Board of Health Quarterly Meeting

December 5, 2024

Richmond, Virginia

WELCOME AND INTRODUCTIONS

AGENDA

Agenda	
Approval of September 19, 2024 Minutes	Gary Critzer, Chair
Commissioner's Report	Karen Shelton, MD State Health Commissioner
Regulatory Action Update	John Kotyk Legislative and Regulatory Coordinator
Public Comment Period	
Break	
Lunch Presentation: General Assembly 2025	Joe Hilbert, Deputy Commissioner, Governmental and Regulatory Affairs Julie Henderson, Director, Office of Environmental Health Services Kim Beazley, Director, Office of Licensure and Certification
Regulations Governing Virginia Critical Congenital Heart Disease Newborn Screening Services 12VAC5-72 (Fast Track Amendments)	Vanessa Walker Harris, MD Director, Office of Family Health Services
Home Care Organization Regulations 12VAC5-381 (Proposed Amendments)	Ms. Beazley
Other Business	
Adjourn	

MINUTES FROM SEPTEMBER 19, 2024

State Board of Health
September 19, 2024, 9:00am

Members Present: James Cole; Gary Critzer, Chair; Michael Desjadon; Elizabeth Ruffin Harrison; Anna Jeng, ScD; Patricia Kinser, PhD; Melissa Nelson, MD; Maribel Ramos; Vickie Runk; Ann B. R. Vaughters, MD; Yesli Vega; Walter Vest, MD; and Cindy Warriner

Maribel Ramos participated virtually from her home in Alexandria for personal reasons.

Members Absent: Douglas Daniels, DVM; Lee Jones, DMD.

Virginia Department of Health (VDH) Staff Present: Marcus Allen, Director, Children and Youth with Special Health Care Needs Program, Office of Family Health Services; Erin Callas, BSN, RN, VDH Agency Star; Michael Capps, Senior Policy Analyst; Jessica Coughlin, VDH Agency Star; Stephanie Dunkel, Deputy Commissioner for Population Health and Preparedness; Laurie Forlano, DO, State Epidemiologist; Joe Hilbert, Deputy Commissioner for Governmental and Regulatory Affairs, Marian Hunter, Public Information Officer; Alexandra Jansson, Senior Policy Analyst; John Kotyk, Legislative and Regulatory Coordinator; R. Christopher Lindsay, Chief Operating Officer; Karen Shelton, MD, State Health Commissioner; Maria Reppas, Director, Office of Communications; and John Ringer, Acting Deputy Commissioner for Administration

Other Staff Present: Robin Kurz, Assistant Attorney General, Office of the Attorney General

Call to Order
Mr. Critzer called the meeting to order at 9:08 am.

Introductions
Mr. Critzer welcomed the new Board members and those in attendance to the meeting. Mr. Critzer informed the Board of the tragic loss of Dr. Jones' daughter. He asked that the Board keep the family in their thoughts and prayers.

Review of Agenda
Ms. Jansson reviewed the agenda and the items contained in the Board's binder.

Approval of June 13, 2024 Minutes
The minutes from the June meeting were reviewed and approved by consensus.

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

- Agency Stars
- Key Personnel Changes
- Communicable Disease Updates
- Harmful Algal Blooms 2024
- Emergency Preparedness
- EMS Update

- Veteran Suicide Prevention
- Maternal Health Updates
- Electronic Health Record Update
- Language Access

There was discussion around COVID vaccines and the bridge program; parvovirus testing availability; membership, and implementation of the reestablishment of the Task Force on Maternal Health Data and Quality Measures (Executive Order 32); and the Veteran Identify Screen and Refer (VISR) partnership with the Department of Veterans Services.

There was also discussion regarding the VDH Internal Audit report concerning the Office of Emergency Medical Services (OEMS). Dr. Shelton informed the Board they would receive copies of the Internal Audit Report and the consultant report from Fitch & Associates. Mr. Critzer provided some additional comments concerning OEMS.

Regulatory Action Update

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

There are 54 pending actions under development:

- 13 NOIRAs
- 10 proposed actions
- 7 final actions
- 24 fast track actions

Since the June 13, 2024, meeting the Commissioner has taken two regulatory actions on behalf of the Board. The first was approval of a Notice of Intended Regulatory Action (NOIRA) for the Sanitary Regulations for Hotels (12 VAC5-431). This action was initiated a result of a recent periodic review. Amendments will remove outdated information, reflect best practices and the most up to date scientific information, and consider public comment and regulatory reduction where possible. The second was approval of a NOIRA for the Regulations Governing Vital Records (12 VAC5-550). This action will provide clarity related to delayed birth filings, clarify requirements for establishment of a new birth certificate for registrants born via surrogacy, make style and form updates as needed, increase certain fees, and consider regulatory reduction where possible.

Mr. Kotyk advised the Board that there are 16 periodic reviews in progress:

- 12 VAC 5-67 Advance Health Care Directive Registry
- 12 VAC 5-125 Regulations for Bedding and Upholstered Furniture Inspection Program
- 12 VAC 5-215 Rules and Regulations Governing Health Data Reporting
- 12 VAC 5-216 Methodology to Measure Efficiency and Productivity of Health Care Institutions
- 12 VAC 5-217 Regulations of the Patient Level Data System
- 12 VAC 5-220 Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations
- 12 VAC 5-371 Regulations for the Licensure for Nursing Facilities

- 12 VAC 5-381 Home Care Organization Regulations
- 12 VAC 5-391 Regulations for the Licensure of Hospices
- 12 VAC 5-405 Rules Governing Private Review Agents
- 12 VAC 5-407 Regulations for the Submission of Health Maintenance Organization Quality of Care Performance Information
- 12 VAC 5-507 Guidelines for General Assembly Nursing Scholarships and Loan Repayment Program Requiring Service in Long-Term-Care Facility
- 12 VAC 5-520 Regulations Governing the State Dental Scholarship
- 12 VAC 5-545 Guidelines for the Nurse Educator Scholarship
- 12 VAC 5-590 Waterworks Regulations
- 12 VAC 5-620 Regulations Governing Application Fees for Construction Permits for Onsite Sewage Disposal Systems and Private Wells

Public Comment Period

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

Spotlight Presentation: Sickle Cell Programs at VDH

Mr. Allen presented on Sickle Cell programs at VDH including the Newborn Screening Bloodspot Program, the Virginia Sickle Cell Awareness Program, and the Adult and Pediatric Comprehensive Sickle Cell Clinic Network. A brief overview and updates for HB 252 Statewide Sickle Cell Disease Registry and HB 255 Adult Wellness Screening were presented to the Board. The Office of Family Health Services plans to further develop their adult clinic programs, and hire a statewide sickle cell coordinator, an epidemiologist, and other registry-related positions.

There was discussion concerning the following:

- How VDH addresses the mistrust of the healthcare system in the adult population, encouraging them to use the Sickle cell registry by focusing on building community partnerships, providing patient education, and public awareness.
- Current partnerships and possible future partnerships with ER physicians and hospital networks along with continuing efforts to reduce ER related crisis visits and produce better patient outcomes. Additionally discussed were possible opportunities for continuing education credits for physicians.
- The importance of care coordination and pain management for this patient population; breaking the drug seeking stigma often associated with the disease and other challenges.
- Electronic Medical Record systems should contain notes from visits from other physicians and will often contain medications prescribed including narcotics.
- Blood donations are welcomed and encouraged as the patients often receive multiple transfusions throughout their lifetime.

Lunch Presentation: Kepone to Blue Zone

Clifford Morris, MD, President, Morris Cardiovascular and Risk Reduction Center, and Director, and Hopewell Blue Zone Project presented on Kepone to Blue Zone: Life Span vs Health Span. Hopewell is known for manufacturing and chemical plants. In the 1970's, Kepone was dumped illegally into the James River, and made its way into Hopewell's water supply. Patients in Hopewell in the 1970's were found to have extremely highly toxic Kepone levels in their blood.

Blue Zones are regions in the world that in studies show the communities have healthier and longer lifespans. Dr. Morris educates the Hopewell community on achieving a heart healthy, pain free, and low medications lifestyle using the Power 9:

- Move naturally (Movement)
- Find your purpose (Mind)
- Slow down (Mind)
- Wine at 4 (Eating right)
- Plant Slant (Eating right)
- 80's rule (Eating right)
- Belong and give back (Connections)
- Loved ones first (Connections)
- Right tribe (Connections)

The goal of the Hopewell Blue Zone project is to make the community of Hopewell a healthier place to live and raise a family by 2025. Dr. Morris has partnered with various stakeholders at the local and state level to get support for the Blue Zone proposal. He wishes to jointly create a vision and support for the community.

There was a brief discussion concerning "Food as Medicine," and the importance of educating people concerning how to make healthy nutrition choices.

Fast Track Action - Amendment to Regulations Governing Virginia Immunization Information System 12VAC5-115

Dr. Forlano presented the Board with Fast Track Action Amendment to 12VAC5-115 Virginia Immunization Information System (VIIS) following the 2024 Periodic Review.

The regulation is necessary to protect the public health, safety, and welfare of individuals by ensuring that public health information associated with immunization records are kept in an efficient, inclusive, and secure system.

The intent of this regulatory action is to amend the chapter governing VIIS as per the 2024 periodic decision. The amendment adds, removes, and updates regulatory language to enhance clarity; clarifies required and authorized participants in the VIIS system, updates the VIIS registration, onboarding, and training processes, clarifies authorized use of VIIS to protect patient confidentiality; updates the VIIS opt-out process; clarifies VIIS access and reactivation processes; and updates the list of demographic information required to be reported and the timing of VIIS immunization data reporting.

Dr. Vaughters moved, and Dr. Kinser seconded, that the Fast Track Amendments be approved.

Counsel for the board addressed questions regarding whether the statutory definition of "healthcare provider" includes pharmacists, and questions regarding the use of "shall" vs. "may." It was confirmed the proposed regulatory language was based on language in the style guide. There was discussion about the patient confidentiality, the timeline and usage for the data, specifically after a patient is deceased.

That motion was approved unanimously by voice vote.

2025 Meeting Dates

Ms. Jansson reviewed the proposed 2025 meeting dates with the Board. Dr. Vest made a motion to approve the meeting dates, seconded by Ms. Warriner. The motion passed unanimously by voice vote.

The approved dates are as follows:

- Thursday, March 20
- Thursday June 12
- Thursday, October 2, and
- Friday, December 12.

Other Business

There was no other business brought before the Board.

Adjourn

The meeting adjourned at 1:44 pm.

Commissioner's Report

Dr. Karen Shelton
State Health Commissioner

Presentation Outline

Agency Stars

Key Personnel Changes

Infectious Disease Update

Hurricane Helene Response

Food Safety for the Holidays

Overdose Prevention

Office of Licensure and Certification

JLARC Report

Language Access

Health Directors Meeting – Fall 2024

Agency Stars

Spartak Veliu

John Ringer

Key Personnel Changes

Chief Financial Officer

Assistant Deputy, Community Health Services

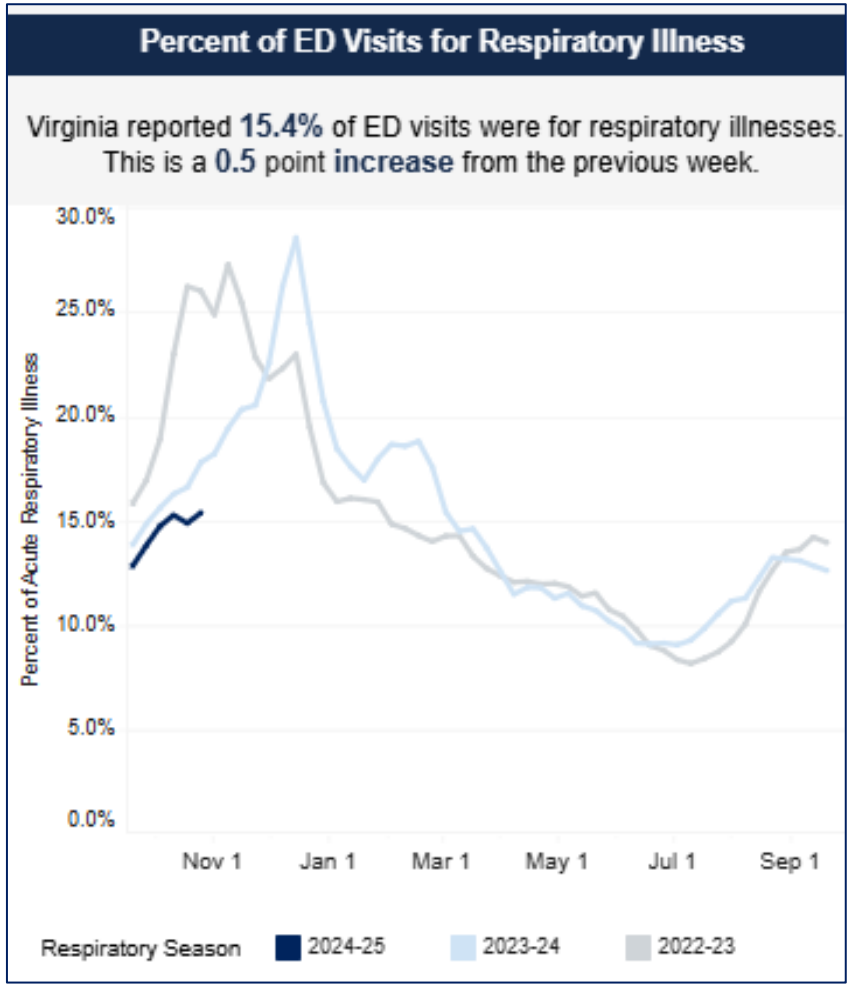
Director, Office of Emergency Medical Services

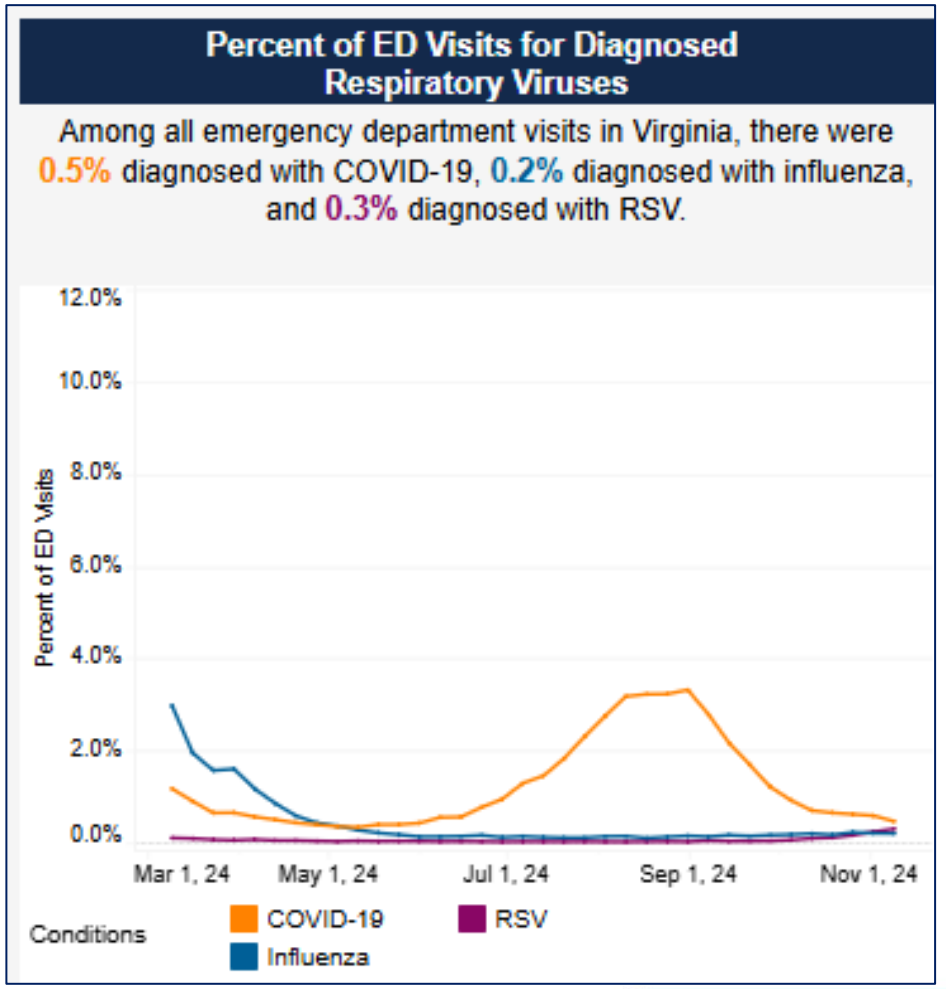
Director, Office of Grants Management

Director, Office of Procurement and General Services

Respiratory Illness Update

For Week Ending November 9, 2024:





