The electrical motor control center and master disconnect
362 switch shall be placed in a secure location above grade and remote from the pump station.
363 Each motor control center shall be provided with a manual override switch. The control panel
364 shall be located to allow for working access, taking into consideration the finished ground
365 surface elevation.

366 8. Alarms. A high water alarm with remote sensing and electrical circuitry separate from the
367 motor control center circuitry shall be provided. The alarm shall be audiovisual and shall alarm
368 in an area where it may be easily monitored. When multiple pumps are utilized, an additional
369 audiovisual alarm shall be provided to alarm when a pump motor fails to start on demand.

370 9. Ventilation. Positive ventilation shall be provided at pumping stations when personnel are
371 required to enter the station for routine maintenance.

372 a. Wet wells. Ventilation may be either continuous or intermittent. Ventilation, if
373 continuous, shall provide at least 12 complete air changes per hour; if intermittent, at
374 least 30 complete air changes per hour. Such ventilation shall be accomplished by
375 mechanical means.

376 b. Dry wells. Ventilation may be either continuous or intermittent. Ventilation, if
377 continuous, shall provide at least six complete air changes per hour; if intermittent, at
378 least 30 complete air changes per hour. Such ventilation shall be accomplished by
379 mechanical means.

380 C. Conveyance pumps and pump stations that move TL-2 effluent or TL-3 effluent to a soil
381 dispersal system shall comply with the following.

382 1. 12VAC5-610-880.A. shall apply except that the minimum velocity in the force main
383 may be reduced to 1 foot per second.

384 2. Pump station wet wells shall provide at least one quarter (1/4) day storage above the
385 high level alarm set point. Alternatively, storage may be provided in a treatment tank
386 such as a recirculation tank, but the maximum water level must be one inch below the
387 invert of the pipe from the septic tank.

388 3. 12-VAC5-610-880.B 2, 3, 4, 5, 7, 8 and 9 shall apply.

389 4. All pumps utilized shall be of the open face centrifugal, vertical turbine, or suction lift
390 type designed to pump sewage.

391 a. Pumps utilized for the purpose of enhancing flow distribution (See [12VAC5-610-](#)
392 [930 A](#)) shall have a minimum capacity of 36 gallons per minute at system head per
393 1200 linear feet of percolation piping.

394 b. Pumps discharging to a low pressure distribution system shall be sized in
395 accordance with [12VAC5-610-940](#).

396 c. Dual alternating pumps are required on systems 1800 linear feet or greater in
397 accordance with [12VAC5-610-930 B](#).

398 d. Submersible pumps shall be so placed that under normal start conditions the
399 pump shall be subjected to a positive suction head.

400 e. When multiple pumps are used, each pump shall have its own separate suction
401 line. Suitable shutoff valves shall be provided on the discharge line and suction line
402 (if provided) for normal pump isolation. A check valve shall be placed in the
403 discharge line between the pump and shutoff valve. When the pump discharge is at
404 a lower elevation than the high liquid level in the pump station, an anti-siphon device
405 shall be provided on the pump discharge. Pumps shall be piped so that they can be
406 removed for servicing without having to dewater the wet well.

407 D. Pumps Integral to Treatment Systems. Pumps integral to treatment systems are pumps
408 that move wastewater within the treatment unit and are required to achieve the desired effluent
409 quality. 12VAC5-610-880.A, B, and C do not apply to these integral pumps.

410 **12VAC5-610-930. Gravity distribution.**

411 Gravity distribution is the conveyance of effluent from a distribution box through the
412 percolation lines at less than full flow conditions. Flow to the initial distribution box may be
413 initiated by pump, siphon or gravity.

414 A. Enhanced flow distribution. Enhanced flow distribution is the initiation of the effluent flow
415 to the distribution box by pump or siphon for the purpose of assuring more uniform flow splitting
416 to the percolation lines. Enhanced flow distribution shall be provided on systems where the flow
417 is split more than 12 times or the system contains more than 1200 linear feet of percolation
418 lines. For the purpose of this chapter, enhanced flow distribution is considered to produce
419 unsaturated soil conditions.

420 B. System size. Distribution systems containing 1800 or more linear feet of percolation
421 piping shall be split into multiple systems containing a maximum of 1200 linear feet of
422 percolation piping per system.

423 C. Distribution boxes. The distribution box is a device for splitting flow equally by gravity to
424 points in the system. Improperly installed distribution boxes are a cause for absorption field
425 malfunction.

426 1. Materials. The preferred material for use in constructing distribution boxes is concrete
427 (3000 psi). Other materials may be considered on a case-by-case basis. All materials
428 must be resistant to both chemical and electrolytic corrosion and must have sufficient
429 structural strength to contain sewage and resist lateral compressive and bearing loads.

430 2. Design. Each distribution box shall be designed to split the influent flow equally
431 among the multiple effluent ports. All effluent ports shall be at the same elevation and be
432 of the same diameter. The elevation of the effluent ports shall be at a lower elevation
433 than the influent port. The placement of the influent ports shall be such as to prevent
434 short circuiting unless baffling is provided to prevent short circuiting. The minimum inside
435 width of a gravity flow distribution box shall be equal to or greater than 12 inches. The
436 inside bottom shall be at least four inches below the invert of the effluent ports and at
437 least five inches below the invert of the influent port. A minimum of eight inches
438 freeboard above the invert of the effluent piping shall be provided. The distribution box
439 shall be fitted with a watertight, removable lid for access.

440 3. Installation. The hole for placement of the distribution box shall be excavated to
441 undisturbed soil. The distribution box shall be placed in the excavation and stabilized.
442 The preferred method of stabilizing the distribution box is to bond the distribution box to
443 a four inch poured in place Portland cement concrete pad with dimensions six inches
444 greater than the length and width dimensions of the distribution box. The box shall be
445 permanently leveled and checked by water testing. Conduits passing through the walls
446 of a distribution box shall be provided with a water stop.

447 D. Lead or header lines. Header or lead lines are watertight, semirigid or rigid lines that
448 convey effluent from a distribution box to another box or to the percolation piping.

449 1. Size. The lead or header lines shall have an internal diameter of four inches.

450 2. Slope. Minimum slope shall be two inches per 100 feet.

451 3. Materials. The lead or header lines shall have a minimum crush strength of 1500
452 pounds per foot and may be constructed of cast iron, plastic, vitrified clay or other
453 material resistant to the corrosive action of sewage.

454 4. Appurtenances.

455 a. Joints. Lead or header lines shall have joints of the compressions type with the
456 exception of plastic lead or header lines which may be welded sleeve, chemically
457 fused or clamped (noncorrosive) flexible sleeve.

458 b. Adapters. Joining of lead or header lines of different size or material shall be
459 accomplished by use of a manufactured adapter specifically designed for the
460 purpose.

461 c. Valves. Valves shall be constructed of materials resistant to the corrosive action of
462 sewage. Valves placed below ground level shall be provided with a valve box and a
463 suitable valve stem so that it may be operated from the ground surface.

464 5. Construction.

465 a. Bedding. All lead or header lines shall be bedded to supply uniform support and
466 maintain grade and alignment along the length of the lead or header lines. Special
467 care shall be taken when using semirigid pipe.

468 b. Backfilling and tamping. Lead and header lines shall be backfilled and tamped as
469 soon as possible after the installation of the lead or header lines has been approved.
470 Material for backfilling shall be free of large stones and debris.

471 6. Termination. Header or lead lines shall extend for a minimum distance of two feet into
472 the absorption trenches.

473 E. Gravity percolation lines. Gravity percolation lines are perforated or open joint pipes that
474 are utilized to distribute the effluent along the length of the absorption trenches.

475 1. Size. All gravity percolation lines shall have an internal diameter of four inches.

476 2. Slope. The slope of the lines shall be uniform and shall not be less than two inches or
477 more than four inches per 100 feet.

478 3. Design. Effluent shall be split by the distribution system so that all gravity percolation
479 lines installed shall receive an equal volume of the total design effluent load per square
480 foot of trench, i.e., the fraction of the flow received by each percolation line divided by
481 the length of the gravity percolation lines shall be equal for all gravity percolation lines in
482 a system.

483 4. Length. No individual gravity percolation line shall exceed 100 feet in length.

484 5. Materials.

485 a. Clay. Clay tile shall be extra-strength and meet current ASTM standards for clay
486 tile.

487 b. Perforated plastic drainage tubing. Perforated plastic drainage tubing shall meet
488 ASTM standards. At not greater than 10 feet intervals the pipe shall be plainly
489 marked, embossed or engraved thereby showing the manufacturer's name or
490 hallmark and showing that the product meets a bearing load of 1,000 lb. per foot. In
491 addition, a painted or other clearly marked line or spot shall be marked at not greater
492 than 10 feet intervals to denote the top of the pipe.

493 The tubing shall have three holes, 1/2 to 3/4 inch in diameter evenly spaced and
494 placed within an arc of 130 degrees, the center hole being directly opposite the top
495 marking.