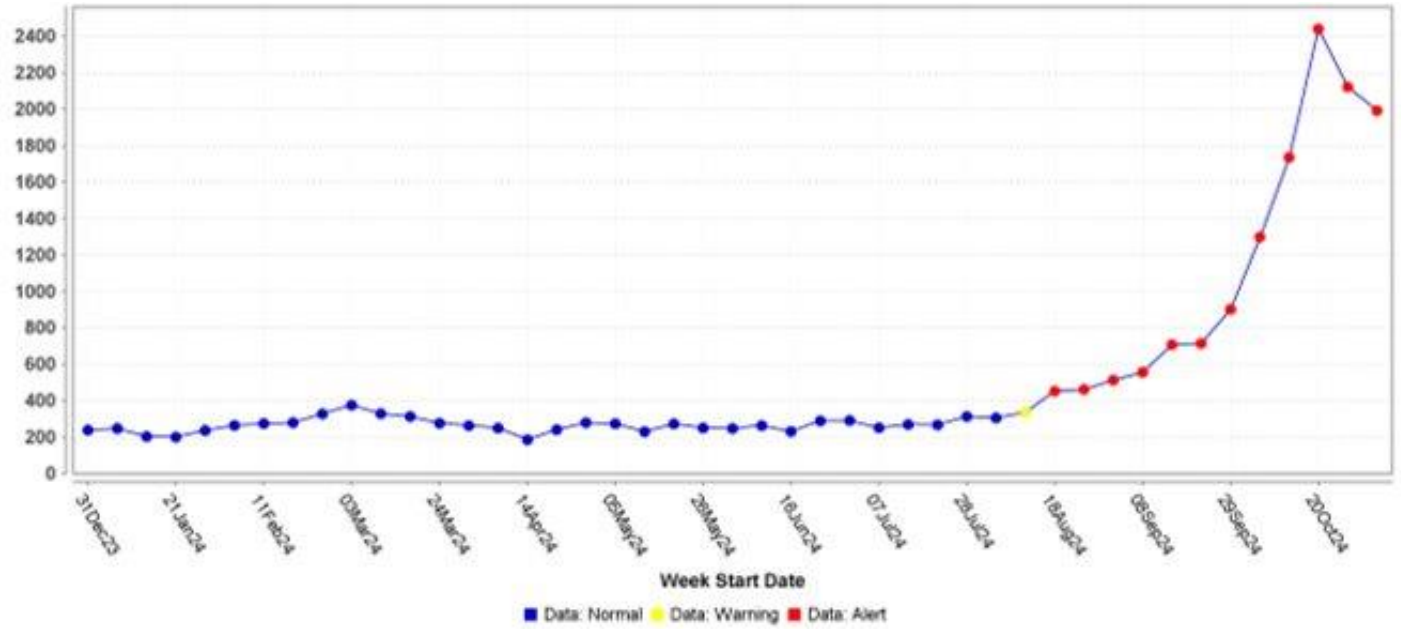
Source: [Respiratory Illness Dashboard](#) (updated November 12, 2024)

VDH VIRGINIA DEPARTMENT OF HEALTH

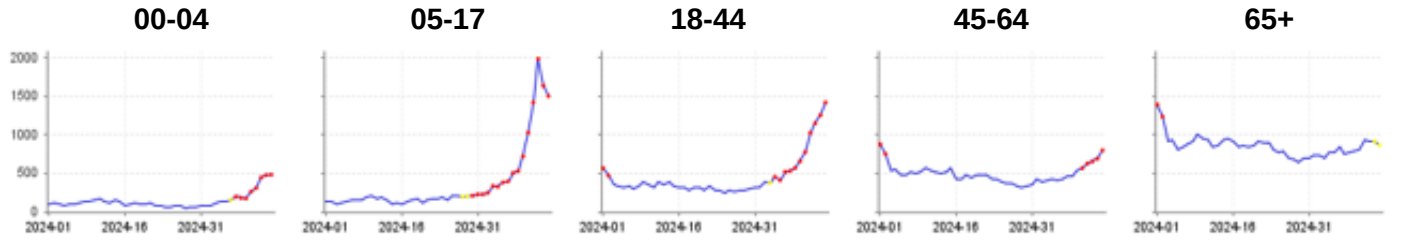
Increase in Pneumonia

- A significant rise in pneumonia, particularly among school-aged children has been observed in ED and urgent care data in Virginia
- LHD have responded to numerous outbreaks of pneumonia in K-12 schools
- Laboratory testing has identified a variety of pathogens, primarily rhinoviruses/enteroviruses as well as *Mycoplasma pneumoniae*.
- VDH is sharing communication with clinicians for awareness and guidance recommendations

Weekly ED and Urgent Care Visits with Diagnosed Pneumonia Among 0-17 Year Olds, Virginia, 2024



Weekly ED and Urgent Care Visits with Diagnosed Pneumonia By Age, Virginia, 2024



Source: Virginia ESSENCE, limitations apply (updated November 12, 2024)

HPAI A(H5N1) Virus

- No human or animal cases reported in Virginia
- The risk to the public remains low
- LHDs have administered flu vaccines to 86 people considered at higher risk of exposure to H5N1
- CDC expanded testing and post-exposure prophylaxis recommendations, and focused PPE guidance to further reduce risk of infection

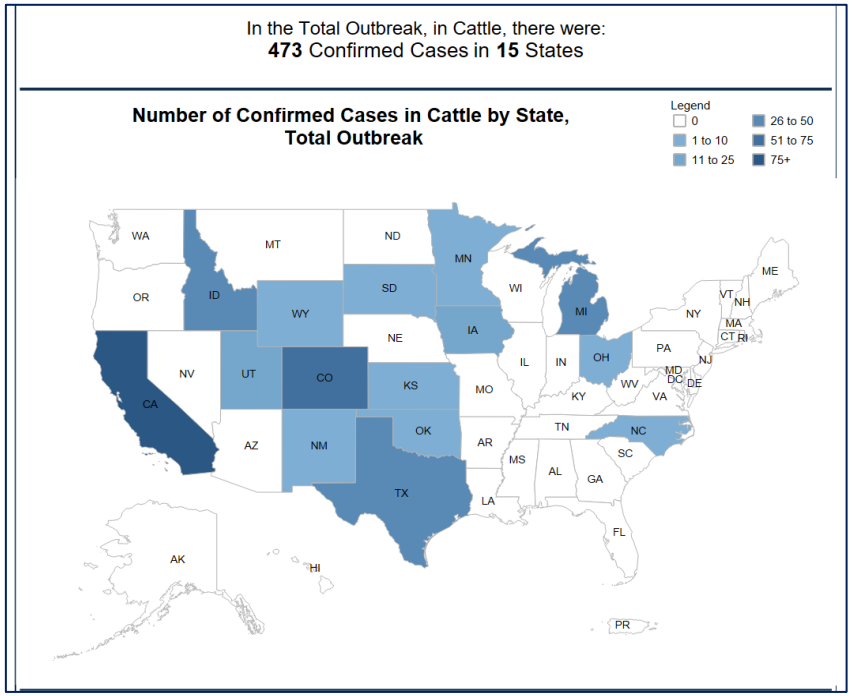
CDC: Confirmed Human Cases by Exposure Source

Confirmed human case summary during the 2024 outbreak, by state and exposure source

Exposure Source

	Cattle	Poultry	Unknown	State Total
Source Total	25	20	1	46

USDA: HPAI Confirmed Cases in Livestock Herds



Source: CDC H5N1 Bird Flu: Current Situation Summary (updated November 8, 2024), USDA Situational Update (updated November 8, 2024)

VDH VIRGINIA DEPARTMENT OF HEALTH

Marburg Virus Disease Outbreak in Rwanda

- On Sep. 27, 2024, Republic of Rwanda's Ministry of Health declared outbreak
  - As of Nov. 9, 66 cases, including 15 deaths
- Most cases are in HCP working at 2 healthcare facilities in Kigali
- Public health officials are tracing contacts, vaccinating contacts and HCP with investigational vaccine, and conducting exit screening
- Oct. 16 DHS starts redirecting travelers from Rwanda and CDC airport screening
- **Currently, no cases in United States and risk is considered low**

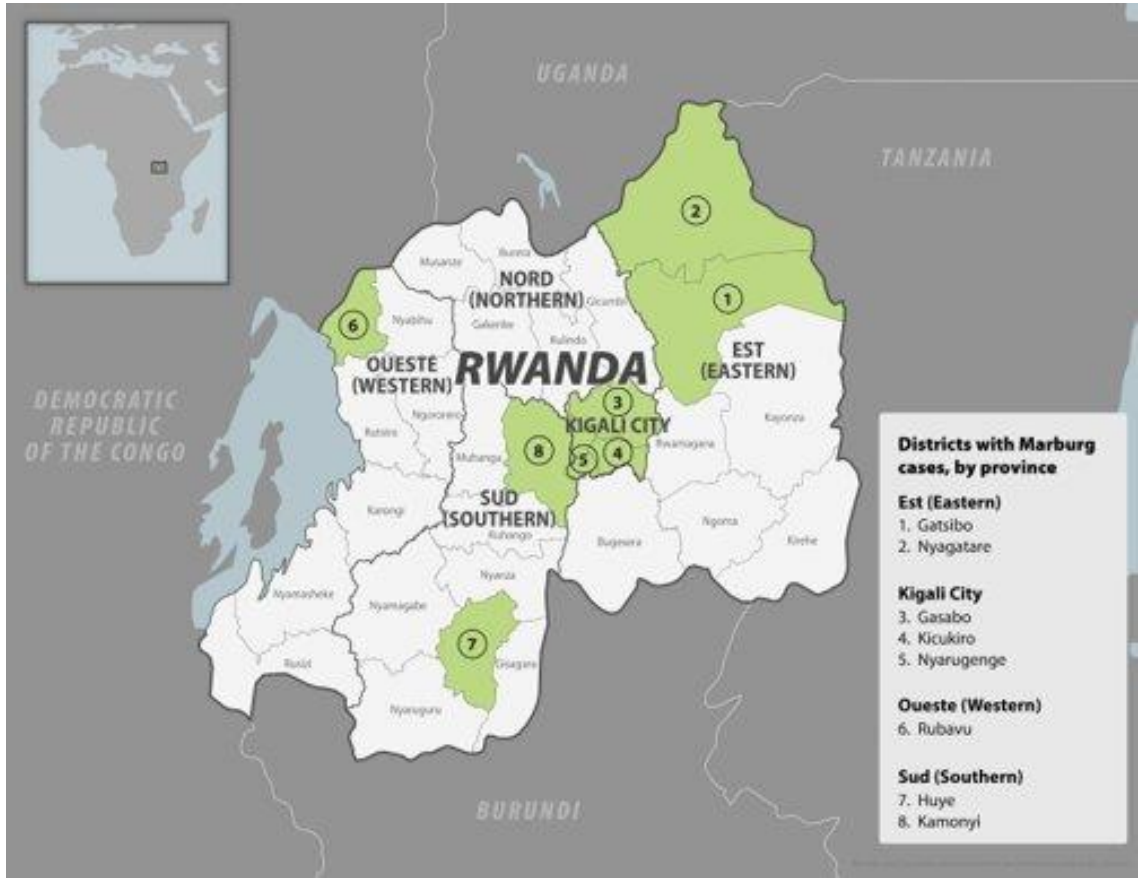
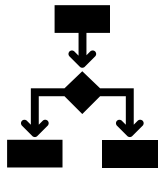


Image source: [CDC Interim Recommendations for Post-Arrival Public Health Management of Travelers from Rwanda]

VDH Preparedness and Response

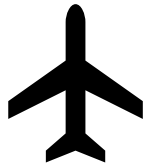


Established ICS on Oct. 8

- Includes Clinical Consult Group to support LHDs

Sharing info with providers and public

- Issued Clinician Letter on Oct. 8
- Launched Marburg Outbreak in Rwanda website on Oct. 21
- Presented to VHHA members on Oct. 23
- Provided Infection Prevention and Control webinar for frontline facilities on Nov. 12
- Planning Designated Infection Control Training for EMS Infection Control Officers



Started traveler monitoring on Oct. 16

- Developed guidance for VDH staff, and provided training on Oct. 17 and Oct. 25
- Developed handout for travelers arriving at Dulles who are staying in Virginia

Engaging partners and updating plans and tools

- Pre-positioned DCLS test kits at select hospitals and 35 LHDs
- Issued Declaration of MVD as a Communicable Disease of Public Health Threat for Virginia on Oct. 14

Hurricane Helene Response

- Incident Coordination
- Public Health Surveillance
- Public Information & Outreach
- Disaster Shelters
- Vaccinations
- Local Health District Staff & MRC Volunteers
- Drinking Water
- Healthcare Coordination
- Recovery

https://www.vdh.virginia.gov/news/hurricane-helene-post-storm-response/

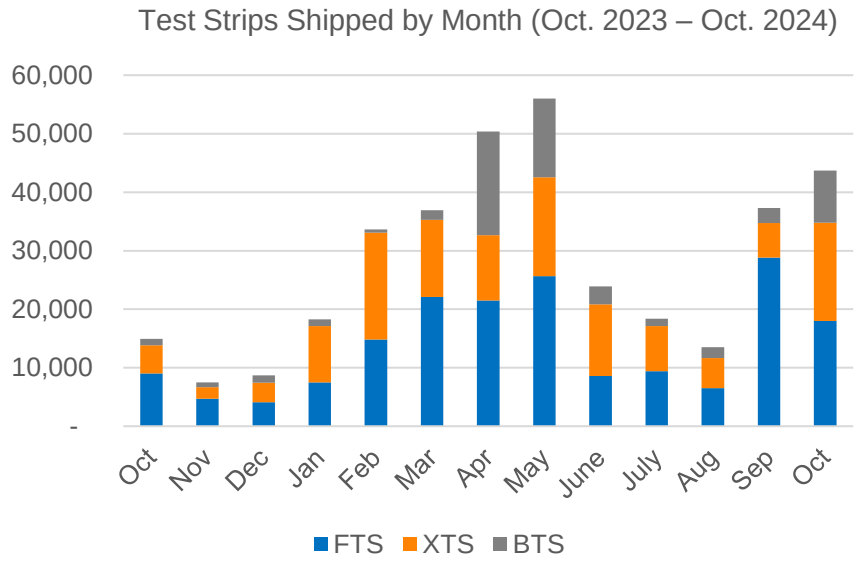
Food Safety for the Holidays

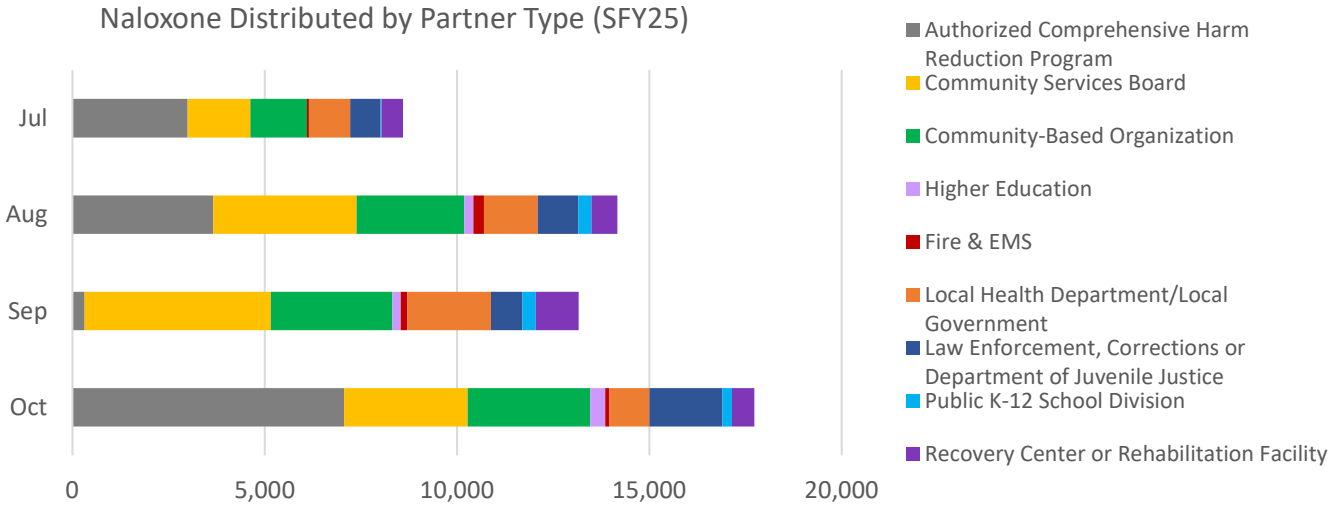
November and December are **#FoodSafetyFridays.**

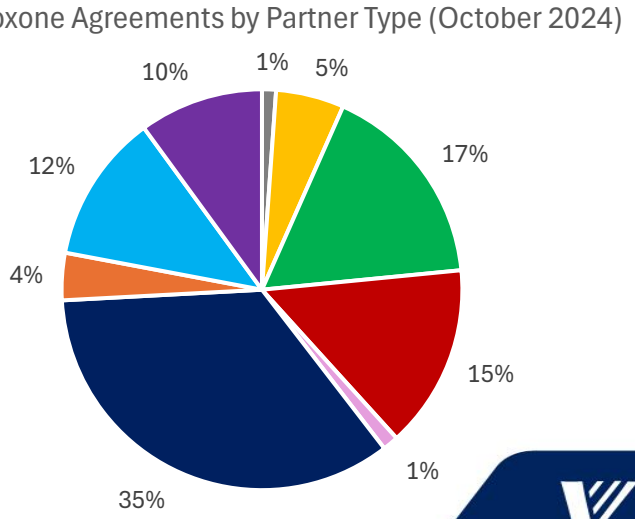
Each Friday, VDH shares tips —**hand washing, separating raw and cooked foods, cooking to the right temperature, and storing foods properly**— that you can do to avoid a holiday disaster and make sure everyone has a safe and joyful time.

Naloxone Distribution Update

- VDH distributed 142,179 naloxone kits to eligible partners in SFY24, a 21% increase in distribution from the previous fiscal year. VDH also executed 150 new naloxone agreements with partners, a 30% increase from the previous fiscal year.
- VDH continues to increase distribution of harm reduction test strips (inclusive of fentanyl, xylazine, and benzodiazepine test strips) and expand distribution to additional partner types.
- VDH has increased engagement with LHDs through quarterly naloxone data reports and meetings with regional partners, which has increased strategic distribution
- In SFY25, VDH has distributed over 54,000 naloxone kits to partners and maintains naloxone agreements with 710 partner organizations that serve high-risk individuals







VDH VIRGINIA DEPARTMENT OF HEALTH

Big Bet Against Overdose

- Kentucky, Tennessee, West Virginia, and Virginia participated in a two-day discussion on developing an approach to reduce the supply and demand of substances driving central Appalachia's overdose epidemic.
- VA leadership participated from public health and public safety.
- Commitment to further cross-state and cross-sector conversations was made.

Operation FREE

- VDEM and VDH, through the Virginia Emergency Support Team (VEST), supported the Secretary of Public Safety and Homeland Security and Governor's approach to Operation FREE (Fentanyl Reduction Enforcement & Eradication) Virginia
  - The VEST consists of 105 + Executive Branch Agencies, private sector partners, and volunteer organizations tasked with responsibilities in the Commonwealth of Virginia Emergency Operations Plan.
- Main Priorities: Education, Information Sharing, Public Messaging
- Weekly Situation Reports were released by VDEM and highlighted VDH Overdose Incident Management Team (IMT) efforts, including:
  - Overdose Death Trends
  - Emergency Department Visit Trends for Unintentional Drug Overdose
  - Needs Assessment Tool for Drug Overdose and Related Outcomes
  - Opioid Reversal Agent (Naloxone) and Fentanyl Test Strip Distribution Program
  - Comprehensive Harm Reduction

Office of Licensure and Certification

Current challenges for nursing home licensure and inspection

- 57% increase in nursing home complaints from 2018 to 2023
- Over 800 nursing home complaints received to date in 2024
- Loss of long-term care MFIs, supervisors and other FTEs to other state agencies, notably to the Department of Health Professions – unable to negotiate counteroffers
- Onboard timeframe for new MFIs for required CMS training and surveyor certification is at least one year – limited preceptors for training
- Flat funding from CMS since FFY2015 (nursing home MFI positions are 80% federal funded) - 7 positions held vacant - 22 total LTC vacancies
- Hospital and nursing home license fees have not increased in 45 years

Office of Licensure and Certification

Current Actions of OLC

- Proposed legislative actions regarding nursing home and hospital licensure fees, and intermediate sanctions for nursing homes Budget request for intermediate sanctions and MFI salary increases
- Initiating RFP for contract surveyors (two different vendors to assist with nursing home survey and complaint backlogs)
- Temporary compensation increase for MFI preceptors; preceptors did not receive additional compensation previously
- Active recruitment for eight nursing home MFIs and other positions (LTC Supervisor, Training Manager, and a second Complaint Intake Analyst)

JLARC Report – VDH Financial Management Staffing and Accountability

Areas of Focus

- Major Factors Affecting VDH's Performance
- Financial Management
- Staffing
- Office of Human Resources

31 Recommendations

VDH Response to JLARC Report

VDH concurs with all 31 recommendations

The challenges raised in the report were created over multiple years and will take multiple years to fully correct.

- Committed to solving them by placing the appropriate financial and operational controls and hiring in the right leaders to drive change in the Agency.
- COO leads Monthly Operating Reviews of all Offices
- Established CFO and Controller positions, established Office of Grants Administration

Committed to transparency and ethical use of taxpayer dollars.

- Building a culture of accountability

Language and Disability Access

Language and Disability Access Workgroup Developing Agency Plan

- 19 members representing 12 districts and 7 offices

Needs Assessment will Inform Plan Development

- We received 31 survey responses from Health Districts and Offices. These responses provided crucial insights into their needs when serving the Limited English Proficiency community.

VDH has been collaborating with the Office of the Secretary of Health and Human Resources, and other state agencies including DMAS, DSS and VITA

- VITA has signed a contract with Thunder Cat Technology LLC to translate all state agency websites

Language and Disability Access

Interpreter Training

42 bilingual VDH staff have completed the 40-hour professional interpreter training,

- 16 are in progress and 24 did not complete it in the 6-months period, but they have been given an extension.

VDH is also providing "layperson" interpreter training

- Three full sessions of 15 staff each are scheduled, with more to come

Translation Library

- 53 critical, frequently used agency documents have been translated into 12 languages, and posted on the VDH Internet page
- 29 additional documents are pending translation

Language and Disability Access

Equipment Purchase

- Dual Handset Telephones: ideal for front desks, reception desks, and office's visits to improve privacy while providing over the telephone
- Equipment Carts: This rolling cart is an excellent tool for services that frequently require on-demand language interpretation services, as it combines mobility, ease of use, and audio clarity in a single package. This system allows the patient to relate to the same interpreter, even if they need to move to different offices within the same visit.
- iPad: The iPad enhances communication by providing on-demand language services through video remote interpreting, over-the-phone interpreting, and American Sign Language

Health Director's Meeting – *The Future of Public Health*

October 21-23, 2024 – Charlottesville, VA







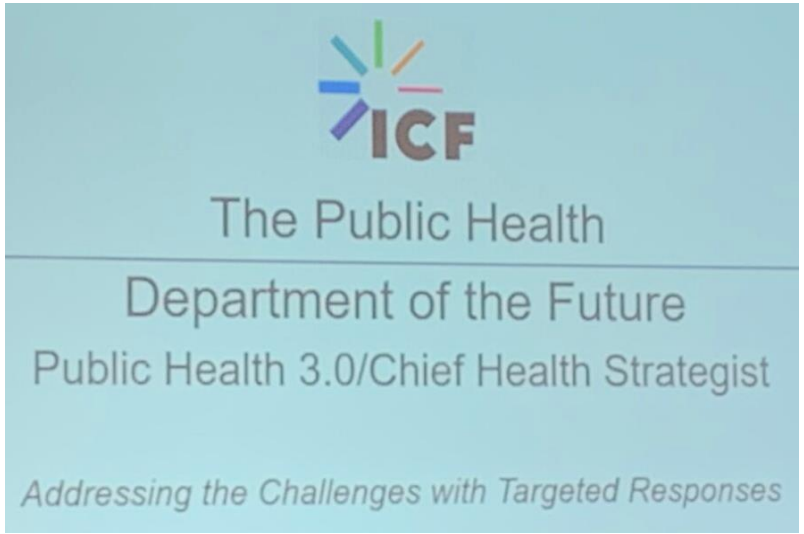












Questions

REGULATORY ACTION UPDATE

State Board of Health
Regulatory Action Update
December 5, 2024

Overview of Pending Regulatory Actions:

There are 56 pending actions under development:

- 14 NOIRAs
- 10 proposed actions
- 7 final actions
- 25 fast track actions

A spreadsheet containing additional detail concerning each of these actions is attached.

A Norice of Intended Regulatory Action (NOIRA) is the first stage in the standard rulemaking process in Virginia. It describes the nature and scope of the regulatory changes being considered. Should a NOIRA be approved, the next stage in the rulemaking process (the proposed stage) would involve the drafting of actual amending regulatory language for consideration. The proposed stage—if approved—is in turn followed by the final stage. Each of these three stages includes a public comment period.

The Virginia Administrative Process Act (§ 2.2-4000 et. seq. of the Code of Virginia) provides that certain types of regulatory actions are exempt from certain requirements of the state regulatory process. This includes regulatory actions that are:

i. Necessary to conform to changes in Virginia statutory law or the appropriation act where no agency discretion is involved, or
ii. Necessary to meet the requirements of federal law or regulations, provided such regulations do not differ materially from those required by federal law or regulation, and the Registrar has so determined in writing.

The Administrative Process Act also describes a "Fast Track" rulemaking process, which is utilized for regulations that are expected to be noncontroversial. The Fast Track process generally involves an action with a single stage.

Regulatory Actions Taken by the Commissioner on Behalf of the Board pursuant to § 32.1-20 of the Code of Virginia since the September 19, 2024 Board Meeting while the Board was not in Session:

Approved Results of Periodic Review of Regulations (8):

Advance Healthcare Directive Registry (12VAC5-67)

• Decision: Amend the regulation to better align the chapter with current practice, update existing regulatory language to conform to the form and style requirements of the Virginia Registrar of Regulations, consider opportunities for regulatory reduction, and amend the chapter to clarify advance care planning documentation that may be stored in the Advance Healthcare Directory Registry and who may access the documentation.

Rules and Regulations Governing Health Data Reporting (12VAC5-215)

• Decision: Amend the regulations to align the chapter with the current practices regarding specifications for health care institutions, filing requirements, due dates, fee structure and financial information that is periodically published and disseminated regarding health data. The Board will also incorporate the provisions of 12VAC5-216 – Methodology to Measure Efficiency and Productivity of Health Care Institutions into this chapter, as 12VAC5-216 will be repealed. Additionally, amendments that reduce regulatory requirements on Virginians will be considered where possible.

Methodology to Measure Efficiency and Productivity of Health Care Institutions (12VAC5-216)

• Decision: Repeal the chapter and incorporate provisions into 12VAC5-215 – Rules and Regulations Governing Health Data Reporting.

Regulations of the Patient Level Data System (12VAC5-217)

- Decision: Amend the regulations to better align with current practice, update existing regulatory language to conform to the form and style requirements of the Virginia Registrar of Regulations, and identify opportunities for regulatory reduction, while continuing to fulfill the Board's statutory mandate to protect the citizens of the Commonwealth.

Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations (12VAC5-220)

- Decision: Repeal and replace the regulations to incorporate various statutory and legislative mandates that have been omitted from previous actions, to update the regulation to reflect the current requirements within the *Form, Style and Procedure Manual for Publication of Virginia Regulations* administered by the Virginia Registrar of Regulations, and to consider opportunities for regulatory reduction where possible.

Regulations for the Licensure of Hospices (12VAC5-391)

- Decision: Amend the regulations to comply with the *Form, Style and Procedure Manual for Publication of Virginia Regulations* maintained by the Virginia Registrar of Regulations, update provisions to include current clinical and industry practices, and consider opportunities for regulatory reduction where possible.

Rules Governing Private Review Agents (12VAC5-405)

- Decision: Amend the regulations to update the language to conform to the Form, Style and Procedures Manual for Publication of Virginia Regulations administered by the Virginia Registrar of Regulations in order to make the language clearer and more understandable, and to consider opportunities for regulatory reduction where possible.

Procedures for the Submission of Health Maintenance Organization Quality of Care Performance Information (12VAC5-407)

- Decision: Amend the regulations to make format and style changes, update code references, align provisions of the chapter with current practices and procedures, add clarifying language and remove any unnecessary, duplicative, or non-regulatory language.

*Approved suspension of the effective date of **subdivision F6** of 12VAC5-630-410*

- Pursuant to § 2.2-4015 A 4 of the Code of Virginia, the Commissioner approved the suspension of the effective date of **subdivision F6** of 12VAC5-630-410, related to Private Well Regulations to address public comment received. This regulation was adopted by the State Board of Health on September 22, 2022 and published in 41:4 VA.R. 531-558 October 7, 2024.
- The State Board of Health received multiple public comments objecting to specific provisions in subsection F6 of 12VAC5-630-410. As a result, the State Health Commissioner, pursuant to her authority in § 32.1-20, readopted subdivision F6 of 12VAC5-630-410, as amended, on November 1, 2024.

Non-Regulatory Actions Taken by the Commissioner on Behalf of the Board since the September 19, 2024 Board Meeting while the Board was not in Session:

None

Periodic Review of Regulations

The process for conducting periodic reviews of regulations is governed by the Virginia Administrative Process Act and Executive Order 19 (2022).

All regulations are to be reviewed every four years to determine whether they should be continued without change or be amended or repealed, consistent with the stated objectives of applicable law, to minimize the economic impact on small businesses in a manner consistent with the stated objectives of applicable law.

VDH has 9 periodic reviews in progress:

Chapter		Status
12 VAC 5-125	Regulations for Bedding and Upholstered Furniture Inspection Program	Intend to issue result after current action becomes effective.
12 VAC 5-371	Regulations for the Licensure of Nursing Facilities	Issued with NOIRA, Result will be published with Proposed stage.
12 VAC 5-381	Home Care Organization Regulations	Issued with NOIRA, Result will be published with Proposed stage.
12 VAC 5-507	Guidelines for General Assembly Nursing Scholarships and Loan Repayment Program Requiring Service in a Long-Term-Care Facility	Result under OCOM review
12 VAC 5-520	Regulations Governing the State Dental Scholarship Program	Intend to issue result after current action becomes effective.
12 VAC 5-545	Guidelines for the Nurse Educator Scholarship	Result under OCOM review
12 VAC 5-590	Waterworks Regulations	Result under OCOM review
12 VAC 5-620	Regulations Governing Application Fees for Construction Permits for Onsite Sewage Disposal Systems and Private Wells	Intend to issue result after current action becomes effective.

Executive Branch Review Activity Completed since the September 19, 2024 Board Meeting:

The Department of Planning and Budget completed the review of:

- NOIRA for the Board of Health Regulations Governing Vital Records (12VAC5-550)

The Secretary of Health and Human Resources completed the review of:

- Fast Track Amendments to the Food Regulations (12VAC5-421)
- Fast Track Amendments to the Rules and Regulations Governing Campgrounds (12VAC5-450)

The Office of Regulatory Management completed the review of:

- Fast Track Amendments to the Food Regulations (12VAC5-421)
- NOIRA to Amend Migrant Labor Camp Regulations (12VAC5-501)
- Final Amendments to the Rainwater Harvesting System Regulations (12VAC5-635)

The Governor approved:

- Fast Track Amendments to the Food Regulations (12VAC5-421)
- NOIRA to Amend Migrant Labor Camp Regulations (12VAC5-501)
- Final Amendments to the Rainwater Harvesting System Regulations (12VAC5-635)

PUBLIC COMMENT

Public Comment Period

- There is a two minute time limit for each person to speak.
- We will be calling from the list in the room.
- After the 2 minute public comment limit is reached we will let you complete the sentence and move on to the next attendee.
- We will call the name of the person on list and also the name of the person is next on the list.

LUNCH PRESENTATION: GENERAL ASSEMBLY 2025

VDH VIRGINIA DEPARTMENT OF HEALTH

2025 Agency Bills

Joe Hilbert
Deputy Commissioner for Governmental and Regulatory Affairs

Lance Gregory
Director, Division of Onsite Water and Wastewater Service
Office of Environmental Health Services

Kim Beazley
Director, Office of Licensure and Certification

Rules of Engagement

Each year all agencies are given the opportunity to submit legislative proposals for consideration by the Administration. The Administration has approved three VDH Agency Bills for 2025.

VDH is responsible for collaborating and communicating with the Administration, legislators, Board of Health members and stakeholders in order to generate and maintain support for its Agency Bills such that they will be passed and signed into law.

VDH staff may reach out to Board of Health members for certain types of assistance.

Removal of $1 Fee for AOSS O&M Reporting

Brief History of Alternative Onsite Sewage Systems (AOSS)

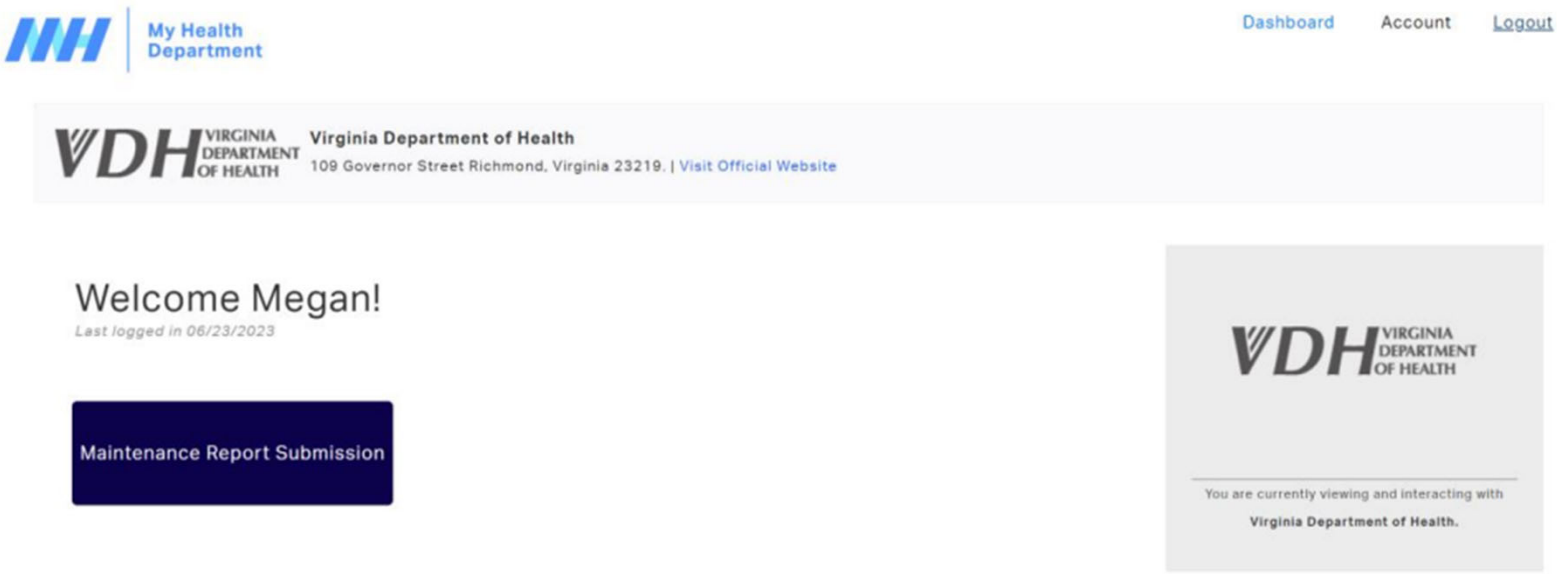
- 1990's – GMP's issued for individual treatment devices.
- Early 2000's – Increased adoption.
- Early 2000's – Local prohibitions on use.
- 2007 – Legislation to develop specific regulations for AOSS.
  - Including operation and maintenance (O&M) reporting.
- 2010 – Emergency regulations for AOSS.
- 2011 – Final regulation for AOSS.

Removal of $1 Fee for AOSS O&M Reporting

Operation and Maintenance Requirements in 12VAC5-613

- Owner's shall:
  - Have the system operated and maintained by a licensed operator.
  - Operator to visit the property at least annually (more frequent for large systems).
- Operator's shall:
  - Conduct all required sampling.
  - Inspect the entire system.
  - **File reports using VDH's web-based reporting system.**

Removal of $1 Fee for AOSS O&M Reporting



Removal of $1 Fee for AOSS O&M Reporting

Section 32.1-164 of the Code of Virginia

*2. The licensed operator to provide a report on the results of the site visit utilizing the web-based system required by this subsection. **A fee of $1 shall be paid** by the licensed operator at the time the report is filed. Such fees shall be credited to the Onsite Operation and Maintenance Fund established pursuant to § 32.1-164.8;*

Removal of $1 Fee for AOSS O&M Reporting

VDH is proposing to eliminate the $1 fee.