496 Spacing of each set of three holes shall be at four inch intervals along the tube. If
497 there is any break in the continuity of the tubing, an appropriate connection shall be
498 used to join the tubing.

499 6. Installation.

500 a. Crushed stone or gravel. Clean gravel or crushed stone having a size range from
501 1/2 inch to 1-1/2 inches shall be utilized to bed the gravity percolation lines.

502 Minimum depth of gravel or crushed stone beneath the percolation lines shall be six
503 inches. Clean course silica sand (does not effervesce in presence of dilute

504 hydrochloric acid) may be substituted for the first two inches (soil interface) of the
505 required six inches of gravel beneath the percolation lines. The absorption trench
506 shall be backfilled to a depth of two inches over the gravity percolation lines with the
507 same gravel or crushed stone. Clean sand, gravel or crushed stone shall be free of
508 fines, clay and organic materials.

509 b. Grade boards or stakes. Grade boards or stakes placed in the bottom or sidewalls
510 of the absorption trench shall be utilized to maintain the grade on the gravel for
511 placement of the gravity percolation lines. Grade stakes shall not be placed on
512 centers greater than 10 feet.

513 c. Placement and alignment. Perforated gravity percolation piping shall be placed so
514 that the center hole is in the horizontal plane and interfaces with the minimum six
515 inches of graded gravel. When open joint piping is utilized the upper half of the top of
516 the 1/4-inch open space shall be covered with tar paper or building paper to block
517 the entrance of fines into the pipe during the backfilling operation. All gravity
518 percolating piping shall be placed in the horizontal center of the absorption trench
519 and shall maintain a straight alignment and uniform grade.

520 d. Backfilling. After the placement of the gravity percolation piping the absorption
521 trench shall be backfilled evenly with crushed stone or gravel to a depth of two
522 inches over the piping. Untreated building paper or other suitable material shall be
523 placed at the interface of the gravel and soil to prevent migration of fines to the
524 trench bottom. The remainder of the trench shall be backfilled with soil to the ground
525 surface.

526 F. Gravelless material is a proprietary product specifically manufactured to disperse effluent
527 within the absorption trench of an onsite sewage system without the use of gravel. Gravelless
528 material may include chamber, bundled expanded polystyrene, and multi-pipe systems. The
529 division shall maintain a list of all generally approved gravelless material. Gravelless material on
530 the generally approved list may be used in accordance with Table 5.4 of 12VAC5-610-950.

531 1. Gravelless material that received general approval as of December 12, 2013, shall
532 retain such status when used in accordance with the requirements of this chapter. After
533 December 12, 2013, the division shall review and evaluate new applications for general
534 approval pursuant to the requirements of this chapter.

535 a. Any manufacturer of gravelless material may submit an application for general
536 approval to the division using a form provided by the division. A complete application
537 shall include the manufacturer's contact information, product specifications, product
538 approvals in other states or territories, installation manual, and other information
539 deemed necessary by the division to determine compliance with this chapter.

540 b. The manufacturer of gravelless material shall identify in the application for general
541 approval any recommendation that deviates from the requirements of this chapter. If
542 the recommendation is approved by the division, then the manufacturer shall include
543 the deviation in the gravelless material's installation manual.

544 2. Gravelless material shall have the following minimum characteristics for general
545 approval:

546 a. The minimum exterior width shall be at least 90% of the total width of the
547 absorption trench. The exterior width of a chamber system shall be measured at the
548 edge or outer limit of the product's contact with the trench bottom unless the division
549 determines a different measurement is required based on the gravelless material's
550 design. The exterior width of bundled expanded polystyrene and multi-pipe systems
551 shall be measured using the outside diameter of the bundled gravelless material
552 unless the division determines a different measurement is required based on the

553 gravelless material's design. The division shall establish the exterior width of any
554 gravelless material that is not considered a chamber, bundled expanded polystyrene,
555 or multi-pipe system.

556 b. Gravelless material shall have a minimum height of eight inches to provide a
557 continuous exchange of air through a permeable interface.

558 c. Gravelless material shall have a permeable interface that shall be located along
559 the trench bottom and trench sidewalls within the absorption trench.

560 d. Gravelless material shall provide a minimum storage capacity of 1.3 gallons per
561 square foot of trench bottom area.

562 e. Gravelless material shall pose no greater risk to surface water and groundwater
563 quality than gravel in absorption trenches. Gravelless material shall be constructed to
564 maintain structural integrity such that it does not decay or corrode when exposed to
565 effluent.

566 f. Gravelless material shall have a minimum load rating of H-10 or H-20 from the
567 American Association of State Highway and Transportation Officials or equivalent
568 when installed in accordance with the manufacturer's specifications and minimum
569 specified depth of cover in nontraffic or traffic areas, respectively.

570 3. For designs using gravelless material, the absorption trenches shall receive an equal
571 volume of effluent per square foot of trench. Trench bottom area shall be equal to or
572 greater than the minimum area requirements contained in Table 5.4 or Table 5.5 of
573 12VAC5-610-950. Trench sidewall shall not be included when determining minimum
574 area requirements. When open-bottom gravelless material is utilized, it shall provide a
575 splash plate at the inlet of the trench or other suitable method approved by the
576 manufacturer to reduce effluent velocity.

577 4. Installation of gravelless material shall comply with this chapter and the approved
578 installation manual unless the department grants a deviation pursuant to 12VAC5-610-
579 660 or the division has granted a deviation identified in the installation manual.

580 5. Gravelless material shall contain a pressure percolation line along the entire length of
581 the trench when low pressure distribution is utilized pursuant to 12VAC5-610-940 D.

582 6. When pumping effluent to overcome gravity, any open-bottom gravelless material
583 shall provide a high-flow splash plate at the inlet of the trench or other suitable method
584 approved by the manufacturer to reduce effluent velocity.

585 7. When enhanced flow distribution is used, open-bottom gravelless material shall
586 contain a percolation pipe that extends a minimum of 10 feet from the trench's
587 intersection with the header line. The percolation pipe shall be installed in accordance
588 with the manufacturer's approved installation manual. The dosing volume shall be a
589 minimum 39 gallons per 100 linear feet of absorption trench.

590 8. Gravelless material may be substituted for gravel in accordance with this chapter,
591 provided that the certifying licensed professional engineer or onsite soil evaluator
592 approves the substitution. The certifying licensed professional engineer or onsite soil
593 evaluator shall document the substitution and related design changes on the inspection
594 report submitted in accordance with 12VAC5-610-330. A new construction permit
595 pursuant to 12VAC5-610-310 is not required for the substitution.

596 **12VAC5-610-950. Absorption area design.**

597 A. The absorption area is the undisturbed soil medium utilized for absorption of the effluent.
598 The absorption area includes the infiltrative surface in the absorption trench and the soil
599 between and around the trenches when trenches are used.

600 B. Suitability of soil horizon. The absorption trench bottom shall be placed in the soil horizon
601 or horizons with an average estimated or measured percolation rate less than 120 minutes per
602 inch. Soil horizons are to be identified in accordance with 12VAC5-610-480. The soil horizon
603 must meet the following minimum conditions:

604 1. It shall have an estimated or measured percolation rate equal to or less than 120
605 minutes per inch;

606 2. The soil horizon or horizons shall be of sufficient thickness so that at least 12 inches
607 of absorption trench sidewall is exposed to act as an infiltrative surface; and

608 3. If no single horizon meets the conditions in subdivision 2 of this subsection, a
609 combination of adjacent horizons may be utilized to provide the required 12-inch sidewall
610 infiltrative surface. However, no horizon utilized shall have an estimated or measured
611 percolation rate greater than 120 minutes/inch.

612 C. Placement of absorption trenches below soil restrictions. Placement of the soil absorption
613 trench bottom below soil restrictions as defined in 12VAC5-610-490 D, whether or not there is
614 evidence of a perched water table as indicated by free standing water, ~~or gray mottlings or~~
615 ~~elevation~~ or redoximorphic features including concentrations, depletions, or stains, nodules, or
616 concretions of iron and manganese, requires a special design based on the following criteria:

617 1. The soil horizon into which the absorption trench bottom is placed shall be a Texture
618 Group I, II or III soil or have an estimated or measured percolation rate of less than 91
619 minutes per inch.

620 2. The soil horizon shall be a minimum of three feet thick and shall exhibit no
621 characteristics that indicate wetness or restriction of water movement. The absorption
622 trench bottom shall be placed so that at least two feet of the soil horizon separates the
623 trench bottom from the water table or rock. At least one foot of the absorption trench side
624 wall shall penetrate the soil horizon.

625 3. A lateral ground water movement interceptor (LGMI) shall be placed upslope of the
626 absorption area. The LGMI shall be placed perpendicular to the general slope of the
627 land. The invert of the LGMI shall extend into, but not through, the restriction and shall
628 extend for a distance of 10 feet on ~~either side~~ both sides of the absorption area (See
629 12VAC5-610-700 D 3).

630 4. Pits shall be constructed to facilitate soil evaluations as necessary.

631 D. Sizing of absorption trench area for septic tank effluent.

632 1. Required area. The total absorption trench bottom area required shall be based on the
633 average estimated or measured percolation rate for the soil horizon or horizons into
634 which the absorption trench is to be placed. If more than one soil horizon is utilized to
635 meet the sidewall infiltrative surface required in subsection B of this section, the
636 absorption trench bottom area shall be based on the average estimated or measured
637 percolation rate of the "slowest" horizon. The trench bottom area required in square feet
638 per 100 gallons (Ft²/100 Gals) of sewage applied for various soil percolation rates is
639 tabulated in Table 5.4. The area requirements are based on the equation:

640
$$\log y = 2.00 + 0.008 (x)$$

641 where y = Ft²/100 Gals

642 x = Percolation rate in minutes/inch

643 Notwithstanding the above, the minimum absorption area for single family residential
644 dwellings shall be 400 square feet.

645 2. Area reduction. See Table 5.4 for area reduction when gravelless material or low
646 pressure distribution is utilized. A reduction in area shall not be permitted when flow

647 diversion is utilized with low pressure distribution. When gravelless material is utilized,
648 the design width of the trench shall be used to calculate minimum area requirements for
649 absorption trenches.

650 E. Minimum cross section dimensions for absorption trenches.

651 1. Depth. The minimum trench sidewall depth as measured from the surface of the
652 mineral soil shall be 12 inches when placed in a landscape with a slope less than 10%.
653 The installation depth shall be measured on the downhill side of the absorption trench.
654 When the installation depth is less than 18 inches, the depth shall be measured from the
655 lowest elevation in the microtopography. All systems shall be provided with at least 12
656 inches of cover to prevent frost penetration and provide physical protection to the
657 absorption trench; however, this requirement for additional cover shall not apply to
658 systems installed on slopes of 30% or greater. Where additional soil cover must be
659 provided to meet this minimum, it must be added prior to construction of the absorption
660 field, and it must be crowned to provide positive drainage away from the absorption field.
661 The minimum trench depth shall be increased by at least five inches for every 10%
662 increase in slope. Sidewall depth is measured from the ground surface on the downhill
663 side of the trench.

664 2. Width. All absorption trenches utilized with gravity distribution shall have a width of
665 from 18 inches to 36 inches. All absorption trenches utilized with low pressure
666 distribution shall have a width of eight inches to 24 inches.

667 F. Lateral separation of absorption trenches. The absorption trenches shall be separated by
668 a center to center distance no less than three times the width of the trench for slopes up to 10%.
669 However, where trench bottoms are two feet or more above rock, pans and impervious strata,
670 the absorption trenches shall be separated by a center to center distance no less than three
671 times the width of the trench for slopes up to 20%. The minimum horizontal separation distance
672 shall be increased by one foot for every 10% increase in slope. In no case shall the center to
673 center distance be less than 30 inches.

674 G. Slope of absorption trench bottoms.

675 1. Gravity distribution. The bottom of each absorption trench shall have a uniform slope
676 not less than two inches or more than four inches per 100 feet.

677 2. Low pressure distribution. The bottom of each absorption trench shall be uniformly
678 level to prevent ponding of effluent.

679 H. Placement of absorption trenches in the landscape.

680 1. The absorption trenches shall be placed on contour.

681 2. When the ground surface in the area over the absorption trenches is at a higher
682 elevation than any plumbing fixture or fixtures, sewage from the plumbing fixture or
683 fixtures shall be pumped.

684 I. Lateral ground water movement interceptors. Where subsurface, laterally moving water is
685 expected to adversely affect an absorption system, a lateral ground water movement interceptor
686 (LGMI) shall be placed upslope of the absorption area. The LGMI shall be placed perpendicular
687 to the general slope of the land. The invert of the LGMI shall extend into, but not through, the
688 restriction and shall extend for a distance of 10 feet on either side of the absorption area.

Table 5.4.
Area Requirements for Absorption Trenches Receiving Septic Tank Effluent.

Percolation Rate	Area Required (Ft ² /100 Gals)	Area Required (Ft ² /Bedroom)
------------------	---	--

(Minutes/Inch)	Gravity	Gravity Gravelless	Low Pressure Distribution	Gravity	Gravity Gravelless	Low Pressure Distribution
5	110	83	110	165	124	165
10	120	90	120	180	135	180
15	132	99	132	198	149	198
20	146	110	146	218	164	218
25	158	119	158	237	178	237
30	174	131	164	260	195	255
35	191	143	170	286	215	260
40	209	157	176	314	236	264
45	229	172	185	344	258	279
50	251	188	193	376	282	293
55	275	206	206	412	309	309
60	302	227	217	452	339	325
65	331	248	228	496	372	342
70	363	272	240	544	408	359
75	398	299	251	596	447	375
80	437	328	262	656	492	394
85	479	359	273	718	539	409
90	525	394	284	786	590	424
95	575	489	288	862	733	431
100	631	536	316	946	804	473
105	692	588	346	1038	882	519
110	759	645	379	1138	967	569
115	832	707	416	1248	1061	624
120	912	775	456	1368	1163	684

689 J. Controlled blasting. When rock or rock outcroppings are encountered during construction
690 of absorption trenches the rock may be removed by blasting in a sequential manner from the top
691 to remove the rock. Percolation piping and sewer lines shall be placed so that at least one foot
692 of compacted clay soil lies beneath and on each side of the pipe where the pipe passes through
693 the area blasted. The area blasted shall not be considered as part of the required absorption
694 area.

695 K. Trenches receiving TL-2 effluent or TL-3 effluent are exempt from the increase in trench
 696 depth with slope and the soil cover requirements as found in [12VAC5-610-950.E](#). The following
 697 additional requirements shall apply.

- 698 1. Soil dispersal loading rates shall not exceed the values in Table 5.5.
- 699 2. The minimum vertical separation to a limiting feature shall be maintained under the
 700 entire infiltrative surface in accordance with [12VAC5-613-80](#).
- 701 3. The minimum soil cover, after settling, shall be 6 inches as measured from the
 702 finished ground surface to the uppermost limit of the dispersal media (or gravelless
 703 material) utilized in the absorption area. On sloping sites, cover shall be tied back into
 704 the existing slope to facilitate stabilization of the slope and maintenance of the site. The
 705 soil cover, with amendments as needed, shall be of a quality, character, and fertility
 706 suitable to establish a vegetative cover that is uniform and sufficiently mature to survive
 707 and inhibit erosion.
- 708 4. The minimum installation depth is equal to the sidewall of the dispersal system
 709 construction as described in [12VAC5-610-930.F](#) (gravelless), [12VAC5-610-940](#), and
 710 [12VAC5-610-950.E.1](#). On sloping sites, the minimum installation depth is measured on
 711 the downhill side of the absorption trench.
- 712 5. When trenches are installed at less than 12 inches from the ground surface, timed
 713 dosing shall be used to disperse the effluent.
- 714 6. For slopes up to 15 percent slope, there are not any soil texture group limitations for
 715 shallow placed trenches receiving TL-2 effluent or TL-3 effluent. For slopes over 15
 716 percent, trench systems installed in Texture Group III and IV soils shall have a 12 inch or
 717 greater installation depth.
- 718 7. Designs supported by Division approved manufacturer's design manuals may deviate
 719 from [12VAC5-610-950.K4](#) and [K5](#).
- 720 8. Notwithstanding the above, the minimum absorption area for a single family
 721 residential dwelling receiving TL-2 effluent or TL-3 effluent shall be 400 square feet.

722
723

<u>Table 5.5 Soil Absorption Area Loading Rates for Systems Receiving TL-2 or TL-3 Effluent</u>								
<u>Percolation Rate (mpi)</u>	<u>TL-2 Effluent</u>				<u>TL-3 Effluent</u>			
	<u>Pressure Trench* Loading (gpd/ft²)</u>	<u>Gravity Trench* Loading (gpd/ft²)</u>	<u>Drip** Loading) (gpd/ft²)</u>	<u>Pad/Mound Loading** (gpd/ft²)</u>	<u>Pressure Trench* Loading (gpd/ft²)</u>	<u>Gravity Trench* Loading (gpd/ft²)</u>	<u>Drip** Loading (gpd/ft²)</u>	<u>Pad/Mound Loading** (gpd/ft²)</u>
<u>5</u>	<u>1.8</u>	<u>1.80</u>	<u>0.60</u>	<u>1.20</u>	<u>3.0</u>	<u>3.00</u>	<u>1.00</u>	<u>1.66</u>
<u>10</u>	<u>1.67</u>	<u>1.67</u>	<u>0.56</u>	<u>1.11</u>	<u>2.67</u>	<u>2.67</u>	<u>0.89</u>	<u>1.66</u>
<u>15</u>	<u>1.53</u>	<u>1.53</u>	<u>0.51</u>	<u>1.02</u>	<u>2.33</u>	<u>2.33</u>	<u>0.78</u>	<u>1.66</u>
<u>20</u>	<u>1.4</u>	<u>1.40</u>	<u>0.47</u>	<u>0.93</u>	<u>2.0</u>	<u>2.00</u>	<u>0.67</u>	<u>1.66</u>
<u>25</u>	<u>1.30</u>	<u>1.30</u>	<u>0.43</u>	<u>0.86</u>	<u>1.75</u>	<u>1.75</u>	<u>0.58</u>	<u>1.33</u>
<u>30</u>	<u>1.2</u>	<u>1.13</u>	<u>0.40</u>	<u>0.80</u>	<u>1.5</u>	<u>1.41</u>	<u>0.50</u>	<u>1.11</u>