- Reports submitted without a fee – incomplete.
- Operators accidentally submitting same report multiple times.
- Cost to the agency to collect outweighs benefits.
  - 184,451 AOSS Reports (as of November 8, 2024).
  - Typically generates less than $15,000 annually.
- Aligns with reporting for conventional systems (2023).

Hospital and Nursing Home Licensure Fees

Licensure service charges ($1.50 per bed, minimum of $75 and capped at $500 per facility) for the operation of inpatient hospitals/nursing homes and $75 for outpatient surgical hospitals are established by § 32.1-130 and have not been adjusted since their enactment in 1979.

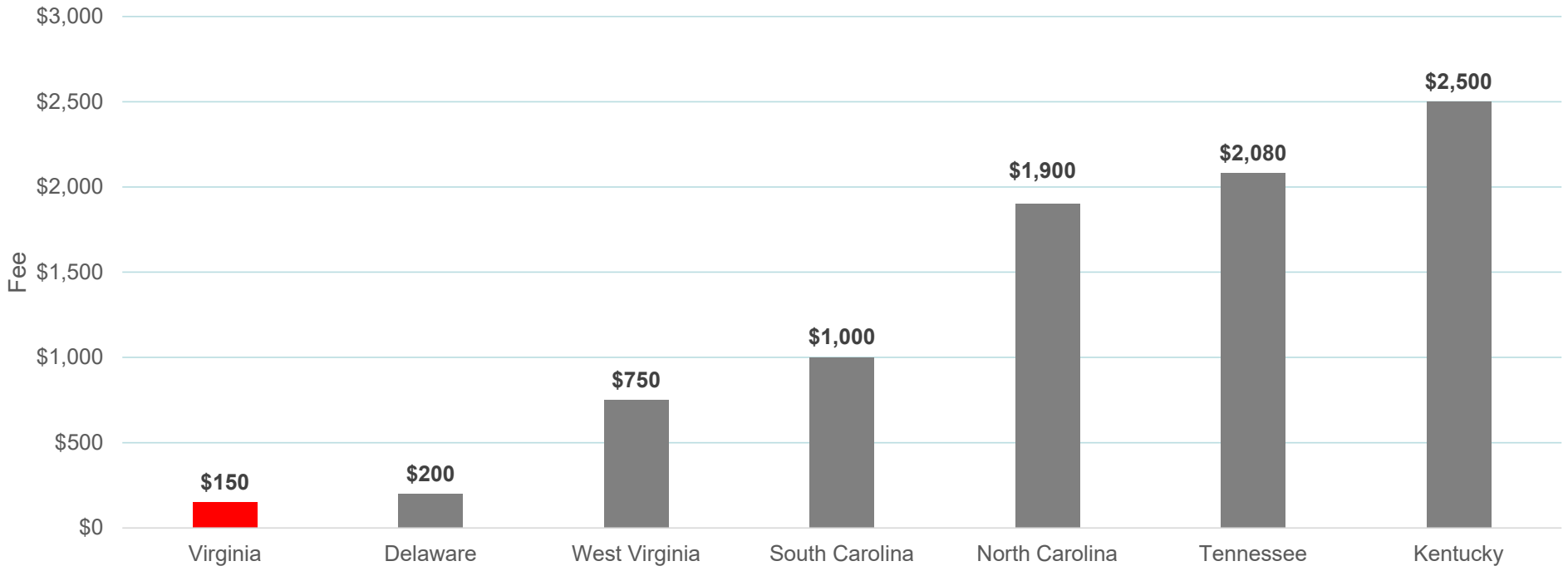
At approximately $85,000/year, the current annual amount of licensure fee revenue is not sufficient to fund even one medical facilities inspector position.

The Board currently has authority to set fees for:

- Home Care Organization licensure pursuant to Va. Code § 32.1-162.9
- Hospice licensure pursuant to Va. Code § 32.1-162.3
- Certificate of Public Need program pursuant to Va. Code § 32.1-102.2.

Hospital and Nursing Home Licensure Fees

Assuming an inpatient hospital has 100 beds, fee comparisons to other states:



Hospital and Nursing Home Licensure Fees

In SFY24, VDH collected on average $230 per inpatient hospital, $86 per outpatient surgical hospital, $190 per nursing home.

By comparison, the Virginia Department of Health Professions —which can set its own fees by regulations—charges the following for an individual's initial professional license:

- $302 per physician
- $315 per nursing home administrator
- $235 per pharmacist
- $190 per registered nurse, and
- $170 per licensed practical nurse

Hospital and Nursing Home Licensure Fees

VDH is proposing to modify the licensure fee structure for hospitals and nursing homes

- Fees would be determined by a schedule established in regulation by the State Board of Health
- Fees set by the Board of Health may only be at a rate necessary to support the costs of the licensure and inspection program
- Current fee structure would remain in place until regulations take effect

Intermediate Sanctions for Violations of Nursing Home Licensure Requirements

Nursing home residents are a vulnerable population that require/deserve protection

State penalties that can be imposed are either extreme (revoke/suspend license; prohibit/restrict new admissions) or can only be imposed by a court (monetary penalties).

In practice, VDH relies on the Centers for Medicare and Medicaid Services (CMS) and its separate federal sanctioning power to compel compliance.

Any penalties imposed in Virginia are being imposed by the CMS, not by VDH.

Intermediate Sanctions for Violations of Nursing Home Licensure Requirements

Other State agencies that license health care facilities (i.e. DBHDS and DSS) have authority to impose intermediate sanctions. The health regulatory boards under DHP also have authority to impose intermediate sanctions.

- Options include monetary penalties, authority to place the violating entity on probation, and requiring the completion of a corrective action plan.

Other States also have authority to impose intermediate sanctions on nursing homes

- All other states in CMS Region 3 (Delaware, DC, Maryland, Pennsylvania, West Virginia) have the authority to impose intermediate sanctions against nursing homes, including civil monetary penalties

Intermediate Sanctions for Violations of Nursing Home Licensure Requirements

- VDH is proposing to consolidate existing penalties and create a series of additional, intermediate sanctions for violations.

- The State Board of Health would need to promulgate emergency regulations for procedures to administer the sanctions in conformity with the Administrative Process Act (§ 2.2-4000 et seq.) and for criteria on choice of and level of sanction imposed.

Questions

Regulations Governing Virginia Critical Congenital Heart Disease Newborn Screening Services
12VAC5-72
Fast Track Amendments

Vanessa Walker Harris, MD
Director
Office of Family Health Services

COMMONWEALTH of VIRGINIA

Department of Health

Karen Shelton, MD
State Health Commissioner

P O BOX 2448
RICHMOND, VA 23218

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

MEMORANDUM

DATE: October 10, 2024

TO: Virginia State Board of Health

FROM: Vanessa Walker Harris, MD
Director, Office of Family Health Services

SUBJECT: Fast Track Action – Amend Regulations Governing Virginia Newborn Screening Services Following Periodic Review

---

Enclosed for your review and approval is a fast-track regulation to amend 12VAC5-71.

This regulatory action seeks to amend 12VAC5-71 - Regulations Governing Virginia Newborn Screening Services by repealing sections concerning Critical Congenital Heart Disease (CCHD) newborn screening and creating a new chapter (12VAC5-72) to house the CCHD newborn screening regulations in order to improve clarity of regulatory requirements. The action also provides minor updates to reflect current best practices and scientific information relevant to CCHD. Additionally, this action amends both 12VAC5-71 and the newly created 12VAC5-72 to provide stylistic updates to improve the clarity of the regulations and ensure compliance with the *Virginia Register of Regulations Form, Style and Procedure Manual.*

The State Board of Health is requested to approve the Fast Track action. Should the Board approve the action, the amendments will be submitted to the Executive Branch review process. Following Executive Branch review and approval, the proposed regulatory text will be published in the Virginia Register of Regulations and on the Virginia Regulatory Town Hall website. A 30-day public comment period will begin. Fifteen days after the close of the public comment period, the regulation will become effective.

townhall.virginia.gov

Fast-Track Regulation
Agency Background Document

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-71
VAC Chapter title(s)	Regulations Governing Virginia Newborn Screening Services
Action title	Amend Regulations Following Periodic Review
Date this document prepared	October 10, 2024

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

Brief Summary

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

This regulatory action seeks to amend 12VAC5-71 - Regulations Governing Virginia Newborn Screening Services by repealing sections concerning Critical Congenital Heart Disease (CCHD) newborn screening and creating a new chapter (12VAC5-72) to house the CCHD newborn screening regulations in order to improve clarity of regulatory requirements. The action also provides minor updates to reflect current best practices and scientific information relevant to CCHD. Additionally, this action amends both 12VAC5-71 and the newly created 12VAC5-72 to provide stylistic updates to improve the clarity of the regulations and ensure compliance with the *Virginia Register of Regulations Form, Style and Procedure Manual.*

The existing Critical Congenital Heart Disease (CCHD) newborn screening regulations are housed alongside the dried blood spot newborn screening regulations in Chapter 71 of the Virginia Administrative Code. These regulations outline regulatory requirements for CCHD protocols, screenings, results reporting, care coordination, records, and screening refusals. VDH introduced the CCHD regulations in 2014 and the regulations became effective in 2016, but they have not been updated since that time.

While the dried blood spot and CCHD newborn screening regulations are currently housed in the same chapter, a separate regulatory chapter exists for the hearing newborn screening program. Because regulations for both dried blood spot newborn screening and CCHD newborn screening are included in 12VAC5-71 confusion from regulants, specifically with the Out-of-Hospital (OOH) birth community, has been reported. While dried blood spot regulations apply to all births (including OOH births and OOH birth providers), CCHD regulations do not apply to OOH births or birth providers. Promulgating CCHD regulations into their own chapter would provide consistency across the newborn screening programs and clarify roles and responsibilities of the health care providers for the different newborn screenings.

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.

AAP – American Academy of Pediatrics

CCHD – Critical Congenital Heart Disease

OOH – Out of Hospital

VDH – Virginia Department of Health

Statement of Final Agency Action

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

Mandate and Impetus

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

Consistent with Virginia Code § 2.2-4012.1, also explain why this rulemaking is expected to be noncontroversial and therefore appropriate for the fast-track rulemaking process.

In 2014, VDH proposed regulations for CCHD newborn screening to be added to 12VAC5-71, adding sections 12VAC5-71-210 to 12VAC5-71-260. These regulations were initially adopted as emergency regulations in 2015, and later adopted as permanent regulations in October 2016.

Pursuant to Executive Order 19 (2022) the Office of Family Health Services (OFHS) conducted a periodic review of 12VAC5-71 – Regulations Governing Virginia Newborn Screening Services. This regulatory action is intended to implement the Board's decision in the chapter's most recent periodic review. The periodic review, filed on July 29, 2021, resulted in a decision to amend the regulations. This proposed regulatory action follows the recommendation of that periodic review.

Consistent with *Virginia Code § 2.2-4012.1,* this rulemaking is expected to be noncontroversial because it is moving existing regulations into a new chapter and making minor edits that will not substantially affect existing requirements or the stakeholders who are required to follow these regulations.

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.

§ 32.1-12 of the Code of Virginia authorizes the State Board of Health to make, adopt, promulgate and enforce regulations.

§ 32.1-65.1 of the Code of Virginia requires Critical Congenital Heart Disease newborn screening to be conducted on every infant born in the Commonwealth of Virginia based on standards set forth by the American Academy of Pediatrics (AAP).

§ 32.1-67 of the Code of Virginia requires the Board of Health to promulgate regulations as necessary to implement Newborn Screening Services.

Purpose

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

§ 32.1-65 of the Code of Virginia sets forth requirements for mandatory newborn screening tests for all infants born in the Commonwealth, "in order to prevent intellectual disability and permanent disability or death."

§ 32.1-65.1 of the Code of Virginia directs the Board to "require every hospital in the Commonwealth having a newborn nursery to perform a critical congenital heart defect screening test using pulse oximetry or other Board-approved screening test that is based on standards set forth by the American Academy of Pediatrics on every newborn in its care when such infant is at least 24 hours old but no more than 48 hours old or, in cases in which the infant is discharged from the hospital prior to reaching 24 hours of age, prior to discharging the infant."

§ 32.1-67 of the Code of Virginia requires the Board to promulgate regulations necessary to implement Newborn Screening Services and the Children with Special Health Care Needs Program.

The proposed regulatory change is needed to provide clarity within the newborn screening programs, specifically, clarifying roles and responsibilities of health care providers based on different newborn screenings. There has been confusion reported by Out-of-Hospital (OOH) providers regarding the newborn screening regulations as written, as not all regulations are applicable to all birth providers.

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 fast track regulatory amendments will remove sections 12VAC5-71-210 to 12VAC5-71-260, relating to CCHD newborn screenings, and create a new chapter, 12VAC5-72, to house those regulations.

Additionally, the fast track amendments update and add to existing definitions applicable to the new chapter; update regulatory language to provide consistency and compliance with the Virginia Register's style requirements; update language throughout 12VAC5-71 and the newly created 12VAC5-72 to ensure alignment with the most recent best practices and scientific information on CCHD; more clearly identify the CCHD Newborn Screening Program within VDH as the program assigned to oversee the mandate and regulations; clarify the process for parents and providers to document refusals of screenings; and add additional information regarding confidentiality of the screening results.

Issues

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

The primary advantage to the public, agency, Commonwealth, and other relevant stakeholders is improved clarity of the regulations for regulants, including hospitals and healthcare providers. Clarifying language addresses the roles and responsibilities of providers related to newborn screening services, specifically screening for CCHD and reporting results of CCHD newborn screenings.

There are no obvious disadvantages to the public, agency, Commonwealth, and other relevant stakeholders for the adoption of this regulatory change.

Requirements More Restrictive than Federal

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

There are no applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

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

Other State Agencies Particularly Affected
There is no other state agency particularly affected by this regulation change.

Localities Particularly Affected
There are no known localities particularly affected by this regulation change.

Other Entities Particularly Affected
There are no known other entities particularly affected by this regulation change.

Economic Impact

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

Impact on State Agencies

For your agency: projected costs, savings, fees or revenues resulting from the regulatory change, including: a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources	The regulatory change has no economic impact on VDH.
For other state agencies: projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.	This regulatory change has no economic impact on other state agencies.
For all agencies: Benefits the regulatory change is designed to produce.	This regulatory change is intended to improve the health and well-being of individuals in Virginia by improving clarity regarding CCHD screening and reporting requirements, which will in turn allow VDH to better identify children with CCHD who might benefit from support services.

Impact on Localities

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

Projected costs, savings, fees or revenues resulting from the regulatory change.	This regulatory change has no economic impact on localities.
Benefits the regulatory change is designed to produce.	This regulatory change is intended to improve the health and well-being of individuals in Virginia by improving clarity regarding CCHD screening and reporting requirements, which will in turn allow VDH to better identify children with CCHD who might benefit from support services.

Impact on Other Entities

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

Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect.	No entities are known to be particularly affected by the proposed regulation change.
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.	$0
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.	$0
Benefits the regulatory change is designed to produce.	$0

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.

Alternatives to this regulatory change are limited to maintaining the status quo – not amending the regulations. As the regulations as written may cause confusion with regard to provider duties and responsibilities as they relate to newborn screenings, the Board has determined that amendments are necessary.

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

Regulatory Flexibility Analysis

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

There are no known alternatives to the regulatory change. The regulations only require what is necessary for hospitals and providers to do regarding newborn screening and reporting of CCHD in order to be compliant with the Code of Virginia and also ensure that the agency is effectively tracking CCHD and providing supports for families whose children have confirmed CCHD.

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

Public Participation

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

Consistent with § 2.2-4011 of the Code of Virginia, if an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

If you are objecting to the use of the fast-track process as the means of promulgating this regulation, please clearly indicate your objection in your comment. Please also indicate the nature of, and reason for, your objection to using this process.

The 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:

Lauren Staley, MPH
Virginia Department of Health
109 Governor Street
Richmond, VA 23219
Office: (804) 864-7579
Fax: (804) 588-5098
lauren.staley@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
12VAC5-71-10		Definitions	**Change:** Remove unnecessary definitions for terms no longer appearing in 12VAC5-71 – “Abnormal screening results”, “Echocardiogram”, “population-based”, and “Screening Technology” **Intent:** Provide clarity and consistency throughout the regulations **Rationale:** Clear and consistent definitions ensure accurate interpretation of the regulations. **Likely Impact:** Improvements in readability and comprehension of the regulations by regulations
12VAC5-71-150		Responsibilities of the Care Connection for Children network	**Change:** Remove critical congenital heart disease as a service provided by the Care Connection for Children network

			Intent: Remove CCHD from 12VAC5-71 and move reference to 12VAC5-72 **Rationale:** Creating a new chapter to exclusively house CCHD regulations will clarify regulations. **Likely Impact:** Greater readability and comprehension of the regulations.
12VAC5-71-210		Critical congenital heart disease screening protocols	**Change:** Repeal section **Intent:** Move CCHD regulations to new chapter. **Rationale:** Creating a new chapter to exclusively house CCHD regulations will clarify regulations. **Likely Impact:** Improved clarity of the regulations
12VAC5-71-220		Critical congenital heart disease screening	**Change:** Repeal section **Intent:** Move CCHD regulations to new chapter. **Rationale:** Creating a new chapter to exclusively house CCHD regulations will clarify regulations. **Likely Impact:** Improved clarity of the regulations.
12VAC5-71-230		Critical congenital heart disease screening results.	**Change:** Repeal section **Intent:** Move CCHD regulations to new chapter. **Rationale:** Creating a new chapter to exclusively house CCHD regulations will clarify regulations. **Likely Impact:** Improved clarity of the regulations
12VAC5-71-240		Referral for care coordination	**Change:** Repeal section **Intent:** Move CCHD regulations to new chapter.

			Rationale: Creating a new chapter to exclusively house CCHD regulations will clarify regulations. **Likely Impact:** Improved clarity of the regulations
12VAC5-71-250		Critical congenital heart disease screening records	**Change:** Repeal section **Intent:** Move CCHD regulations to new chapter. **Rationale:** Creating a new chapter to exclusively house CCHD regulations will clarify regulations. **Likely Impact:** Improved clarity of the regulations.
12VAC5-71-260		Parent or guardian refusal for screening.	**Change:** Repeal section **Intent:** Move CCHD regulations to new chapter. **Rationale:** Creating a new chapter to exclusively house CCHD regulations will clarify regulations. **Likely Impact:** Improved clarity of the regulations
	12VAC5-72-10	Definitions	**Change:** Add definitions for newly created Chapter **Intent:** Provide clear usage of words and terms for 12VAC5-72 **Rationale:** Clearly defining words and terms used throughout the chapter will prevent confusion and improve readability and comprehension. **Likely Impact:** Clearly understandable regulations
	12VAC5-72-20	Critical congenital heart disease screening protocols	**Change:** Add section containing regulations from 12VAC5-71-210. Formatting changes to adhere to the

			Virginia Register style guide. Removed referenced guidance document, as it is not longer applicable. I**ntent:** Move regulations from 12VAC5-71 into 12VAC5-72. Improve readability and compliance with the Virginia Register of Regulations Form and Style guide. Remove unnecessary references to documents. **Rationale:** Delineating regulations based on services provided may result in improved clarity and reduce confusion of regulants. **Likely Impact:** Improved clarity and consistency of the regulations.
	12VAC5-72-30	Critical congenital heart disease screening	**Change:** Add section containing regulations from 12VAC5-71-220. Formatting changes to adhere to the Virginia Register style guide. Updated reference to CCHD new section. Specified responsible party for screening procedures. Consolidated and clarified information. I**ntent:** Move regulations from 12VAC5-71 into 12VAC5-72. Improve readability and compliance with the Virginia Register of Regulations Form and Style guide. **Rationale:** Delineating regulations based on services provided may result in improved clarity and reduce confusion of regulants. **Likely Impact:** Improved clarity and consistency of the regulations.
	12VAC5-72-40	Critical congenital heart disease screening results	**Change:** Add section containing regulations from 12VAC5-71-230. Formatting changes to adhere to the Virginia Register style guide. Updated reference to CCHD

			new section. Consolidated and clarified information. I**ntent:** Move regulations from 12VAC5-71 into 12VAC5-72. Improve readability and compliance with the Virginia Register of Regulations Form and Style guide. **Rationale:** Delineating regulations based on services provided may result in improved clarity and reduce confusion of regulants. **Likely Impact:** Improved clarity and consistency of the regulations.
	12VAC5-72-50	Provides conditions under which a referral for care coordination should be made	**Change:** Add section containing regulations from 12VAC5-71-240. Formatting changes to adhere to the Virginia Register style guide. Updated reference to CCHD new section. Consolidated and clarified information. I**ntent:** Move regulations from 12VAC5-71 into 12VAC5-72. Improve readability and compliance with the Virginia Register of Regulations Form and Style guide. Remove unnecessary references to documents. **Rationale:** Delineating regulations based on services provided may result in improved clarity and reduce confusion of regulants. **Likely Impact:** Improved clarity and consistency of the regulations.
	12VAC5-72-60	Provides CCHD screening program information that hospitals must make available upon request.	**Change:** Add section containing regulations from 12VAC5-71-240. Formatting changes to adhere to the Virginia Register style guide. Updated reference to CCHD new section. Consolidated and clarified information. Clarified who will receive the

			information. Removed repetitive information. I**ntent:** Move regulations from 12VAC5-71 into 12VAC5-72. Improve readability and compliance with the Virginia Register of Regulations Form and Style guide. **Rationale:** Delineating regulations based on services provided may result in improved clarity and reduce confusion of regulants. **Likely Impact:** Improved clarity and consistency of the regulations.
	12VAC5-72-70	Provides for refusal of screening by a parent or guardian in certain situations	**Change:** Add section containing regulations from 12VAC5-71-260. Formatting changes to adhere to the Virginia Register style guide. Specified responsible party for screening procedures and process for documenting the refusal. I**ntent:** Move regulations from 12VAC5-71 into 12VAC5-72. Improve readability and compliance with the Virginia Register of Regulations Form and Style guide. **Rationale:** Delineating regulations based on services provided may result in improved clarity and reduce confusion of regulants. **Likely Impact:** Improved clarity and consistency of the regulations
	12VAC5-72-80	Provides the responsibilities of the Care Connection for Children network	**Change:** Add section containing certain regulations from 12VAC5-71-150. Formatting changes to adhere to the Virginia Register style guide. I**ntent:** Move regulations from 12VAC5-71 into 12VAC5-72. Improve readability and compliance with the Virginia

			Register of Regulations Form and Style guide. **Rationale:** Delineating regulations based on services provided may result in improved clarity and reduce confusion of regulants. **Likely Impact:** Improved clarity and consistency of the regulations.
	12VAC5-72-90	Procedures to maintain confidentiality of information	**Change:** Add section containing certain regulations from 12VAC5-71-190. Formatting changes to adhere to the Virginia Register style guide. I**ntent:** Move regulations from 12VAC5-71 into 12VAC5-72. Improve readability and compliance with the Virginia Register of Regulations Form and Style guide. **Rationale:** Delineating regulations based on services provided may result in improved clarity and reduce confusion of regulants. **Likely Impact:** Improved clarity and consistency of the regulations.
	FORMS	Provides for Documents Incorporated by Reference (DIBR)	**Change:** Add DIBRs necessary for this chapter

Office of Regulatory Management

Economic Review Form

Agency name	Virginia Department of Health (VDH)
Virginia Administrative Code (VAC) Chapter citation(s)	12 VAC5-71
VAC Chapter title(s)	Regulations Governing Virginia Newborn Screening Services
Action title	Amend Regulations Following Periodic Review
Date this document prepared	10/10/24
Regulatory Stage (including Issuance of Guidance Documents)	Fast-track

Cost Benefit Analysis

Complete Tables 1a and 1b for all regulatory actions. You do not need to complete Table 1c if the regulatory action is required by state statute or federal statute or regulation and leaves no discretion in its implementation.

Table 1a should provide analysis for the regulatory approach you are taking. Table 1b should provide analysis for the approach of leaving the current regulations intact (i.e., no further change is implemented). Table 1c should provide analysis for at least one alternative approach. You should not limit yourself to one alternative, however, and can add additional charts as needed.

Report both direct and indirect costs and benefits that can be monetized in Boxes 1 and 2. Report direct and indirect costs and benefits that cannot be monetized in Box 4. See the ORM Regulatory Economic Analysis Manual for additional guidance.

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

(1) Direct & Indirect Costs & Benefits (Monetized)	Direct Costs: There are no monetized direct costs associated with this action. Indirect Costs: There are no monetized indirect costs associated with this action. Direct Benefits: There are no monetized direct benefits associated with this action. Indirect Benefits: There are no monetized indirect benefits associated with this action.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) $0	(b) $0
(3) Net Monetized Benefit	$0	
(4) Other Costs & Benefits (Non-Monetized)	There are no non-monetized costs associated with the proposed changes. The non-monetized benefit of the proposed changes is that improved clarity of the regulations may result in a greater understanding among stakeholders (particularly hospitals and health care providers) of the screening and reporting requirements for CCHD. Clearer requirements will help ensure that more children are screened for CCHD and that results are correctly reported to VDH. This in turn will allow the CCHD Newborn Screening Program at VDH to improve health outcomes by connecting children with CCHD and their families to appropriate services.	
(5) Information Sources	Public comment during the periodic review suggested that the regulations as currently written (the CCHD newborn screening regulations and the dried blood spot newborn screening regulations in the same chapter) causes confusion, as not all regulations in Chapter 71 are applicable to all birth providers.	

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

(1) Direct & Indirect Costs & Benefits (Monetized)	Direct Costs: There are no monetized direct costs associated with this action. Indirect Costs: There are no monetized indirect costs associated with this action. Direct Benefits: There are no monetized direct benefits associated with this action.

	Indirect Benefits: There are no monetized indirect benefits associated with this action.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) $0	(b) $0
(3) Net Monetized Benefit	$0	
(4) Other Costs & Benefits (Non-Monetized)	Failure to repeal, promulgate, and update the CCHD newborn screening regulations could result in a continued lack of clarity by health care providers and hospitals about screening and reporting requirements for CCHD. Clarity is necessary to ensure that all eligible children are screened for CCHD and results are correctly reported to VDH, so that the CCHD Newborn Screening Program at VDH may identify children and families that may need to be connected to services.	
(5) Information Sources	Stakeholder and agency staff input	

Table 1c: Costs and Benefits under Alternative Approach(es)

(1) Direct & Indirect Costs & Benefits (Monetized)	Section 32.1-65.1 of the Code of Virginia requires critical congenital heart disease newborn screening to be conducted on every infant born in the Commonwealth of Virginia, and Section 32.1-67 of the Code of Virginia requires the Board of Health to promulgate regulations as necessary to implement these screenings. Alternatives to this regulatory change are limited to maintaining the status quo – not amending the regulations. As the regulations as written may cause confusion with regard to provider duties and responsibilities as they relate to newborn screenings, the Board has determined that amendments are necessary.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) N/A	(b) N/A
(3) Net Monetized Benefit	N/A	

(4) Other Costs & Benefits (Non-Monetized)	N/A
(5) Information Sources	N/A

Impact on Local Partners

Use this chart to describe impacts on local partners. See Part 8 of the ORM Cost Impact Analysis Guidance for additional guidance.

Table 2: Impact on Local Partners

(1) Direct & Indirect Costs & Benefits (Monetized)	Direct Costs: There are no monetized direct costs for local partners associated with this action. Costs associated with administering CCHD screenings will remain the same. Indirect Costs: There are no monetized indirect costs for local partners associated with this action. Direct Benefits: There are no monetized direct benefits for local partners associated with this action. Indirect Benefits: There are no monetized indirect benefits for local partners associated with this action.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) $0	(b) $0
(3) Other Costs & Benefits (Non-Monetized)	There are no non-monetized costs associated with the proposed changes in the guidance document. The non-monetized benefit of the proposed changes to the regulations is a greater understanding among health care providers and hospitals regarding screening and reporting requirements for CCHD.	
(4) Assistance	No assistance to local partners is required as a result of these changes.	
(5) Information Sources	Stakeholder and staff input.	

Impacts on Families

Use this chart to describe impacts on families. See Part 8 of the ORM Cost Impact Analysis Guidance for additional guidance.

Table 3: Impact on Families

(1) Direct & Indirect Costs & Benefits (Monetized)	Direct Costs: There are no monetized direct costs for families associated with this action. Indirect Costs: There are no monetized indirect costs for families associated with this action. Direct Benefits: There are no monetized direct benefits for families associated with this action. Indirect Benefits: There are no monetized indirect benefits for families associated with this action.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) $0	(b) $0
(3) Other Costs & Benefits (Non-Monetized)	There are no non-monetized costs associated with the proposed changes in the guidance document. The non-monetized benefit of the proposed changes to the regulations is that with increased clarity for health care providers and hospitals, VDH hopes to receive more consistent CCHD screening results, which in turn will allow the CCHD Newborn Screening Program at VDH to better understand the prevalence of CCHD and refer children with CCHD and their families to services.	
(4) Information Sources	Stakeholder input	

Impacts on Small Businesses

Use this chart to describe impacts on small businesses. See Part 8 of the ORM Cost Impact Analysis Guidance for additional guidance.

Table 4: Impact on Small Businesses

(1) Direct & Indirect Costs & Benefits (Monetized)	Direct Costs: There are no monetized direct costs for small businesses associated with this action. Indirect Costs: There are no monetized indirect costs for small businesses associated with this action.

	Direct Benefits: There are no monetized direct benefits for small businesses associated with this action. Indirect Benefits: There are no monetized indirect benefits for small businesses associated with this action.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) $0	(b) $0
(3) Other Costs & Benefits (Non-Monetized)	There are no non-monetized costs or benefits associated with these changes for small businesses, as this program does not involve or affect small businesses.	
(4) Alternatives	N/A	
(5) Information Sources	N/A	

Changes to Number of Regulatory Requirements

Table 5: Regulatory Reduction

For each individual action, please fill out the appropriate chart to reflect any change in regulatory requirements, costs, regulatory stringency, or the overall length of any guidance documents.

Change in Regulatory Requirements

VAC Section(s) Involved*	Authority of Change	Initial Count	Additions	Subtractions	Total Net Change in Requirements
12VAC5-71-10	**(M/A):**	0	0	0	0
	(D/A):	0	0	0	0
	(M/R):	0	0	0	0
	(D/R):	0	0	0	0
12VAC5-71-150	**(M/A):**	3	0	0	0
	(D/A):	0	0	0	0
	(M/R):	0	0	0	0
	(D/R):	0	0	0	0
12VAC5-71-190	**(M/A):**	3	0	0	0
	(D/A):	0	0	0	0
	(M/R):	0	0	0	0
	(D/R):	0	0	0	0
12VAC5-71-210	**(M/A):**	4	0	4	-4
	(D/A):	0	0	0	0
	(M/R):	0	0	0	0
	(D/R):	0	0	0	0
12VAC5-71-220	**(M/A):**	4	0	4	-4
	(D/A):	0	0	0	0
	(M/R):	0	0	0	0
	(D/R):	0	0	0	0
12VAC5-71-230	**(M/A):**	12	0	12	-12
	(D/A):	0	0	0	0
	(M/R):	0	0	0	0
	(D/R):	0	0	0	0
12VAC5-71-240	**(M/A):**	1	0	1	-1

	(D/A):	0	0	0	0
	(M/R):	1	0	1	-1
	(D/R):	0	0	0	0
12VAC5-71-250	**(M/A):**	1	0	1	-1
	(D/A):	1	0	1	-1
	(M/R):	4	0	4	-4
	(D/R):	0	0	0	0
12VAC5-71-260	**(M/A):**	1	0	1	-1
	(D/A):	0	0	0	0
	(M/R):	2	0	2	-2
	(D/R):	0	0	0	0
12VAC5-72-10	**(M/A):**	0	0	0	0
	(D/A):	0	0	0	0
	(M/R):	0	0	0	0
	(D/R):	0	0	0	0
12VAC5-72-20	**(M/A):**	0	4	0	+4
	(D/A):	0	0	0	0
	(M/R):	0	0	0	0
	(D/R):	0	0	0	0
12VAC5-72-30	**(M/A):**	0	4	0	+4
	(D/A):	0	0	0	0
	(M/R):	0	0	0	0
	(D/R):	0	0	0	0
12VAC5-72-40	**(M/A):**	0	12	0	+12
	(D/A):	0	0	0	0
	(M/R):	0	0	0	0
	(D/R):	0	0	0	0
12VAC5-72-50	**(M/A):**	0	1	0	+1
	(D/A):	0	0	0	0
	(M/R):	0	1	0	+1
	(D/R):	0	0	0	0
12VAC5-72-60	**(M/A):**	0	1	0	+1

	(D/A):	0	1	0	+1
	(M/R):	0	4	0	+4
	(D/R):	0	0	0	0
12VAC5-72-70	**(M/A):**	0	1	0	+1
	(D/A):	0	0	0	0
	(M/R):	0	2	0	+2
	(D/R):	0	0	0	0
12VAC5-72-80	**(M/A):**	0	0	0	0
	(D/A):	0	0	0	0
	(M/R):	0	0	0	0
	(D/R):	0	0	0	0
12VAC5-72-90	**(M/A):**	0	0	0	0
	(D/A):	0	0	0	0
	(M/R):	0	0	0	0
	(D/R):	0	0	0	0
				Grand Total of Changes in Requirements:	**(M/A): 0**
					(D/A): 0
					(M/R): 0
					(D/R): 0

Key:
Please use the following coding if change is mandatory or discretionary and whether it affects externally regulated parties or only the agency itself:
(M/A): Mandatory requirements mandated by federal and/or state statute affecting the agency itself
(D/A): Discretionary requirements affecting agency itself
(M/R): Mandatory requirements mandated by federal and/or state statute affecting external parties, including other agencies
(D/R): Discretionary requirements affecting external parties, including other agencies

Cost Reductions or Increases (if applicable)

VAC Section(s) Involved*	**Description of Regulatory Requirement**	**Initial Cost**	**New Cost**	**Overall Cost Savings/Increases**

Other Decreases or Increases in Regulatory Stringency (if applicable)

VAC Section(s) Involved*	Description of Regulatory Change	Overview of How It Reduces or Increases Regulatory Burden

Length of Guidance Documents (only applicable if guidance document is being revised)

Title of Guidance Document	Original Word Count	New Word Count	Net Change in Word Count

*If the agency is modifying a guidance document that has regulatory requirements, it should report any change in requirements in the appropriate chart(s).

Project 7747 - Fast-Track

Department of Health

Move critical Congenital Heart Disease Provisions from Chapter 71 into New Regulatory Chapter

12VAC5-71-10. Definitions.

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

~~"Abnormal screening results" means, in 12VAC5-71-210 through 12VAC5-71-250 only, all results that indicate the newborn has not passed the CCHD screening.~~

"Attending physician" means the physician in charge of the infant's care.

"Board" means the State Board of Health.

"Business days" means Monday through Friday from 9 a.m. to 5 p.m., excluding federal and state holidays.

"Care Connection for Children" means a statewide network of centers of excellence for children with special health care needs (CSHCN) that provides leadership in the enhancement of specialty medical services, care coordination, medical insurance benefits evaluation and coordination, management of the CSHCN pool of funds, information and referral to CSHCN resources, family-to-family support, and training and consultation with community providers on CSHCN issues.

"Care coordination" means a process that links individuals and their families to services and resources in a coordinated effort to maximize their potential and provide them with optimal health care.

"Certified nurse midwife" means a person licensed to practice as a nurse practitioner in the Commonwealth pursuant to § 54.1-2957 of the Code of Virginia and in accordance with Part II (18VAC90-30-60 et seq.) of 18VAC90-30 and 18VAC90-30-121, subject to 18VAC90-30-160.