<u>35</u>	<u>1.10</u>	<u>0.98</u>	<u>0.37</u>	<u>0.73</u>	<u>1.38</u>	<u>1.22</u>	<u>0.46</u>	<u>0.95</u>
<u>40</u>	<u>1.00</u>	<u>0.84</u>	<u>0.33</u>	<u>0.66</u>	<u>1.25</u>	<u>1.05</u>	<u>0.42</u>	<u>0.83</u>
<u>45</u>	<u>0.90</u>	<u>0.73</u>	<u>0.30</u>	<u>0.60</u>	<u>1.13</u>	<u>0.91</u>	<u>0.38</u>	<u>0.74</u>
<u>50</u>	<u>0.8</u>	<u>0.62</u>	<u>0.27</u>	<u>0.53</u>	<u>1.0</u>	<u>0.77</u>	<u>0.33</u>	<u>0.67</u>
<u>55</u>	<u>0.76</u>	<u>0.57</u>	<u>0.25</u>	<u>0.50</u>	<u>0.94</u>	<u>0.71</u>	<u>0.31</u>	<u>0.61</u>
<u>60</u>	<u>0.71</u>	<u>0.51</u>	<u>0.24</u>	<u>0.47</u>	<u>0.89</u>	<u>0.64</u>	<u>0.30</u>	<u>0.55</u>
<u>65</u>	<u>0.67</u>	<u>0.46</u>	<u>0.22</u>	<u>0.44</u>	<u>0.83</u>	<u>0.57</u>	<u>0.28</u>	<u>0.51</u>
<u>70</u>	<u>0.62</u>	<u>0.41</u>	<u>0.21</u>	<u>0.41</u>	<u>0.78</u>	<u>0.51</u>	<u>0.26</u>	<u>0.48</u>
<u>75</u>	<u>0.58</u>	<u>0.36</u>	<u>0.19</u>	<u>0.38</u>	<u>0.72</u>	<u>0.46</u>	<u>0.24</u>	<u>0.44</u>
<u>80</u>	<u>0.53</u>	<u>0.32</u>	<u>0.18</u>	<u>0.35</u>	<u>0.67</u>	<u>0.40</u>	<u>0.22</u>	<u>0.42</u>
<u>85</u>	<u>0.49</u>	<u>0.28</u>	<u>0.16</u>	<u>0.33</u>	<u>0.61</u>	<u>0.35</u>	<u>0.20</u>	<u>0.39</u>
<u>90</u>	<u>0.44</u>	<u>0.24</u>	<u>0.15</u>	<u>0.30</u>	<u>0.56</u>	<u>0.30</u>	<u>0.19</u>	<u>0.37</u>
<u>95</u>	<u>0.4</u>	<u>0.20</u>	<u>0.13</u>	<u>0.27</u>	<u>0.5</u>	<u>0.25</u>	<u>0.17</u>	<u>0.35</u>
<u>100</u>	<u>0.37</u>	<u>0.19</u>	<u>0.12</u>	<u>0.25</u>	<u>0.46</u>	<u>0.23</u>	<u>0.15</u>	<u>0.33</u>
<u>105</u>	<u>0.34</u>	<u>0.17</u>	<u>0.11</u>	<u>0.23</u>	<u>0.43</u>	<u>0.21</u>	<u>0.14</u>	<u>0.32</u>
<u>110</u>	<u>0.31</u>	<u>0.16</u>	<u>0.10</u>	<u>0.21</u>	<u>0.39</u>	<u>0.19</u>	<u>0.13</u>	<u>0.30</u>
<u>115</u>	<u>0.28</u>	<u>0.14</u>	<u>0.09</u>	<u>0.19</u>	<u>0.35</u>	<u>0.18</u>	<u>0.12</u>	<u>0.29</u>
<u>120</u>	<u>0.25</u>	<u>0.13</u>	<u>0.08</u>	<u>0.17</u>	<u>0.32</u>	<u>0.16</u>	<u>0.11</u>	<u>0.28</u>

724

725 *Loading rates to trenches, whether gravity or pressure dosed, are based on the gallons per
726 day of wastewater applied to the bottom of the trench.

727 **Loading rates to drip systems, pads, and mounds are based on the infiltrative surface area
728 provided and are on an aerial basis.

729

730 **12VAC5-610-955. Drip dispersal.**

731 A. Drip dispersal applies wastewater in an even and controlled manner over an absorption
732 area. Drip dispersal system components may include treatment components, a flow equalization
733 pump tank, a filtration system, a flow measurement method, supply and return piping, small
734 diameter pipe with emitters, air/vacuum release valves, redistribution control, and
735 electromechanical components or controls.

736 B. Drip dispersal system tubing shall be color coded and certified by the manufacturer as
737 designed and manufactured for the dispersal of wastewater. All drip dispersal system tubing
738 shall be equipped with emitters approved for use with wastewater. For the application of septic
739 tank effluent, the tubing must have self-cleaning emitters.

740 1. The minimum linear feet of tubing in the system shall be one-half of the minimum soil
741 absorption area in square feet.

- 742 2. All tubing shall be placed on contour.
- 743 3. Except as provided by 12VAC5-613, drip systems dispersing septic tank effluent shall
744 comply with the requirements of 12VAC5-610-594.
- 745 4. Drip systems dispersing secondary effluent or better require a minimum of six inches
746 of cover over the tubing. Cover may be achieved by a combination of installation depth
747 and Group II or Group III soil cover or other approved material over the drip field.
- 748 5. The discharge rate of any two emitters shall not vary by more than 10% in order to
749 ensure that the effluent is uniformly distributed over the entire drip field or zone.
- 750 6. The emitters shall be evenly spaced along the length of the drip tubing at not less than
751 six inches or more than 24 inches apart.
- 752 7. The system design shall protect the drip emitters and system from the effects of
753 siphoning or backflow through the emitters.
- 754 C. Drip dispersal systems shall comply with the following minimum soil absorption area
755 requirements:
- 756 1. For the dispersal of septic tank effluent, the minimum soil absorption area for a drip
757 system shall be calculated by multiplying the trench bottom area required for a low
758 pressure distribution system in Table 5.4 of 12VAC5-610-950 by three.
- 759 2. For the dispersal of ~~secondary or better effluent~~ TL-2 effluent or TL-3 effluent, the
760 minimum soil absorption area shall be in accordance with Table 5.5 of 12VAC5-610-950.
761 ~~calculated by multiplying the trench bottom area for pressure distribution systems in~~
762 ~~accordance with subdivision 10 of 12VAC5-613-80 by three.~~
- 763 3. Air/vacuum release valves shall be located at the high points of the supply and return
764 manifolds to each zone.
- 765 D. All drip dispersal systems shall be equipped with devices or methods to restrict effluent
766 from draining by gravity to portions of a zone or laterals lower in elevation. Variable distribution
767 due to gravity drainage shall be 10% or less within a zone.
- 768 E. A minimum of six hours of emergency storage above the high water alarm in the pump
769 chamber shall be provided. The equalization volume shall be equal to 18 hours of storage. The
770 equalization volume shall be measured from the pump off level to the high water alarm level. An
771 audio/visual alarm meeting the requirements of 12VAC5-610-880 B 8 shall be provided for the
772 pump chamber.
- 773 F. Each drip dispersal zone shall be time-dosed over a 24-hour period. The dose volume
774 and interval shall be set to provide unsaturated flow conditions. Demand dosing is prohibited.
775 Minimum dose volume per zone shall be 3.5 times the liquid capacity of the drip laterals in the
776 zone plus the liquid capacity of the supply and return manifold lines (which drain between
777 doses) accounting for instantaneous loading and drain back.
- 778 1. At each dosing cycle, the system design shall only allow a full dose volume to be
779 delivered.
- 780 2. For design flows greater than 1,000 gallons per day, a means to take each zone off
781 line separately shall be provided. The system shall have the capability to bypass each
782 zone that is taken out of service such that each subsequent dose is dispersed to the
783 next available zone in sequence.
- 784 G. Filtration shall be provided to remove suspended solids and prevent clogging of emitters.
785 The filtration design shall meet the drip tubing manufacturer's particle size requirements for
786 protection of the emitters at a flow rate equal to or greater than the rate of forward flushing.
787 Filter flush water shall be returned to the treatment system at a point where the residuals and

788 volume of the flush water do not negatively impact the effluent quality or exceed the hydraulic
789 design capacity of the treatment system.

790 H. A means for measuring or estimating total flow dispersed to the soil absorption area and
791 to verify field dosing and field flushing rates shall be provided.