"Chief executive officer" means a job descriptive term used to identify the individual appointed by the governing body to act in its behalf in the overall management of the hospital. Job titles may include administrator, superintendent, director, executive director, president, vice-president, and executive vice-president.

"Child" means a person less than 18 years of age and includes a biological or an adopted child, as well as a child placed for adoption or foster care unless otherwise treated as a separate unit for the purposes of determining eligibility and charges under these regulations.

"Commissioner" means the State Health Commissioner, his duly designated officer, or agent.

"Confirmatory testing" means a test or a panel of tests performed following a screened-abnormal result to verify a diagnosis.

"Core panel conditions" means those heritable disorders and genetic diseases considered appropriate for newborn screening. The conditions in the core panel are similar in that they have (i) specific and sensitive screening tests, (iii) a sufficiently well understood natural history, and (iii) available and efficacious treatments.

"Critical congenital heart disease" or "CCHD" means a congenital heart disease that places a newborn at significant risk of disability or death if not diagnosed and treated soon after birth. The disease may include, but is not limited to, hypoplastic left heart syndrome, pulmonary atresia (with intact septum), tetralogy of fallot, total anomalous pulmonary venous return, transposition of the great arteries, tricuspid atresia, and truncus arteriosus.

"CCHD screening" means the application of screening technology to detect CCHD.

"Department" means the state Department of Health.

"Dried-blood-spot specimen" means a clinical blood sample collected from an infant by heel stick method and placed directly onto specially manufactured absorbent specimen collection (filter) paper.

~~"Echocardiogram" means a test that uses an ultrasound to provide an image of the heart.~~

"Guardian" means a parent-appointed, court-appointed, or clerk-appointed guardian of the person.

"Healthcare provider" means a person who is licensed to provide health care as part of his job responsibilities and who has the authority to order newborn dried-blood-spot screening tests.

"Heritable disorders and genetic diseases" means pathological conditions (i.e., interruption, cessation or disorder of body functions, systems, or organs) that are caused by an absent or defective gene or gene product, or by a chromosomal aberration.

"Hospital" means any facility as defined in § 32.1-123 of the Code of Virginia.

"Infant" means a child less than 12 months of age.

"Licensed practitioner" means a licensed health care provider who is permitted, within the scope of his practice pursuant to Chapter 29 (§ 54.1-2900 et seq.) or Chapter 30 (§ 54.1-3000 et seq.) of Title 54.1 of the Code of Virginia, to provide care to a newborn.

"Low protein modified foods" means foods that are (i) specially formulated to have less than one gram of protein per serving, (ii) intended to be used under the direction of a physician for the dietary treatment of an inherited metabolic disease, (iii) not natural foods that are naturally low in protein, and (iv) prescribed as medically necessary for the therapeutic treatment of inherited metabolic diseases.

"Metabolic formula" means nutritional substances that are (i) prescribed by a health professional with appropriate prescriptive authority; (ii) specifically designed and formulated to be consumed or administered internally under the supervision of such health professional; (iii) specifically designed, processed, or formulated to be distinct in one or more nutrients that are present in natural food; and (iv) intended for the medical and nutritional management of patients with limited capacity to metabolize ordinary foodstuffs or limited capacity to metabolize certain nutrients contained in ordinary foodstuffs.

"Metabolic supplements" means certain dietary or nutritional substances intended to be used under the direction of a physician for the nutritional management of inherited metabolic diseases.

"Midwife" means a person licensed as a nurse practitioner in the category of certified nurse midwife by the Boards of Nursing and Medicine or licensed as a midwife by the Board of Medicine.

"Newborn" means an infant who is 28 days old or less who was born in Virginia.

"Newborn nursery" means a general level, intermediate level, or specialty level newborn service as defined in 12VAC5-410-443 B 1, B 2, and B 3.

"Nurse" means a person holding a current license as a registered nurse or licensed practical nurse by the Virginia Board of Nursing or a current multistate licensure privilege to practice in Virginia as a registered nurse or licensed practical nurse.

"Parent" means a biological parent, adoptive parent, or stepparent.

"Pediatric Comprehensive Sickle Cell Clinic Network" means a statewide network of clinics that are located in major medical centers and provide comprehensive medical and support

services for newborns and children living with sickle cell disease and other genetically related hemoglobinopathies.

"Physician" means a person licensed to practice medicine or osteopathic medicine in the Commonwealth pursuant to Chapter 29 (§ 54.1-2900 et seq.) of Title 54.1 of the Code of Virginia and in accordance with applicable regulations.

"Pool of funds" means funds designated for payment of direct health care services. Access to the pool is not an entitlement and is subject to availability of funds and guidelines that govern its eligibility and coverage of services. Pool of funds is a mix of federal Title V funds and state matching funds.

~~"Population-based" means preventive interventions and personal health services developed and available for the entire infant and child health population of the Commonwealth rather than for individuals in a one-on-one situation.~~

"Preterm infant" means an infant whose birth occurs by the end of the last day of the 36th week following the onset of the last menstrual period.

"Repeat specimen" means an additional newborn dried-blood-spot screening specimen submitted to the testing laboratory voluntarily or by request.

"Resident" means an individual who resides within the geographical boundaries of the Commonwealth.

"Satisfactory specimen" means a newborn dried-blood-spot screening specimen that has been determined to be acceptable for laboratory analyses by the testing laboratory.

"Screened-abnormal" means a newborn dried-blood-spot screening test result that is outside the established normal range or normal value for that test method.

~~"Screening technology" means pulse oximetry testing in the right hand and either foot. Screening technology shall also include alternate medically accepted tests that measure the percentage of blood oxygen saturation, follow medical guideline consensus and recommendations issued by the American Academy of Pediatrics, and are approved by the State Board of Health.~~

"Specialty level nursery" means the same as defined in 12VAC5-410-443 B 3 and as further defined as Level III by the Levels of Neonatal Care, written by the American Academy of Pediatrics Committee on Fetus and Newborn.

"Subspecialty level nursery" means the same as defined in 12VAC5-410-443 B 4.

"Testing laboratory" means the laboratory that has been selected by the department to perform newborn dried-blood-spot screening tests services.

"Total parenteral nutrition" or "TPN" means giving nutrients through a vein for babies who cannot be fed by mouth.

"Treatment" means appropriate management including genetic counseling, medical consultation, and pharmacological and dietary management for infants diagnosed with a disease listed in 12VAC5-71-30 D.

"Unsatisfactory specimen" means a newborn dried-blood-spot screening specimen that is inadequate for performing an accurate analysis.

"Virginia Genetics Advisory Committee" means a formal group that advises the department on issues pertaining to access to clinical genetics services across the Commonwealth and the provision of genetic awareness, quality services, and education for consumers and providers.

"Virginia Newborn Screening System" means a coordinated and comprehensive group of services, including education, screening, follow up, diagnosis, treatment and management, and program evaluation, managed by the department's Virginia Newborn Screening Program and

Virginia Early Hearing Detection and Intervention Program for safeguarding the health of children born in Virginia.

"Virginia Sickle Cell Awareness Program" means a statewide program for the education and screening of individuals for the disease of sickle cell anemia or the sickle cell trait and for such other genetically related hemoglobinopathies.

12VAC5-71-150. Responsibilities of the Care Connection for Children network.

A. The Care Connection for Children network shall provide the following services:

1. Care coordination services for residents of the Commonwealth who are diagnosed with selected heritable disorders ~~,~~ or genetic diseases ~~, or critical congenital heart disease~~ and are referred to the network by the Virginia Newborn Screening Program.

2. Other network services for eligible individuals in accordance with § 32.1-77 of the Code of Virginia and applicable regulations.

B. The Care Connection for Children network shall provide data as needed by the department's newborn screening program.

12VAC5-71-210. ~~Critical congenital heart disease screening protocols.~~ (Repealed.)

~~A. Hospitals shall develop protocols for critical congenital heart disease screening (i) in accordance with 12VAC5-71-220 through 12VAC5-71-260 and (ii) modeled after national recommendations from the American Academy of Pediatrics regarding CCHD, such as those specified in Strategies for Implementing Screening for Critical Congenital Heart Disease (Kemper et al., Pediatrics, November 2011, Volume 128, Issue 5 (2011 Nov;128(5):e1259-67) and Implementing Recommended Screening for Critical Congenital Heart Disease (Martin et al., Pediatrics, 2013, Volume 132, Issue 1 (2013 Jul;132(1):e185-92) and subsequent revisions and editions.~~

~~B. Hospitals shall develop protocols for the physical evaluation by licensed practitioners of newborns with abnormal screening results.~~

~~C. Hospitals shall develop protocols for the referral of newborns with abnormal screening results, if needed, after evaluation.~~

12VAC5-71-220. ~~Critical congenital heart disease screening.~~ (Repealed.)

~~A. A licensed practitioner shall perform the CCHD screening.~~

~~B. Except as specified in subsection C of this section and 12VAC5-71-260, CCHD screening using pulse oximetry shall be performed on every newborn in the birth hospital between 24 and 48 hours of life, or if the newborn is discharged from the hospital before reaching 24 hours of life, the CCHD screening shall be performed as late as practical before discharge.~~

~~C. If CCHD screening using pulse oximetry is not performed, the reason shall be documented in the newborn's medical record. The reasons include but are not limited to:~~

~~1. The newborn's current clinical evaluation has included an echocardiogram that ruled out CCHD;~~

~~2. The newborn has confirmed CCHD;~~

~~3. The newborn is under the care of a specialty level or subspecialty level nursery, in which case the screening shall be performed in accordance with the protocols developed in subsection D of this section; or~~

~~4. The parent or guardian refuses CCHD screening on the basis of religious practices or tenets pursuant to 12VAC5-71-260.~~

~~D. Hospitals shall develop protocols for screening newborns in specialty level nurseries and subspecialty level nurseries.~~

12VAC5-71-230. ~~Critical congenital heart disease screening results.~~ (Repealed.)

~~A. Recording results.~~

~~1. All CCHD screening results shall be recorded in the newborn's medical record.~~

~~2. All CCHD screening results shall be entered into the electronic birth certificate system with the following information:~~

~~a. CCHD screening completed, CCHD pass or fail, and pulse oximetry values, if applicable; or~~

~~b. Not screened pursuant to 12VAC5-71-220 C 4.~~

~~B. Abnormal screening results.~~

~~1. Abnormal screening results shall be reported by the authorized health care provider who conducted the screening to the attending physician or his designee immediately.~~

~~2. A newborn shall be evaluated by an attending physician or his designee according to the timeframes within the hospital protocol developed in accordance with 12VAC5-71-210.~~

~~3. A newborn shall not be discharged from care until:~~

~~a. A cause for the abnormal screening result has been determined and a plan is in place for immediate evaluation at another medical facility; or~~

~~b. An echocardiogram has been performed and read, and an appropriate clinical plan has been developed.~~

~~4. Any diagnosis arising from abnormal screening results shall be entered into the electronic birth certificate system.~~

~~5. The attending physician or his designee shall provide notification of abnormal screening results and any diagnoses to the newborn's parent or guardian and to the primary care provider in charge of the newborn's care after the newborn leaves the hospital.~~

12VAC5-71-240. ~~Referral for care coordination.~~ (Repealed.)

~~A. For any person diagnosed under 12VAC5-71-210 through 12VAC5-71-250, the chief administrative officer of every hospital, as defined in § 32.1-123 of the Code of Virginia, shall make or cause to be made a report to the commissioner in accordance with § 32.1-69.1 of the Code of Virginia.~~

~~B. Upon receiving the notification described in subsection A of this section, the Newborn Screening Program at the Virginia Department of Health shall refer the newborn's parent or guardian to the Care Connection for Children network for care coordination services.~~

12VAC5-71-250. ~~Congenital heart disease screening records.~~ (Repealed.)

~~A. The screening of newborns pursuant to this chapter is a population-based public health surveillance program as defined by the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191; 110 Stat. 2033).~~

~~B. Upon request, a hospital shall make available to the Virginia Congenital Anomalies Reporting and Education System (VaCARES):~~

~~1. Medical records;~~

~~2. Records of laboratory tests; and~~

~~3. Any other information that VaCARES considers necessary to:~~

~~a. Determine final outcomes of abnormal CCHD screening results; or~~

~~b. Evaluate CCHD screening activities in the Commonwealth, including performance of follow-up evaluations and diagnostic tests, initiation of treatment when necessary, and surveillance of the accuracy and efficacy of the CCHD screening.~~

~~C. Information that the Virginia Department of Health receives under this section is confidential and may only be used or disclosed:~~

~~1. For research and collective statistical purposes pursuant to § 32.1-67.1 of the Code of Virginia;~~

~~2. For state or federally mandated statistical reports;~~

~~3. To ensure that the information received by the Virginia Department of Health is accurate and reliable; or~~

~~4. For reporting to the Virginia Congenital Anomalies Reporting and Education System pursuant to § 32.1-69.1 of the Code of Virginia and 12VAC5-191-280. The Newborn Screening Program shall refer the newborn's parent or guardian to the Care Connection for Children network for care coordination services.~~

~~D. The hospital administrator shall ensure that CCHD screening is included in the perinatal quality assurance program and provide the results of the quality improvement program to the Virginia Department of Health upon request.~~

12VAC5-71-260. ~~Parent or guardian refusal for screening.~~ (Repealed.)

~~A. In the instance of parent or guardian refusal of the CCHD screening based on religious practices or tenets, the parent or guardian refusal shall be documented on a refusal form provided by the Virginia Department of Health and made a part of the newborn's medical record.~~

~~B. The administrator of the hospital shall ensure that the Newborn Screening Program at the Virginia Department of Health is notified in writing of the parent or guardian refusal within five days of the newborn's birth.~~

Chapter 72

Regulations Governing Virginia Critical Congenital Heart Disease Newborn Screening Services

12VAC5-72-10. Definitions.

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

"Abnormal screening results" means all results that indicate the newborn has not passed the CCHD screening.

"Attending physician" means the physician in charge of the infant's care.

"Board" means the State Board of Health.

"Care Connection for Children" means a statewide network of centers of excellence for children and youth with special health care needs (CYSHCN) that provides leadership in the enhancement of specialty medical services, care coordination, medical insurance benefits evaluation and coordination, management of the CYSHCN pool of funds, information and referral to CYSHCN resources, family-to-family support, and training and consultation with community providers on CYSHCN issues.

"Care coordination" means a process that links individuals and their families to services and resources in a coordinated effort to maximize their potential and provide them with optimal health care.

"Chief administrative officer" means the individual appointed by the governing body to act in its behalf in the overall management of the hospital, or the Chief administrative officer’s

designee. Job titles may include chief executive officer, administrator, superintendent, director, executive director, president, vice president, and executive vice president.

"Child" means a person less than 18 years of age and includes a biological or an adopted child, as well as a child placed for adoption or foster care unless otherwise treated as a separate unit for the purposes of determining eligibility and charges under these regulations.

"Commissioner" means the State Health Commissioner or the Commissioner's designee.

"Critical congenital heart disease" or "CCHD" means a congenital heart disease that places a newborn at significant risk of disability or death if not diagnosed and treated soon after birth. The disease may include a defect such as hypoplastic left heart syndrome, pulmonary atresia (with intact septum), tetralogy of fallot, total anomalous pulmonary venous return, transposition of the great arteries, tricuspid atresia, or truncus arteriosus.

"CCHD Newborn Screening Program" means the Critical Congenital Heart Disease Newborn Screening Program within the Virginia Department of Health, that provides services including education, follow up, referral, and program evaluation.

"CCHD screening" means the application of screening technology to detect CCHD.

"Department" means the Virginia Department of Health.

"Echocardiogram" means a test that uses an ultrasound to provide an image of the heart.

"Guardian" means a parent-appointed, court-appointed, or clerk-appointed guardian of the person.

"Hospital" means any facility as defined in § 32.1-123 of the Code of Virginia.

"Licensed practitioner" means a licensed health care provider who is permitted, within the scope of his practice pursuant to Chapter 29 (§ 54.1-2900 et seq.) or Chapter 30 (§ 54.1-3000 et seq.) of Title 54.1 of the Code of Virginia, to provide care to a newborn.

"Negative(pass)" means a CCHD screening test result where the pulse oximetry value is 95% or more in the right hand or foot and there is a difference of 3% or less between the pulse oximetry value in the right hand and the pulse oximetry value in a foot.

"Newborn" means an infant who is 28 days old or less who was born in Virginia.

"Parent" means a biological parent, adoptive parent, or stepparent.

"Physician" means a person licensed to practice medicine or osteopathic medicine in the Commonwealth pursuant to Chapter 29 (§ 54.1-2900 et seq.) of Title 54.1 of the Code of Virginia and in accordance with applicable regulations.

"Positive(fail)" means a CCHD screening test result where the pulse oximetry value is 89% or less in either the right hand or foot.

"Resident" means an individual who resides within the geographical boundaries of the Commonwealth.

"Screening technology" means pulse oximetry testing in the right hand and either foot. Screening technology shall also include alternate medically accepted tests that measure the percentage of blood oxygen saturation, follow medical guideline consensus and recommendations issued by the American Academy of Pediatrics, and are approved by the State Board of Health.

"Specialty level nursery" means the equivalent of the definition for Level II defined in Levels of Neonatal Care, written by the American Academy of Pediatrics Committee on Fetus and Newborn.

"Subspecialty level nursery" means the equivalent of the definitions for Levels III and IV defined in Level of Neonatal Care, written by the American Academy of Pediatrics Committee on Fetus and Newborn.

12VAC5-72-20. Critical congenital heart disease screening protocols.

A. A hospital shall develop and implement protocols for:

1. CCHD screening in accordance with this chapter and modeled after national recommendations from the American Academy of Pediatrics regarding CCHD screening;

2. CCHD screening in specialty level nurseries and subspecialty level nurseries;

3. Physical evaluation by licensed practitioners of newborns with abnormal screening results; and

4. Referral of newborns with abnormal screening results, if needed, after evaluation.

12VAC5-72-30. Critical congenital heart disease screening.

A. Except as specified in subsection B of this section and in 12VAC5-72-70, a licensed practitioner shall perform the CCHD screening using pulse oximetry on every newborn in the birth hospital between 24 and 48 hours after birth, or if the newborn is discharged from the hospital fewer than 24 hours after birth, as late as practical before discharge.