792 I. The system shall provide forward field flushing to achieve scouring velocity as specified by
793 the drip tubing manufacturer. Field flushing shall occur on a routine schedule to prevent
794 excessive solids accumulation and clogging. Flush water shall be returned to the treatment
795 system at a point where the residuals and volume of the flush water do not negatively impact
796 the effluent quality or exceed the hydraulic design capacity of the treatment system.

797 J. Electrical components shall be Underwriters Laboratory (UL) listed for the intended
798 purpose. The designer shall provide a description with a schematic diagram of the electrical and
799 control functions in the operation and maintenance manual. The electrical control equipment
800 shall be mounted within a National Electrical Manufacturers Association (NEMA) 4X rated
801 enclosure with a rigid latching door. All switches shall be clearly identified, and all internal wiring
802 shall be factory installed. All wiring shall be installed according to applicable electrical safety
803 codes and the manufacturer's installation schematic.

804 K. All components in a drip dispersal system shall be rated to withstand contact with
805 wastewater and recommended for this application by the manufacturer. All components shall be
806 protected from freezing.

807 L. The designer of the drip dispersal system shall verify the dosing rates, the flushing rates,
808 and other parameters critical to the proper operation of the system at the startup inspection. A
809 summary of the startup inspection shall be included in the operation and maintenance manual
810 and shall include, at a minimum, the dosing volume, the forward flow flushing rate, the pressure
811 head of the system, and verification of proper cycling between zones.

812 **12VAC5-610-960. Elevated sand mound.**

813 A. An elevated sand mound is a soil absorption system that incorporates low pressure
814 distribution and sand filtration to produce treated sewage prior to absorption in the natural
815 underlying soil. The elevated sand mound utilizes less gross soil area than most other soil
816 absorption systems. Elevated sand mounds differ from pads in that elevated sand mounds are
817 always an above ground system, may receive septic tank effluent, always require pressure
818 distribution and the infiltrative surface follows the natural ground surface and contour of the site.

819 ~~B. Mound systems are considered Type III systems (see 12VAC5-610-250 C).~~

820 C. B. Mound systems receiving septic tank effluent shall be designed and constructed in
821 accordance with the Wisconsin Mound Soil Absorption System Siting, Design and Construction
822 Manual prepared by the Small Scale Waste Management Project, School of Natural Resources,
823 College of Agricultural and Life Sciences, University of Wisconsin-Madison dated January 1990
824 2000 or its successor. Drip dispersal or low pressure distribution shall be used.

825 ~~D. C.~~ The manual referred to in subsection C B of this section shall be used for the
826 designated construction of elevated sand mounds. The following criteria are required for all
827 elevated sand mound systems in addition to the requirements found in the manual.

828 ~~1. The construction permit shall require permanent water saving devices; however, there~~
829 ~~shall be no corresponding reduction in the basal area. The construction permit shall be recorded~~
830 ~~and indexed in the grantor index under the holder's name in the land records of the clerk of the~~
831 ~~circuit court having jurisdiction over the site of the sewage disposal system pursuant to~~
832 ~~12VAC5-610-250 J.~~

833 2.1. The proposed mound site shall be fenced, roped or otherwise secured, and marked, to
834 prevent damage by vehicular traffic. Activities on the mound site shall be severely limited in
835 order to protect it to the greatest extent possible.

836 3. ~~Formal plans and specifications, prepared by a licensed professional engineer in~~
837 ~~accordance with 12VAC5-610-250 G, shall be required and must be approved by the health~~
838 ~~department prior to any site-disturbing activities.~~

839 4. ~~The local health department shall be notified at least 48 hours before any work begins~~
840 ~~on the site, including delivery of materials. The mound must be constructed during dry weather~~
841 ~~and soil conditions. The contractor shall schedule a conference with the local health department~~
842 ~~to review the plans and specifications prior to beginning any phase of construction, including~~
843 ~~delivery of materials.~~

844 5. ~~3. Wooded sites shall not be used unless it is shown by the applicant that the wooded site~~
845 ~~is the only site available, and if the applicant can demonstrate that the site can be properly~~
846 ~~prepared (plowed). If a wooded site is used, trees shall be removed by cutting them off at~~
847 ~~ground level, leaving the stumps in place. The cut trees shall be removed using methods that do~~
848 ~~not require driving equipment over the mound site and that do not result in the removal of any~~
849 ~~soil from the site. Larger basal areas may be required on wooded sites.~~

850 6. ~~4. When the depth to a restriction, shrink-swell soils or a water table is less than 24~~
851 ~~inches, pretreatment sufficient to produce a secondary TL-2 effluent or TL-3 effluent may be~~
852 ~~used to reduce these distances as shown in Table 4.4. in accordance with 12VAC5-613-80.~~

853 5. The minimum absorption area for single family residential dwellings shall be 400
854 square feet.

855 D. Elevated sand mounds receiving TL-2 effluent or TL-3 effluent shall adhere to the
856 following additional design criteria.

857 1. The basal area (interface of fill sand and original soil surface) loading rate shall not
858 exceed the values found in Table 5.5.

859 2. The minimum sand depth under the dispersal system is 6 inches.

860 3. The minimum soil cover, after settling, shall be 6 inches as measured from the
861 finished ground surface to the uppermost limit of the dispersal media (or gravelless
862 material) utilized in the absorption area. The finished sideslopes cannot exceed 1:4
863 (rise:run). The soil cover, with amendments as needed, shall be of a quality, character,
864 and fertility suitable to establish a vegetative cover that is uniform and sufficiently mature
865 to survive and inhibit erosion.

866 4. Vertical separation to limiting features as found in 12VAC5-613-80 shall be
867 maintained under the entire infiltrative surface of the basal area.

868 5. Designs supported by Division approved manufacturer's design manuals may deviate
869 from pressure dosing but require dosing to a gravity distribution system at a minimum.

870 **12VAC5-610-966. Pads.**

871 A. A pad is an absorption area wider than 3 feet but not longer than 100 feet with a level
872 infiltrative surface where the bottom of the pad meets the original soil. The minimum standoff to
873 a limiting feature in accordance with 12VAC5-613-80 is to be met under the entire infiltrative
874 surface.

875 B. The minimum effluent quality dispersed to a pad is TL-2 effluent and pad bottom loading
876 rates shall not exceed the values for pads noted in Table 5.5.

877 C. The longest dimension of the basal area of the pad, its length, shall be oriented parallel to
878 the natural surface topographic contours. Minor deviations from surface contours are acceptable
879 as long as the bottom of the pad is level (the entire bottom surface of the pad is at the same
880 elevation, not to exceed 10% of the depth of the pad from the ground surface or plus or minus 2
881 inches, whichever is less), and intersects a similar soil horizon across its surface.

882 D. Pads and trenches may be used together in a single system when the respective pad or
883 trench subsystems follow the respective design criteria found in this chapter and are separated
884 by a minimum of 6 feet between the sidewall of the pad and the trench. When multiple pads are
885 used on a site, the pads must be separated by the width of the pad as measured perpendicular
886 to the natural surface topographic contour.

887 E. Pads shall be limited to sites with slopes of 10% or less (less than or equal to 10 feet of
888 rise for every 100 feet of run).

889 F. Dosing. All pads must be dosed. Pad systems over 1,000 gallons per day must be
890 pressure dosed. When pads are installed at less than 12 inches from the ground surface, timed
891 dosing shall be used to disperse the effluent.

892 G. The minimum absorption area for single family residential dwellings shall be 400 square
893 feet.

894 H. Pad Construction.

895 1. Gravel pads shall have a minimum installation depth of 12 inches, unless in
896 Texture Group I or II soils where the installation depth can be reduced to 8 inches.
897 On sloping sites, the minimum installation depth is measured on the downhill side of
898 the pad infiltrative surface. The construction of the pad's gravity percolation line and
899 gravel bedding shall follow [12VAC5-610-930E](#) with the exception that the bottom of
900 the pad is level and not sloping. Piping shall have a maximum center to center
901 spacing of 9 feet.

902 2. Gravel pads utilizing low pressure distribution shall follow [12VAC5-610-940](#) for
903 construction and dosing cycle (volume). Gravel pads using low pressure distribution
904 shall have a minimum installation depth of 12 inches, unless in Texture Group I or II
905 soils where the installation depth can be reduced to 8 inches. On sloping sites, the
906 minimum installation depth is measured on the downhill side of the pad infiltrative
907 surface. Piping shall have a maximum center to center spacing of 9 feet.

908 3. Pads utilizing gravelless material as found in [12VAC5-610-930F](#) shall follow
909 [12VAC5-630F](#) and the manufacturer's instructions on minimum depth of installation,
910 but in no case shall a pad be installed at less than 8 inches from the original soil
911 surface. Gravelless material shall have a maximum center to center spacing of 9
912 feet. On sloping sites, the minimum installation depth is measured on the downhill
913 side of the pad infiltrative surface.

914 4. Designs supported by a Division approved manufacturer's design manual may
915 deviate from the maximum slope, depth of installation, separation distance between
916 pads, and timed dosing when the dispersal area is constructed in accordance with
917 the approved manual.