B. If CCHD screening using pulse oximetry is not performed, the licensed practitioner shall document the reason in the newborn's medical record. The reasons include:

1. The newborn's current clinical evaluation includes an echocardiogram that ruled out CCHD;

2.The newborn has confirmed CCHD;

3.The newborn is under the care of a specialty level or subspecialty level nursery, in which case the screening shall be performed in accordance with the specific protocols developed pursuant to subdivision A 2 of 12VAC5-72-20; or

4. The parent or guardian refuses CCHD screening on the basis of religious practices or tenets.

12VAC5-72-40. Critical congenital heart disease screening results.

A. A licensed practitioner shall record the CCHD screening results in the newborn's medical record.

B. The hospital shall enter the CCHD screening results into the electronic birth certificate system with the following information:

1. CCHD screening completed, CCHD negative(pass) or positive(fail), and pulse oximetry values, if applicable; or

2. Not screened pursuant to subdivision B 4 of 12VAC5-72-30.

C. If the results of the CCHD screening are abnormal:

1. The licensed practitioner who conducted the screening shall immediately report the results to the attending physician or the physician’s designee;

2. An attending physician or the physician’s designee shall evaluate the newborn according to the timeframes within the hospital protocol developed pursuant to 12VAC5-72-20; and

3. The hospital may not discharge the newborn until:

a. An attending physician has determined a cause for the abnormal screening result and a plan is in place for immediate evaluation at another medical facility; or

b. A licensed practitioner has performed, and a physician has read, an echocardiogram and an appropriate clinical plan has been developed.

4. The hospital shall enter a diagnosis arising from abnormal screening results into the electronic birth certificate system.

5. The attending physician or the physician’s designee shall provide notification of abnormal screening results and any diagnoses to the newborn's parent or guardian and to the primary care provider who is in charge of the newborn's care after the newborn leaves the hospital.

12VAC5-72-50. Referral for care coordination.

A. For any child diagnosed under 12VAC5-72-10 through 12VAC5-72-60, the chief administrative officer of every hospital shall make or cause to be made a report to the Commissioner in accordance with § 32.1-69.1 of the Code of Virginia.

B. Upon receiving the notification described in subsection A of this section, the CCHD Newborn Screening Program at the department shall refer the child to the Care Connection for Children network for care coordination services as necessary.

12VAC5-72-60. Critical Congenital heart disease screening records.

A. Upon request, a hospital shall make available to the CCHD Newborn Screening Program at the department:

1. Medical records;

2. Records of laboratory tests; and

3. Other information that the CCHD Newborn Screening Program at the department considers necessary to:

a. Determine final outcomes of abnormal CCHD screening results; or

b. Evaluate CCHD screening activities in the Commonwealth, including performance of follow-up evaluations and diagnostic tests, initiation of treatment when necessary, and surveillance of the accuracy and efficacy of the CCHD screening.

12VAC5-72-70. Parent or guardian refusal for screening.

A. If a parent or guardian refuses the CCHD screening based on religious practices or tenets, the licensed practitioner shall document the refusal on the Notification of Parental Refusal of Dried-Blood Spot and Critical Congenital Heart Disease Screening form and document the refusal in the newborn's medical record.

B. The hospital shall ensure that the CCHD Newborn Screening Program at the department is notified in writing of the refusal within five days of the newborn's birth.

12VAC5-72-80. Responsibilities of the Care Connection for Children network.

A. The Care Connection for Children network shall provide:

1. Care coordination services for residents of the Commonwealth who are diagnosed with CCHD and referred to the network by the CCHD Newborn Screening Program at the department; and

2. Other network services for eligible individuals in accordance with § 32.1-77 of the Code of Virginia and applicable regulations.

B. The Care Connection for Children network shall, upon request, provide data to the CCHD Newborn Screening Program at the department.

12VAC5-72-90. Confidentiality of information.

A. The department's employees and contractors shall maintain, store, and safeguard client records from unauthorized access as required by law.

B. Information that the CCHD Newborn Screening Program at the department receives under this section is confidential and may only be used or disclosed:

1. For research and collective statistical purposes pursuant to § 32.1-67.1 of the Code of Virginia;

2. For state or federally mandated statistical reports;

3. To ensure that the information received by the CCHD Newborn Screening Program at the department is accurate and reliable;

4. To perform quality improvement and assurance activities including ensuring hospital reporting.

FORMS (12VAC5-72)

Notification of Parental Refusal of Dried-Blood Spot and Critical Congenital Heart Disease Screening (rev. 4/2015)

Documents Incorporated by Reference (12VAC5-72)

Levels of Neonatal Care, Policy Statement from Committee on Fetus and Newborn, American Academy of Pediatrics, August 27, 2012

Home Care Organization Regulations
12VAC5-381
Fast Track Amendments

Kimberly Beazley
Director
Office of Licensure and Certification

COMMONWEALTH of VIRGINIA

Department of Health

Karen Shelton, MD
State Health Commissioner

P O BOX 2448
RICHMOND, VA 23218

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

MEMORANDUM

DATE: November 1, 2024

TO: State Board of Health

FROM: Kimberly Beazley
Director, Office of Licensure and Certification

SUBJECT: Proposed Amendments to the Regulations for the Licensure of Home Care Organizations (12VAC5-381-10) 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.*) after assessment and receipt of public comment.

12VAC5-381 governs the licensure of Home Care Organizations (HCO) in the Commonwealth. This action proposes comprehensive amendments to this chapter, which include amendments to: (i) Clarify and expand existing regulatory language by providing additional detail for certain processes and requirements, (ii) update existing regulatory language that is inconsistent or outdated, (iii) revise language to conform to the *Form, Style, and Procedure Manual for Publication of Virginia Regulations*, and (iv) adjust HCO licensure fees.

The State Board of Health is requested to approve the proposed amendments. Should the Board approve the proposed amendments, they 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 60-day public comment period. A public hearing will be held following the publication of this stage of this regulatory action.

townhall.virginia.gov

Proposed Regulation
Agency Background Document

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12 VAC5-381
VAC Chapter title(s)	Regulations for the Licensure of Home Care Organizations
Action title	Amend Regulations Following Assessment and Receipt of Public Comment
Date this document prepared	10/01/2024

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

Brief Summary

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

12VAC5-381 governs the licensure of home care organizations (HCO) in the Commonwealth. This action proposes comprehensive amendments to this Chapter, include amendments to: (i) Clarify and expand existing regulatory language by providing additional detail for certain processes and requirements, (ii) update existing regulatory language that is inconsistent or outdated, (iii) revise language to conform to the *Form, Style, and Procedure Manual for Publication of Virginia Regulations*, (iv) adjust HCO licensure fees.

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 the State Board of Health.

"Commissioner" means the State Health Commissioner

"HCO" means a home care organization.

"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 the ORM procedures, "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

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 19 (2022).

The Administrative Process Act allows for public comment period for periodic reviews of regulations. This action includes amendments resulting from the review of public comment.

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 is 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 regulants' ability to comply, out of date regulations may refer to standards and practices that are not current and reducing regulatory burden on home care organizations to allow these regulants 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 Regulations."

Section 10 Definitions
Added new definitions for "Board", "Business day", "Client", "Home health services", "Independent contractor", "Inspector", Legal representative", "Owner", "Parent HCO", "Patient", "Pharmaceutical services", "Plan of care" "Practitioner or health care practitioner", and "Skilled services director". Revised definitions for "Activities of daily living", "Administer", "Administrator", "Barrier crime" (formerly "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", "Discharge or termination summary", "Organization", "Person", and "Service area".

Section 20 License
Revised to clarify the conditions under which the commissioner may issue an HCO license, and the disclosures that are needed for a parent HCO to add a branch office to its license.

Section 30 Exemption from licensure
Revised to clarify who may be exempted from licensure, ways in which to request an exemption, and the obligation to inform the agency if the exemption eligibility is lost. Includes definitions for "beautician services", "chore services",

Section 35 Total geographic area and office location
New section – Requiring licensees or applicants for licensure to indicate the total geographic area that the HCO intends to serve. Requires that the parent HCO office and any branch office or drop site of an HCO shall be located within the geographic area it serves.

Section 40 License application; initial and renewal

Renamed section from “License application; initial and renewal” to “Request for initial license issuance.” Language regarding licensure renewal was moved to a new section (see Section 45 below). Added language to identify an applicant’s responsibilities when applying more clearly for initial licensure, the initial licensure process, when the commissioner may deny licensure, and an applicant’s ability to reapply if denied licensure.

Section 45 License expiration and renewal
*New section - Adds language regarding licensure renewal (moved here from Section 40) and modifies language to identify a licensee’s responsibilities when applying for renewal of licensure more clearly, the renewal licensure process, and an HCO’s options if it failed to timely renew.

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.

Section 65 License reinstatement
*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 fees were enacted in 2006 and accounting for Legislative action regarding inspecting branch offices (2018) and authorizing triennial licensure (2022). Clarifies that fees are nonrefundable.

Section 80 On-site inspections
Revised to explain the on-site inspection process and an HCO’s obligations more clearly during and after the inspection; increases inspection frequency from biennial to triennial. Revised text to better align with the definitions included in Section 10 of this Chapter.

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 better align with the definitions included in Section 10 of this Chapter.

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 better align with the definitions included in Section 10 of this Chapter.

Section 120 Variances

Renamed “Allowable variances.” Revised text to reflect that only commissioner may grants variances and to clarify the variance request process.

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 align with statutory provisions.

Section 140 Return of a license
Repealed; consolidated with Section 60.

Section 150 Management and administration
Revised text to align with Section 10’s definitions more closely 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 better align with the definitions included in Section 10 of this Chapter. 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 align with Section 10’s definitions more closely and for improved clarity. Added language to clarify responsibilities of a designated administrator and requires certain training and experience requirements for said administrator. Adds language to require an HCO to notify the OLC given a change of administrator, to provide an administrator’s resume or curriculum vitae to OLC, and to appoint a qualified person to act in the absence of an administrator.

Section 180 Written policies and procedures
Renamed “Policies and procedures.” Revised text to better align with the definitions included in Section 10 of this Chapter. 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 better align with the definitions included in Section 10 of this Chapter. 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 align with Section 10’s definitions more closely and to clarify that job description requirements apply to all workers, whether compensate or not, whether employed or contracted. Revised text to require orientation include fraud, abuse, and neglect training.

Section 210 Indemnity coverage
Revised text to align with Section 10’s definitions more closely 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 better align with the definitions included in Section 10 of this Chapter.

Section 230 Client rights
Renamed “Client and patient rights.” Revised text to align with Section 10’s definitions more closely and to align with the rights language more closely for home health agency patients.

Section 240 Handling complaints received from clients
Renamed section from "Handling complaints received from clients" to "Complaint handling procedures." Revised text to better align with the definitions included in Section 10 of this Chapter. Revised text to expand complaint record retention from 3 to 5 years.

Section 250 Quality improvement
Revised text to improve clarity and better align with the definitions included in Section 10 of this Chapter.

Section 260 Infection control
Revised text to add requirement for an employee health program and to better align with the definitions included in Section 10 of this Chapter. Remove infection control activities that are now found in Section 180.

Section 270 Drop sites
Revised text to improve clarity and better align with the definitions included in Section 10 of this Chapter.

Section 280 Client record system
Renamed Section from "Client record system" to "Clinical record system. Revised text to improve clarity and better align with the definitions included in Section 10 of this Chapter.
Clarified the necessary components of the "medical plan of care" or "plan of care".

Section 290 Home attendants
Revised text 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 specify that pharmaceutical services are a type of skilled services, to improve clarity and to better align with the definitions included in Section 10 of this Chapter.

Section 310 Nursing services
Revised text to better align with the definitions included in Section 10 of this Chapter, 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 better align with the definitions included in Section 10 of this Chapter, to improve 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 better align with the definitions included in Section 10 of this Chapter, to improve 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 better align with the definitions included in Section 10 of this Chapter, to improve 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 section "Pharmaceutical services." Revised text to better align with the definitions included in Section 10 of this Chapter and to remove policies and procedures that are now found in Section 180.

DOCUMENTS INCORPORATED BY REFERENCE (12VAC5-381)
Removed: Personal Care Aide Training Curriculum, 2003 Edition, Virginia Department of Medical Assistance Services.

Added: U.S. Centers for Disease Control and Prevention Standard Precautions for All Patient Care, April 3, 2024.
U.S. Centers for Disease Control and Prevention Injection Safety Guidelines, 2007.

Issues

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

The primary advantage to the public is 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 are 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. This proposed regulatory action was previously withdrawn on April 7, 2022, after concerns were raised regarding the economic impact of requiring HCOs to secure commercial real estate for their business activities. This requirement has since been removed from the proposed regulatory language of this action.

There are other pertinent matters of interest to the regulated community, government officials and the public that the Board is not proposing changes to in this regulatory action. Chapter 470 of the 2021 Acts of Assembly, Special Session I directs the board to promulgate regulations for HCOs that govern the delivery of personal care services which shall provide for supervision of home care attendants providing personal care services by a licensed nurse through use of interactive audio or video technology. A separate regulatory action has been initiated to amend Section 360 and all amendments for that section will be addressed in that separate regulatory action and not in the present one. Chapter 172 of the 2022 Acts of Assembly directs the board to change home care organization licenses from an annual license to a three-year license. This act also mandated that the fee for renewal of a home care organization license shall be $1,500 until such time as the Board of Health may amend or repeal regulations for the licensure of home care organizations. These changes are addressed in a separate regulatory action from this action and separately from the action previously mentioned regarding 12VAC5-381-360.

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

Consistent with § 2.2-4007.04 of the Code of Virginia, identify any other state agencies, localities, or other entities particularly affected by the regulatory change. Other entities could include local partners such as

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

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

Economic Impact

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

Impact on State Agencies

For your agency: projected costs, savings, fees, or revenues resulting from the regulatory change, including: a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources.	There are no projected costs, savings, or revenue loss resulting from the regulatory change. The agency estimates that the proposed triennial fees in Section 70 would result in a minimum triennial fee revenue of $4,680,500. This assumes that licensee numbers (1,866), branch office numbers (163), and applicant numbers (approximately 900 triennially) remain relatively stable. The number of licensees requesting a material change to their license is highly variable and difficult to predict, making fee revenue projections from that fee equally difficult to predict. A legislative change to the HCO licensure length (from 1 year to 3 years) also means that the previously steady stream of triennial revenue from this program is now uneven and much more unpredictable. Any revenue collected in "flush" years will be needed to cover the "lean" years where revenue is dramatically lower than expenditures. The agency is proposing to introduce a new reinstatement process that currently has no analog in its other licensure programs, so it is difficult to predict what fee revenue may result from HCOs utilizing that process. OLC currently has seven FTE Health Care Compliance Specialists II who conduct HCO licensure inspections; however, three of the seven FTEs are grant-funded and the funding for these positions will cease on June 30, 2027. Each FTE inspector can perform an annual

	average of 60 HCO inspections, which includes biennial licensure inspections, initial licensure inspections, and complaint inspections. Assuming the number of regulants remains relatively stable, there would be approximately 904 biennial inspections due every year. This would require a total staff of 10 FTE inspectors, two FTE supervisors, and two FTE administrative supports. Based on current salaries and fringe benefit calculations for these positions from SFY2024, the agency would have a total staffing cost of $2,001,885. This amount includes expenditures for a state-issued vehicle ($4,200), lodging ($8,000), gasoline ($2,410), and meals and incidentals ($7,175) for each of the 14 inspectors. For an exact breakdown of costs, please consult the Economic Review Form submitted concurrently with the proposed regulatory change.
For other state agencies: projected costs, savings, fees, or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.	There are no projected costs, savings, fees, or revenues resulting from the regulatory change for other state agencies.
For all agencies: 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 Localities

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

Projected costs, savings, fees, or revenues resulting from the regulatory change.	There are no projected costs, savings, fees, or revenues resulting from the regulatory change for localities.
Benefits the regulatory change is designed to produce.	This regulatory action is designed to promote and ensure the health and safety of clients and patients who receive personal care services and skilled services from HCOs, including ensuring the agency has sufficient fee revenue to support adequate staff to perform inspections and other oversight functions.

Impact on Other Entities

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

Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be	The individuals, businesses, or other entities likely to be affect by the regulatory change include persons seeking services from an HCO;

affected, include a specific statement to that effect.	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 September 20, 2024, there are 1,866 licensed HCOs in Virginia and 163 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 cost of $2,000 fee per initial triennial 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 $1,500 triennial renewal fee per license renewal application, with a 163 HCOs incurring an additional triennial 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 smaller minority of HCOs incurring an additional triennial cost of $750 for each branch office they operate. 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. 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. 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.
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.

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 alternatives were 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

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

In developing the proposed regulations, the Board considered that the affected industry consists primarily of small businesses. Providing a small business exemption would result in an 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 EO 19 and the ORM procedures, e.g., is necessary for the protection of public health, safety, and welfare; minimizes the economic impact on small businesses consistent with the stated objectives of applicable law; and is clearly written and easily understandable. In addition, as required by § 2.2-4007.1 E and F of the Code of Virginia, discuss the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation; (3) the complexity of the regulation; (4) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the

length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation. Also, discuss why the agency's decision, consistent with applicable law, will minimize the economic impact of regulations on small businesses.

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. 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 nine years since the regulation has undergone periodic review.

There is a continued need for this regulation because the mandate to regulate home care organizations still exists in the Code of Virginia. Three 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.