918 I. The minimum soil cover, after settling, shall be 6 inches as measured from the finished
919 ground surface to the uppermost limit of the dispersal media (or gravelless material) utilized in
920 the absorption area. If the cover is mounded above grade, the finished sideslope cannot exceed
921 1:4 (rise:run). The soil cover, with amendments as needed, shall be of a quality, character, and
922 fertility suitable to establish a vegetative cover that is uniform and sufficiently mature to survive
923 and inhibit erosion.



COMMONWEALTH of VIRGINIA

Department of Health

P O BOX 2448

RICHMOND, VA 23218

M. NORMAN OLIVER, MD, MA
STATE HEALTH COMMISSIONER

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

MEMORANDUM

DATE: September 8, 2021

TO: Virginia State Board of Health

FROM: Heather Board, Acting Director, Office of Family Health Services

SUBJECT: Final Stage – Regulations Governing Virginia Newborn Screening Services

The Virginia Newborn Screening Program has initiated the final stage to amend the existing newborn screening regulation to add spinal muscular atrophy (SMA) and X-linked adrenoleukodystrophy (X-ALD) to the newborn screening panel. Approval of this regulatory action would result in amending 12VAC5-71 to revise Section 30, which lists the specific disorders and genetic diseases that must be screened in Virginia. All Virginia newborns would be screened for SMA and X-ALD at birth. The Virginia Department of Health works in partnership with the Department of General Services' Division of Consolidated Services to provide blood spot newborn screening services.

Upon approval by the Board, the final regulation will be submitted to the Regulatory Town Hall to begin the Executive Branch Review Process. Following approval by the Governor, it will be published in the Virginia Register of Regulations for a 30-day final adoption and public comment period.



townhall.virginia.gov

Final Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-71
VAC Chapter title(s)	Regulations Governing Virginia Newborn Screening Services
Action title	Amend regulations to add SMA and X-ALD to the Virginia Newborn Screening System core panel of heritable disorders and genetic diseases.
Date this document prepared	7/12/2021

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

Brief Summary

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

The proposed regulatory action would amend the existing newborn screening regulation to add spinal muscular atrophy (SMA) and X-linked adrenoleukodystrophy (X-ALD) to the newborn screening panel. Blood spot newborn screening services are provided by the Department of General Services' Division of Consolidated Laboratory Services (DCLS) in partnership with the Virginia Department of Health (VDH). SMA is a genetic disorder that is estimated to occur in approximately 9.1 out of every 100,000 live births. X-ALD is a genetic disorder that is estimated to occur in approximately 6 out of every 100,000 live births. Treatment for both X-ALD and SMA is available if detected early. Screening is necessary, as these disorders cannot be detected at birth through physical examinations. The additions of SMA and X-ALD to the newborn screening panel have been recommended by the Virginia Genetics Advisory Committee. On the national level, these disorders have been added to the core panel of 35 genetic disorders included in the Recommended Uniform Screening Panel (RUSP) of the U.S. Secretary of Health and Human Services' (HHS) Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC).

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.

ACHDNC – Advisory Committee on Heritable Disorders in Newborns and Children

DCLS – Division of Consolidated Laboratory Services

HHS – Health and Human Services

RUSP – Recommended Uniform Screening Panel

SMA – spinal muscular atrophy

VDH – Virginia Department of Health

VNSP – Virginia Newborn Screening Program

X-ALD – X-linked adrenoleukodystrophy

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.

Enter statement here

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.

There are no changes to the previously reported information.

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.

The State Board of Health is authorized to make, adopt, promulgate and enforce regulations by Section 32.1-12 of the Code of Virginia.

Section 32.1-65 of the Code of Virginia requires newborn screening to be conducted on every infant born in the Commonwealth of Virginia.

Section 32.1-67 of the Code of Virginia requires the Board of Health to promulgate regulations as necessary to implement Newborn Screening Services. The regulations are required to include a list of newborn screening tests pursuant to Section 32.1-65.

Purpose

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

Spinal muscular atrophy is a genetic disorder characterized by weakness and wasting (atrophy) in muscles used for movement (skeletal muscles). SMA is caused by a loss of specialized nerve cells, called motor neurons, which control muscle movement. SMA affects 9.1 out of every 100,000 births and there are five classification types. Type 0 often leads to fetal loss or newborns with significant involvement and death in early infancy; this is the rarest and most severe form of the condition. Type I, the most common form, leads to progressive weakness in the first six months of life and, without targeted intervention, death prior to two years of age. Type II is associated with progressive weakness by 15 months of life and, without targeted intervention, respiratory failure and death after the third decade of life. Types III and IV are associated with progressive weakness that develops after one year of life or in adulthood, and most individuals have a normal lifespan. Treatment for SMA generally includes a disease-modifying therapy that uses FDA-approved Spinraza, as well as clinical care support therapies such as nutritional support, respiratory support, pulmonary care, orthopedic and rehabilitation care, and palliative care.

X-linked adrenoleukodystrophy is a genetic disorder that occurs primarily in males, mainly affecting the nervous system and the adrenal glands. In the United States, X-ALD affects 6 out of every 100,000 births, regardless of sex. There are three distinct types of X-ALD: a childhood cerebral form, an adrenomyeloneuropathy type, and a form called Addison disease only. Childhood cerebral X-ALD is the most serious form of X-ALD and it usually presents between 2.5 and 10 years of age. It is associated with rapid neurologic decline and death or disability an average three years after onset. Signs and symptoms of the adrenomyeloneuropathy type appear between early adulthood and middle age. People with X-ALD whose only symptom is adrenocortical insufficiency are said to have the Addison disease only form, which is the mildest form of the three types. In these individuals, adrenocortical insufficiency can begin anytime between childhood and adulthood. Treatment for X-ALD is difficult to predict since symptom onset varies and, in many cases, might not occur until after infancy. Treatment options include hormone therapy and hematopoietic stem cell transplantation (HSCT), depending on the severity of the disorder.

All newborns in Virginia would be screened for SMA and X-ALD as a result of this proposed regulatory action. Screening for SMA and X-ALD can provide affected infants the benefit of early diagnosis and treatment. Screening is an effective diagnostic tool since these disorders cannot be detected at birth through a physical examination. Laboratory screening is available at a cost.

The addition of SMA and X-ALD to the core panel will result in an increase to the newborn screening fee. The VDH Office of Family Health Services has a longstanding partnership with DCLS to provide blood spot newborn screening services. The Virginia Newborn Screening Program is solely funded through Enterprise Funding, which is generated from the collection of fees from dried blood spot specimen kits sold to submitting birthing facilities and health care providers statewide. As of October 1, 2019, the newborn screening fee is \$138 per card. To implement these two screenings statewide, DCLS will require infrastructure investment that includes additional laboratory equipment; programmatic staff; application development to incorporate screening results; incorporation of new education modules; identification of specialized medical support systems for infants and their families; and family support and case management services for infants diagnosed with SMA or X-ALD. Adding SMA to the newborn screening

panel resulted in an increase of \$2.16, and adding X-ALD to the newborn screening resulted in an increase of \$10.84 per sample, for a total of \$13 for both of these disorders. The \$13 increase is included in the \$138 screening fee that went into effect October 2019.

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 proposed changes to 12 VAC 5-71 will revise Section 30, which lists the specific disorders and genetic diseases that must be screened in Virginia, by adding SMA and X-ALD to the state's core panel. Currently, DCLS analyzes biological markers that may be indicative of 31 certain disorders that constitute the core panel. Section 32.1-67 of the Code of Virginia requires that this list of screened disorders be in the regulation. Section 32.1-65 of the Code requires that Virginia's screening tests are consistent with the panel recommended by the U.S. Secretary of HHS ACHDNC.

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 of the proposed regulatory action to the public is that screening for SMA and X-ALD can provide affected infants the benefit of early diagnosis and treatment. Screening is an effective diagnostic tool since these disorders cannot be detected at birth through a physical examination. The primary disadvantage to the public is that adding these two screenings to the panel results in a cost increase.

A primary advantage of the proposed regulatory action to the agency is that the action aligns with the recommendation from the Virginia Genetics Advisory Committee to add SMA and X-ALD to the state's core panel. This also aligns with the panel recommended by the U.S. Secretary of HHS ACHDNC.

A disadvantage to the regulated community, government officials and the public is the projected increase in the cost of the two screenings. Newborn screening is a fee-for-service program, and the fee is paid by hospitals and other screeners who must purchase the filter paper kits used for blood spot collection. Most screening is performed in hospitals, with about 10-15% of screening performed by private physicians and military facilities. Hospitals do not generally pass on these costs to patients because third party payers usually pay a negotiated bundled amount per delivery, and Medicaid reimbursed delivery payment is set by the state. Self-pay patients may be responsible to pay the screening fee themselves if they have the resources to do so.

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 changes to the previously reported information.

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.

There are no changes to the previously reported information.

Public Comment

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

Committer	Comment	Agency response
Various	VDH received 64 comments from various members of the public in support of this regulatory action to add SMA and X-ALD to Virginia’s newborn screening panel.	VDH concurs with the comments in support of the proposed regulatory amendment to add SMA and X-ALD to Virginia’s newborn screening panel. No response is required.
Bret Rawlings, Virginia Hospital and Healthcare Association	Mr. Rawlings expressed concerns regarding the economic impact of the amended regulation on hospitals, birthing centers, midwives, and infants and their families. These concerns mainly address the costs highlighted in proposed stage agency background document and the Department of Planning and Budget’s Economic Impact Analysis, which detail costs for the Department of General Services (DGS) Division of Consolidated Laboratory Services (DCLS) to implement the addition of SMA and X-ALD to the newborn screening panel. The costs are supported by fee increases to DCLS’s dried blood spot specimen kits that went into effect in October 2019 and that these increased fees have been passed on to hospitals, birthing centers, and infants and their families. Mr. Rawlings	VDH concurs that this regulatory amendment and associated fee increases to DCLS’s dried blood spot specimen kits potentially results in an economic impact to hospitals, birthing centers, midwives, and infants and their families.

	<p>summarized that the approach to fund conditions that are added to the newborn screening panel by increasing fees for the dried blood spot kits is not sustainable.</p> <p>Mr. Rawlings recommended: “One possible option to address this in the Newborn Screening Regulations would be to limit DCLS authorization to establish fees or implement increases to fees to include only certain incremental variable costs incurred in performing tests. For example, the costs required to purchase additional instruments or equipment needed to perform the test, additional space and related build-out costs, and software costs could not be included in the fee. Such costs would either need to be absorbed by DCLS or funded through DCLS or Department appropriation requests to the General Assembly.”</p>	<p>VDH concurs that there is an option to amend the regulatory language to limit fee increases related to adding new disorders to the newborn screening panel in the future. However, the fee increase to support the addition of SMA and X-ALD to the panel went into effect October 1, 2019. The regulation is currently undergoing periodic review and a stakeholder workgroup of the Newborn Screening Advisory Committee will review the regulation and make suggested amendments. The recommendation to amend 12-VAC5-71-100 will be put forth for consideration during the regulatory process.</p> <p>VDH does not concur that the costs to add new disorders to the newborn screening panel in the future should be absorbed by DCLS. VDH will follow the established process for developing and submitting a budget proposal request for a General Assembly appropriation for costs related to adding new disorders to the newborn screening panel in accordance with the regulation and when required. The costs for adding SMA and X-ALD to the newborn screening panel are supported by fee increases that went into effect October 1, 2019 so a request for an appropriation is not applicable at this time.</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
		There are no new changes or		

		requirements from the previous stage.		
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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
12VAC5-71-30		This section lists the Virginia Newborn Screening System’s core panel of heritable disorders and genetic diseases for which the newborn dried blood spot testing is conducted.	<p>Change: The proposed change would add SMA and X-ALD to the core panel.</p> <p>Intent: Align Virginia Newborn screening panel with the recommendations of the Virginia Genetics Advisory Committee and the U.S. Secretary of HHS ACHDNC.</p> <p>Rationale: Screening for these two additional disorders can provide affected infants the benefit of early diagnosis and treatment.</p> <p>Likely Impact: Better health outcomes and higher infant survival rates.</p>

1 **Project 5996**

2 **Department Of Health**

3 **Amend Regulations to add SMA and X-ALD to the Virginia Newborn Screening System**

4 **12VAC5-71-30. Core panel of heritable disorders and genetic diseases.**

5 A. The Virginia Newborn Screening System, which includes the Virginia Newborn Screening
6 Program, the Virginia Early Hearing Detection and Intervention Program, and the Virginia critical
7 congenital heart disease screening, shall ensure that the core panel of heritable disorders and
8 genetic diseases for which newborn screening is conducted is consistent with but not necessarily
9 identical to the U.S. Department of Health and Human Services Secretary's Recommended
10 Uniform Screening Panel.

11 B. The department shall review, at least biennially, national recommendations and guidelines
12 and may propose changes to the core panel of heritable disorders and genetic diseases for which
13 newborn dried-blood-spot screening tests are conducted.

14 C. The Virginia Genetics Advisory Committee may be consulted and provide advice to the
15 commissioner on proposed changes to the core panel of heritable disorders and genetic diseases
16 for which newborn dried-blood-spot screening tests are conducted.

17 D. Infants under six months of age who are born in Virginia shall be screened in accordance
18 with the provisions set forth in this chapter for the following heritable disorders and genetic
19 diseases, which are identified through newborn dried-blood-spot screening tests:

- 20 1. Argininosuccinic aciduria (ASA);
- 21 2. Beta-Ketothiolase deficiency (BKT);
- 22 3. Biotinidase deficiency (BIOT);
- 23 4. Carnitine uptake defect (CUD);

- 24 5. Classical galactosemia (galactose-1-phosphate uridylyltransferase deficiency) (GALT);
- 25 6. Citrullinemia type I (CIT-I);
- 26 7. Congenital adrenal hyperplasia (CAH);
- 27 8. Cystic fibrosis (CF);
- 28 9. Glutaric acidemia type I (GA I);
- 29 10. Hb S beta-thalassemia (Hb F,S,A);
- 30 11. Hb SC-disease (Hb F,S,C);
- 31 12. Hb SS-disease (sickle cell anemia) (Hb F, S);
- 32 13. Homocystinuria (HCY);
- 33 14. Isovaleric acidemia (IVA);
- 34 15. Long chain L-3-Hydroxy acyl-CoA dehydrogenase deficiency (LCHAD);
- 35 16. Maple syrup urine disease (MSUD);
- 36 17. Medium-chain acyl-CoA dehydrogenase deficiency (MCAD);
- 37 18. Methylmalonic acidemia (Methylmalonyl-CoA mutase deficiency) (MUT);
- 38 19. Methylmalonic acidemia (Adenosylcobalamin synthesis deficiency) (CBL A, CBL B);
- 39 20. Multiple carboxylase deficiency (MCD);
- 40 21. Phenylketonuria (PKU);
- 41 22. Primary congenital hypothyroidism (CH);
- 42 23. Propionic acidemia (PROP);
- 43 24. Severe combined immunodeficiency (SCID);
- 44 25. Tyrosinemia type I (TYR I);

- 45 26. Trifunctional protein deficiency (TFP);
- 46 27. Very long-chain acyl-CoA dehydrogenase deficiency (VLCAD);
- 47 28. 3-hydroxy 3-methyl glutaric aciduria (HMG);
- 48 29. 3-Methylcrotonyl-CoA carboxylase deficiency (3-MCC);
- 49 30. Pompe disease; ~~and~~
- 50 31. Mucopolysaccharidosis type I (MPS I);
- 51 32. Spinal muscular atrophy (SMA); and
- 52 33. X-linked adrenoleukodystrophy (X-ALD).

53 E. Infants born in Virginia shall be screened for hearing loss in accordance with provisions set
54 forth in §§ 32.1-64.1 and 32.1-64.2 of the Code of Virginia and as governed by 12VAC5-80.

55 F. Newborns born in Virginia shall be screened for critical congenital heart disease in
56 accordance with provisions set forth in §§ 32.1-65.1 and 32.1-67 of the Code of Virginia and as
57 governed by 12VAC5-71-210 through 12VAC5-71-260.



VIRGINIA'S **Plan For Well-Being**

2021 Update

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INTRODUCTION

Virginia’s State Health Improvement Plan (SHIP), known as the Plan for Well-Being outlined a path for improving the health and well-being of Virginians by 2020 through four aims, 13 goals, and 29 measures. Virginia’s Plan for Well-Being laid out the foundation for giving everyone a chance to live healthy life by: (1) Factoring health into policy decisions related to education, employment, housing, transportation, land use, economic development, and public safety; (2) Investing in the health, education, and development of Virginia’s children; (3) Promoting a culture of health through preventive actions; and (4) Creating a connected system of healthcare. The measure of success is that the percent of adults in Virginia who report positive well-being increases. The previously submitted 2020 Annual Report provided the updated figure for each measure in the Plan for Well-Being.

In Virginia, as in many states, the State Health Assessment (SHA) and SHIP are linked and part of one continuous process. With the expiration of the Plan for Well-Being, Virginia has embarked on conducting a new SHA. This annual report summarizes information regarding the progress of the Virginia Department of Health (VDH) towards the 2021 SHA which will serve as the foundation for the new Plan for Well-Being, Virginia’s SHIP.

STATE HEALTH ASSESSMENT

The Public Health Accreditation Board defines a SHA as “...a collaborative process of collecting and analyzing data and information for use in educating and mobilizing communities, developing priorities, garnering resources and planning actions to improve the population’s health.” A comprehensive SHA supports a state’s ability to identify the status of certain health outcomes and understand where there is need for improvement. This is one of the 10 essential public health services-- to assess health status of populations (Figure 1).



Figure 1.

Note. From The Public Health National Center for Innovations

VDH determined that the SHA would be conducted utilizing the Mobilizing for Action through Planning and Partnerships (MAPP) framework from the National Association of County and City Health Officials (NACCHO). The MAPP framework (Figure 2) is a community-driven strategic planning tool that utilizes six phases to better understand a given community. The process is directed by a steering committee comprised of public and private sector partners.

VDH convened a diverse group of stakeholders and communities to gain a better understanding of the strengths and needs of Virginians and to identify strategies that lead to high impact and equitable health outcomes with the lowest sustainable efforts. VDH began the preliminary work of conducting the SHA in November 2019 with the inaugural meeting of the SHA/SHIP Advisory Council.

The Advisory Council (see Appendix A) was charged to develop recommendations on public health priorities, goals, objectives, and strategies to improve the health of all Virginians and to make Virginia the healthiest state in the nation. The Advisory Council identified the following principles to guide the development of the SHA:

- Partnership focused
- Diverse and inclusive
- Transparent
- Innovative
- Data driven
- Equitable and just

While a SHA describes the health of the state community, it is also important to be able to draw out the health concerns of communities by age, race/ethnicity, socioeconomic status, disease status, gender, and geographic region from within the larger state community.¹ This analysis aids in identifying health disparities and the inequities which result in disparate health outcomes. The Advisory Council determined that the SHA would be guided by health equity as a foundation.



Figure 2

Note. From The National Association of County and City Health Officials

¹ Association of State and Territorial Health Officials. (2018). *State Health Assessment Guidance and Resources*. Arlington: Association of State and Territorial Health Officials.

The Advisory Council reviewed and responded to a list of indicators proposed by VDH based on a review of other state SHAs. VDH began the process of finalizing the indicators to be used in the SHA based on input from the Advisory Council and consideration of the following criteria:

- Magnitude/seriousness of health issue
- Ability to affect change
- Health equity - can we measure disproportionate effect between subpopulations?
- Root cause/social determinants of health (SDOH) - measure SDOH that impact multiple health outcomes
- Quality of the data
- Trend data available?
- Comparison data available?

VDH began planning for a presentation of agreed upon indicator data for the Advisory Council. This interactive meeting would provide an opportunity for the Advisory Council to discuss the data with subject matter experts and data stewards to support a better understanding of the data and identified trends. The meeting, set to occur in March 2020, was cancelled as a result of the COVID-19 pandemic.

State Health Assessment (SHA)

Assess the State



Figure 3

Note: From VDH

VDH efforts related to coordinating the SHA remained on hold until April 2021 when the VDH SHA/SHIP Manager position was filled. VDH resumed the coordination of conducting a SHA per the process identified below (Figure 3).

As the COVID-19 pandemic significantly stressed public health systems in Virginia and throughout the country, gaps in health care for underserved and vulnerable populations were exposed. This combined with the disproportionate impact of COVID-19 on communities of color significantly raised the awareness of the impact of systemic racism on health. As a result of these lessons learned, VDH re-examined the work initiated on the SHA pre-pandemic to ensure the SHA would best reflect the Virginia of today.

The membership of the Advisory Council has been expanded to include more diverse representation and geographic variety. The Advisory Council represents an array of perspectives from multiple agencies within state government, and groups and organizations from outside state government including, but not limited to, hospitals and health care providers, academic institutions, statewide non-profits, and organizations engaged in addressing health and equity in their communities.

VDH has also integrated work supported by the local health districts, the VDH strategic plan, the Office of Health Equity and the 2019 5-year Maternal and Child Health Needs Assessment into the planning process for the SHA. The results of the assessment will:

- Reflect and address the priorities of Virginians
- Be supported by community members and residents
- Include meaningful strategies and areas of focus
- Define clear and measurable outcomes
- Help inform strategic funding and resource allocation
- Demonstrate an intentional and thoughtful health equity approach

As part of the focus on equity and engaging underserved and underrepresented populations, the SHA will engage key populations of focus. These populations include lesbian, gay, bisexual, transgender, queer, intersex, and asexual (LGBTQIA) individuals, the immigrant population, disabled individuals, elderly, youth, and veterans.

DATA MEASURES AND INDICATORS

QUANTITATIVE DATA

Data analysts and epidemiologists at VDH have adjusted the data indicators that will comprise the SHA based on lessons learned during COVID-19 and continued feedback from the Advisory

Council. Where available, data will be stratified by race, gender, income, or education level. Data indicator categories include:

- Demographics
- Leading causes of death
- SDOH
- Access to care
- Chronic diseases and behavioral risk factors
- Mental health
- Alcohol and substance use
- Injury and violence
- Maternal and child health
- Environmental health
- Communicable diseases
- COVID-19

QUALITATIVE DATA

The qualitative data collection of the SHA will provide a deeper understanding of issues the residents of Virginia feel are important to the state and their respective communities. The qualitative data collection will address the following key areas of focus through a statewide survey, focus groups and key informant interviews:

- What is important to our State?
- How is quality of life perceived in our state?
- What assets do we have that can be used to improve community health?

A statewide survey was developed with input from the Advisory Council. The initial list of questions was compiled based on questions from the Advisory Council, questions from other state health assessments and questions from NACCHO's MAPP toolkit. This initial list of questions was sent to the advisory committee for input and guidance. A shared document was created to enable the Advisory Council members to view comments and engage in discussions for a period of two weeks. A final list of questions for the statewide survey has been created.

To assist in eliciting responses, a marketing campaign will promote the online survey to communities and organizations statewide as well as targeting the populations of focus. The survey will remain open for one month to collect responses.

STATE HEALTH ASSESSMENT TIMELINE

January 2022 Data Presentations, discussion, and prioritization

February 2022 Qualitative assessments complete

March 2022 Publish SHA, improvement strategy prioritization, and selection

STATE HEALTH IMPROVEMENT PLAN

A SHIP builds on the SHA’s identified issues to further optimize and prioritize work that is both responsive to the needs of the state’s populations and will make the greatest impact on health promotion and disease prevention.²

The SHIP will be used to set direction for the next five years for budgets, policies, and programs across VDH and by partners from the variety of sectors that contribute to health and equity. The SHIP is the strategic plan for partners to align efforts to address the selected high priorities for reducing inequities; it does not represent the totality of the work for improving each of the health outcomes for all Virginians.

The health improvement goals/outcomes will be broadly stated to include the whole population and indicators will be selected to measure progress on reducing disparities/inequities rather than changing the curve for the whole population. Individuals affected by inequity will be engaged in developing the strategies for improvement by reviewing the potential strategies, offering suggestions based on local knowledge, and identifying options for mobilizing partners.

The Advisory Council will continue to meet on a regular basis to provide overall direction to the development of Virginia’s new SHIP. The Advisory Council will ensure that both the process and product meet the goals of developing a plan for the state to improve population health and advance health equity, based on the best available data on population health trends combined with input from residents of Virginia.

The goal is to publish and implement the SHIP in May 2022.

² Association of State and Territorial Health Officials. (2019). *Developing a State Health Improvement Plan: Guidance and Resources*. Arlington: Association of State and Territorial Health Officials

APPENDIX A

SHA/SHIP Advisory Council Members

First Name	Last Name	Organization
Rochelle	Altholz	Department of Conservation and Resources
Sue	Armstrong	Virginia Housing Development Association
Chethan	Bachireddy	Department of Medical Assistance Services
Eric	Bendfeldt	Virginia Tech
Ruth	Bernheim	University of Virginia
David	Blount	Virginia Association of Planning District Commissioners
Catherine	Brisland	Sentara
Sandy	Chung	Pediatrician/Inova
Mark	Cole	Department of Transportation
Sean	Connaughton	Virginia Hospital and Healthcare Association (VHHA)
Christy	Connolly	Path Foundation
Patrick	Crute	Virginia YMCAs
Deborah	Davis	Virginia Commonwealth University Health
Heather	Fritz	EMS of Virginia
Sheryl	Garland	Virginia Commonwealth University Health
Kathy	Glazer	Virginia Early Childhood Foundation
Andrea	Gregg (on behalf of Duke Storen/PHV)	Department of Social Services
Nia	Harrison	Virginia Board for People with Disabilities
Sam	Hollins	Department of Education
Hamilton	Holloway	Families Forward Virginia
Reese	Jackson	Chesapeake Regional Medical Center
Emily	Keenum	Virginia Early Childhood Foundation
Marty	Kilgore	Virginia Foundation for Healthy Youth
Susie	Lee	Potomac Health Foundation

First Name	Last Name	Organization
Rachel	Lynch	Inova Health
Octavia	Marsh	Hanover Cares
Rufus	Phillips	Virginia Free Clinics
Erik	Rison	Virginia Chamber of Commerce
Travis	Staton	United Way of Southwest Virginia
Jeff	Stover	Department of Health
Rex	Taylor	Virginia State Police
Michelle	Taylor	Virginia Free Clinics
Audrey	Trussell	United Way
Bill	Harrison	Diversity Richmond
John	Maxwell	Virginia Department of Veterans Affairs
Jarene	Fleming	Breast Feeding Advisory Committee
Felica	Baez	Hanover County
Kelly	Cannon	VHHA