Public Comment

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

Commenter	Comment	Agency Response
Marcia A. Tetterton, Virginia Association for Home Care and Hospice	**Part I. Definitions and General Information** 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.~~ 12VAC5-381-120. Variances. A. The ~~OLC~~ Commissioner 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. 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	The Board has responded to each suggestion below, grouped by regulatory section: • 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 indicate which drugs more clearly are reportable and to address CBD

	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.~~ 12VAC5-381-180. Written Policies and Procedures. C. Administrative and operational policies and procedures shall include but are not limited to: 10. Communicable and reportable diseases <u>pursuant to guidelines established by the Virginia Department of Health</u>; <u>18. CBD oil and THC-A oil for medical treatment, prescription or illegal drug abuse by client in the aide's presence; and</u> 12VAC5-381-190. Financial Controls. D. ~~All financial records shall be audited at least triennially by an independent certified public accountant (CPA) or audited as otherwise provided by law.~~ <u>A copy of most recent tax return prepared by an independent</u>	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 derived from is for a 75-hour training program covering these topics • 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.

	financial organization, or an audit, or a balance sheet, or a financial statement prepared by a certified public accounting firm. 12VAC5-381-280. Client Record System. 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~~ ten working days. 12VAC5-381-290.Home Attendants. Home attendants shall be able to speak, read and write English and shall meet one of the following qualifications: 6. Have satisfactorily completed a 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 used to provide instruction under the supervision of a licensed nurse. The 20-hour training program shall address each of the following subject areas: (i) Communications skills, including the ability to read, write and verbally report information to the person receiving services, representatives, other caregivers and supervisor. (ii) Observation, reporting and documentation of patient status and the care or service furnished. (iii) Reading and recording temperature, pulse, and respiration. (iv) Basic infection control procedures. (v) Basic elements of body functioning and changes in body function that must be reported to an aide's supervisor.	• 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.

	(vi) Maintenance of a clean, safe, and healthy environment. (vii) Recognizing emergencies and knowledge of emergency procedures. (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. (ix) Appropriate and safe techniques in personal hygiene and grooming that include (A) Bed bath. (B) Sponge, tub, or shower bath. (C) Hair shampoo, sink, tub, or bed. (D) Nail and skin care. (E) Oral hygiene. (F) Toileting and elimination. (x) Safe transfer techniques and ambulation. (xi) Normal range of motion and positioning. (xii) Adequate nutrition and fluid intake. (xiii) Recognizing and reporting changes in skin condition, including pressure ulcer. (xiv) Any other task that home care organization may choose to provider as permitted under state law. ~~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.~~ **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 ~~primary care~~ ordering physician. E. The medical plan of care shall be reviewed and approved ~~and signed~~ by the ~~primary care~~ ordering physician at least every 60 days. 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.~~ 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, 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. The organization shall have one year from January 1, 2006, to ensure the designated individual meets the qualifications of this standard.	

	Part V. Personal Care Services 12VAC5-381-360. Personal Care Services. 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~~ licensed nurse responsible for the supervision of personal care services. B. The personal care services shall include: 5. Documenting the services delivered in the client's ~~record~~ service plan. 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: 1. ~~Assessment~~ Evaluation of the client's needs; D. The service plan shall be retained in the client's record. Copies of the service plan shall be provided to the client receiving services and reviewed with the assigned home attendant prior to delivering services. E. Supervision of ~~services~~ home attendants shall be provided as often as necessary as determined by the client's ~~needs~~ service plan by a ~~the assessment of the registered~~ licensed health care professional ~~nurse~~, and the organization's written policies not to exceed ~~90~~ 120 days. F. A ~~registered nurse or~~ licensed ~~practical~~ nurse shall be available during all hours that personal care services are being provided.	

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 **Val Hornsby, Policy Analyst, Virginia Department of Health, Office of Licensure and Certification; Mailing Address; 9960 Mayland Drive, Suite 401, Henrico, VA, 23233; Phone: (804)875-1089; Fax: (804)527-4502; Email: regulatorycomment@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 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 the existing VAC Chapter(s) and the proposed regulation. If the 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
381-10	N/A	Defines terms used throughout the regulation	**CHANGE:** Added new definitions for: • business day; • board • 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; • discharge or termination summary; • organization; • person; and • service area. **INTENT:** The intent of these proposed changes is to: • Clarify the difference in authority and responsibility between the administrator, owner, and the governing body; • Add missing definitions for terms that have been the source of confusion for regulants;

			• Eliminate defined terms that do not appear in the regulation; • Clarify what constitutes a business day; • Add definitions so that subsequent regulatory sections are less complex and verbose, such as for inspector, employee, independent contractor, and legal representative; and • ensure terms derived from statute cross-reference the appropriate statutory provision. **RATIONALE:** The rationale behind these proposed changes is: • To 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; • Previously undefined terms that have caused confusion clearly to indicate a need for a definition; • There is no justification to define terms that do not appear in the regulation; • Eliminate confusion about what constitutes a business day since the operating hours and days of an HCO can vary widely from regulant to regulant; • Increase readability of later sections by defining terms rather than trying to define complex subjects within a regulatory requirement; and • Eliminate any conflicts between terms defined in statute and terms defined in this chapter. **LIKELY IMPACT:** The likely impact of these proposed changes is clarity about the meaning of terms and improved readability of later regulatory sections.
381-20	N/A	Describes license issuance and conditions of issuance of a license.	**CHANGE:** Revised regulatory language 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 better align with the definitions included in Section 10 of this Chapter.

			INTENT: The intent of these proposed changes is to: • Rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; • Match regulatory language to statutory language; and • Clarify the necessary information needed by the agency if an HCO wants to open a branch office. **RATIONALE:** The rationale behind these proposed changes is: • The active voice and the use of subparts are the style preferred and recommended by *The Virginia Register of Regulations*; • Reducing conflicts between regulatory language and statutory language reduces confusion for readers; and • Explaining the process to open a branch office in greater detail should result in applicants being better prepared for the process. **LIKELY IMPACT:** The likely impact of these proposed changes is improved readability of the section and improved clarity regarding branch offices.
381-30	N/A	Describes exemptions from licensure.	**CHANGE:** • 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 better align with the definitions included in Section 10 of this Chapter. **INTENT:** The intent of these proposed changes is to: • Rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; • Match regulatory language to statutory language; and • Clarify the exemption process and the requirement to notify the agency if exemption eligibility is lost.

			RATIONALE: The rationale behind these proposed changes is: • The active voice and the use of subparts are the style preferred and recommended by *The Virginia Register of Regulations*; • reducing conflicts between regulatory language and statutory language reduces confusion for readers; and • explaining the exemption process in greater detail should result in applicants being better prepared for the process. **LIKELY IMPACT:** The likely impact of these proposed changes is improved readability of the section and improved clarity regarding the exemption process.
N/A	381-35	N/A	**CHANGE:** • A new section addressing what constitutes total geographic service area and that existing HCOs will have one year to come into compliance upon the effective date of the regulations. • Revised text to better align with the definitions included in Section 10 of this Chapter. **INTENT:** The intent of these proposed changes is to: • write this section in the active voice and break paragraphs with multiple requirements into subparts; • clarify what constitutes total geographic area; and • giving existing regulants time to comply. **RATIONALE:** The rationale behind these proposed changes is: • the active voice and the use of subparts are the style preferred and recommended by *The Virginia Register of Regulations*; • 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; and • one year should be sufficient time for an HCO to move locations, if

			necessary, and to determine what its new total geographic area is. **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.
381-40	N/A	Describes initial and renewal license application processes.	**CHANGE:** • Renamed "Request for initial license issuance." Language regarding licensure renewal was moved to a new section (see Section 45 below). • Added language to identify an applicant's responsibilities when applying more clearly 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 better align with the definitions included in Section 10 of this Chapter. **INTENT:** The intent of these proposed changes is to: • write this section in the active voice and break paragraphs with multiple requirements into subparts; • clarify the initial licensure process; and • clarify the causes for which the State Health Commissioner may deny an initial license. **RATIONALE:** The rationale behind these proposed changes is: • the active voice and the use of subparts are the style preferred and recommended by *The Virginia Register of Regulations*; • the initial licensure process is multi-stage and explaining it in greater detail should result in applicants being better prepared for the process; • applicants should be made aware of what action or inaction of theirs may cause the State Health Commissioner to deny them an initial license.

			LIKELY IMPACT: The likely impact of these proposed changes is improved readability of the section and improved clarity regarding the initial licensure process.
N/A	381-45	N/A	**CHANGE:** The Board is proposing to add a new section as follows: • Language regarding licensure renewal was moved here from Section 40 and modified to identify a licensee's responsibilities when applying for renewal of licensure more clearly, the renewal licensure process, and an HCO's options if it failed to timely renew. • Revised text to better align with the definitions included in Section 10 of this Chapter. **INTENT:** The intent of these proposed changes is to: • write this section in the active voice and break paragraphs with multiple requirements into subparts; • clarify the license expiration and renewal process, and how it intersects with material changes to the license; and • clarify a regulant's options if it fails to timely renew its license. **RATIONALE:** The rationale behind these proposed changes is: • the active voice and the use of subparts are the style preferred and recommended by *The Virginia Register of Regulations*; • license reissuance routinely confused regulants particularly when they were trying to initiate a material change to their license at the same time that they were trying to renew their license. The agency anticipates that the revised terminology and additional clarifying language will reduce confusion; • providing regulants notice of the consequences that result from failing to timely renew should provide sufficient incentive to timely renew. **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.
381-50	N/A	Describes compliance types for all HCOs.	**CHANGE:** The Board is proposing to repeal this section in its entirety because it is duplicative. **INTENT:** The intent of this proposed change is to remove irrelevant information from the regulations. **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. **LIKELY IMPACT:** There is likely no impact to this repeal.
381-60	N/A	Describes processes for changing or reissuance of a license.	**CHANGE:** The Board is proposing the following changes: • 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 better align with the definitions included in Section 10 of this Chapter. **INTENT:** The intent of these proposed changes is to: • rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; • clarify what constitutes a material change to a license and the process for material changes to the license; and • remove confusing language about license reissuance. **RATIONALE:** The rationale behind these proposed changes is: • the active voice and the use of subparts are the style preferred and recommended by *The Virginia Register of Regulations*; • 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 • 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. **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.
N/A	381-65	N/A	**CHANGE:** The Board is proposing to add a new section as follows: • 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. **INTENT:** The intent of these proposed changes is to: • write this section in the active voice and break paragraphs with multiple requirements into subparts; and • create a new licensure process for those HCOs that fail to timely renew their license and wish to remedy the situation within 30 days of expiration. **RATIONALE:** The rationale behind these proposed changes is: • the active voice and the use of subparts are the style preferred and recommended by *The Virginia Register of Regulations*; • 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. **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.
381-70	N/A	Describes HCO fees.	**CHANGE:** The Board is proposing the following changes: • Revises fees to reflect increases in operating costs since last revision at least 15 years ago, including the additional burden of inspecting branch offices and the change to triennial licensure, which were introduced in 2018 and 2022, respectively. • Clarifies that fees are nonrefundable. • Revised text to better align with the definitions included in Section 10 of this Chapter. **INTENT:** The intent of these proposed changes is to: • improve the readability of the fee schedule; • increase fee revenue for the HCO licensure program; and • clarify fees are nonrefundable. **RATIONALE:** The rationale behind these proposed changes is: • it is easier to identify the correct fees listed in a table rather than described in a narrative paragraph; • 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 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 • remove ambiguity regarding whether fees can be refunded. **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.
381-80	N/A	Describes on-site inspection process.	**CHANGE:** The Board is proposing the following changes: • Revised to explain the on-site inspection process and an HCO's obligations more clearly during and after the inspection • Increases inspection frequency from biennial to triennial. • Revised text to better align with the definitions included in Section 10 of this Chapter. **INTENT:** The intent of these proposed changes is to: • rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; and • consolidate relevant sections of the regulation by moving the home visit requirements to this section; • impose time limits around the initiation of an inspection; • affords HCOs the right to redact portions of records; and • removes plan of correction a new section. **RATIONALE:** The rationale behind these proposed changes is: • the active voice and the use of subparts are the style preferred and recommended by *The Virginia Register of Regulations*; • consolidating relevant sections of the regulation allows regulants to locate these requirements more easily; • promotes efficient and effective use of agency resources during inspections by requiring initiation of the inspection within a certain amount of time • ensures the privacy of clients and patients; and • 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. **LIKELY IMPACT:** The likely impact of these proposed changes is improved readability of the section, improved

			inspection completion time, and reduced confusion for regulants.
381-90	N/A	Describes home care visits.	**CHANGE:** The Board is proposing to repeal this section in its entirety. **INTENT:** The intent of this proposed change is to consolidate relevant sections of the regulation by moving these requirements to 12VAC5-381-80. **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. **LIKELY IMPACT:** There is likely no impact as this repeal moving these requirements to 12VAC5-381-80.
381-100	N/A	Describes process of complaint investigations conducted by OLC.	**CHANGE:** The Board is proposing the following changes: • 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 better align with the definitions included in Section 10 of this Chapter. **INTENT:** The intent of these proposed changes is to: • rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; and • give the OLC the flexibility to determine whether a complaint warrants an on-site inspection. **RATIONALE:** The rationale behind these proposed changes is: • the active voice and the use of subparts are the style preferred and recommended by *The Virginia Register of Regulations*; and • encourage efficient and effective use of agency resources in responding to complaints. **LIKELY IMPACT:** The likely impact of these proposed changes is improved readability of the section and a more adaptive and efficient complaint process.

N/A	381-105	N/A	**CHANGE:** The Board is proposing to add a new section as follows: • Consolidates the plan of correction language found in Sections 80 and 100 to ensure the plan of correction is consistent across all occurrences. • Clarifies that an HCO or an applicant for licensure does not have unlimited opportunities to revise unacceptable plans of correction. **INTENT:** The intent of these proposed changes is to: • write this section in the active voice and break paragraphs with multiple requirements into subparts; and • 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. **RATIONALE:** The rationale behind these proposed changes is: • the active voice and the use of subparts are the style preferred and recommended by *The Virginia Register of Regulations*; and • the plan of correction process needs to be more clearly explicated as current ambiguities in the regulation are cause for confusion. **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 regulants.
381-110	N/A	Describes process of conducting criminal background checks.	**CHANGE:** The Board is proposing the following changes: • 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 better align with the definitions included in Section 10 of this Chapter. **INTENT:** The intent of these proposed changes is to:

			• rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; • match regulatory language to statutory language; and • address the applicability of the criminal records check requirement to independent contractors. **RATIONALE:** The rationale behind these proposed changes is: • the active voice and the use of subparts are the style preferred and recommended by *The Virginia Register of Regulations*; • reducing conflicts between regulatory language and statutory language reduces confusion for readers; and • there is not a significant enough difference between independent contractors and temporary staff to justify not requiring criminal records checks. **LIKELY IMPACT:** The likely impact of these proposed changes is improved readability of this section and clarity on how to satisfy the regulatory requirements.
381-120	N/A	Describes variance application and acceptance processes.	**CHANGE:** The Board is proposing the following changes: • Renamed “Allowable variances.” • Revised text to reflect the commissioner grants variances, to clarify the variance request process, and to align with Section 10’s definitions more closely. **INTENT:** The intent of these proposed changes is to: • rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; • clarify that the State Health Commissioner grants variances; • clarify the process for requesting a variance; and • clarifying that the State Health Commissioner can place conditions on variances and can rescind them. **RATIONALE:** The rationale behind these proposed changes is: • the active voice and the use of subparts are the style preferred and

			recommended by *The Virginia Register of Regulations*; • reducing conflicts between regulatory language and statutory language reduces confusion for readers; • establishing a standardized process for variance requests ensures consistent treatment of requests; and • 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. **LIKELY IMPACT:** The likely impact of these proposed changes is improved readability of this section and clarity on how to satisfy the regulatory requirements.
381-130	N/A	Describes process of revocation or suspension of an HCO license.	**CHANGE:** The Board is proposing the following changes: • Renamed "Violation of this chapter or applicable law; denial, revocation, or suspension of a license." • Revised text to match statutory provisions and to align with Section 10's definitions more closely. **INTENT:** The intent of these proposed changes is to: • rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; and • match regulatory language to statutory language. **RATIONALE:** The rationale behind these proposed changes is: • the active voice and the use of subparts are the style preferred and recommended by *The Virginia Register of Regulations*; and • reducing conflicts between regulatory language and statutory language reduces confusion for readers. **LIKELY IMPACT:** The likely impact of these proposed changes is improved readability of this section.
381-140	N/A	Describes process for an HCO to return the license.	**CHANGE:** The Board is proposing to repeal this section in its entirety. **INTENT:** The intent of this proposed change is to consolidate relevant

			sections of the regulation by moving these requirements to 12VAC5-381-60. **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. **LIKELY IMPACT**: There is likely no impact as this repeal moving these requirements to 12VAC5-381-60.
381-150	N/A	Describes management and administration of an HCO.	**CHANGE:** The Board is proposing the following changes: • Revised text to align with Section 10's definitions more closely and removed duplicative subsections. • Added language that HCOs have to document in writing who can act as their agent in transactions with the agency. **INTENT:** The intent of these proposed changes is to: • rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; • 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, 12VAC5-38165, and 12VAC5-381-80; and • require HCOs to document in writing who can take action on its behalf in its interactions with the agency. **RATIONALE:** The rationale behind these proposed changes is: • the active voice and the use of subparts are the style preferred and recommended by *The Virginia Register of Regulations*; • consolidating relevant sections of the regulation allows regulants to locate these requirements more easily; and • the agency has encountered multiple situations where unauthorized persons attempted to modify or gain control of an HCO license and the HCO encounter difficulty demonstrating who had authority to act on its behalf.

			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.
381-160	N/A	Describes the requirements for the organization of the governing body of an HCO.	**CHANGE:** The Board is proposing the following changes: • Revised text to better align with the definitions included in Section 10 of this Chapter. • Added language to require the governing body have a written organizational plan and bylaws, including minimum requirements for the bylaws. **INTENT:** The intent of these proposed changes is to: • rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; • clarify the respective roles of the governing body; and • set minimum requirements for the organizational plan and plans. **RATIONALE:** The rationale behind these proposed changes is: • the active voice and the use of subparts are the style preferred and recommended by *The Virginia Register of Regulations*; • removing ambiguity about the respective responsibilities of administrators and governing bodies will make it easier for HCOs to comply with regulations; and • 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. **LIKELY IMPACT:** The likely impact of these proposed changes is improved readability of this section and clarity on how to satisfy the regulatory requirements.
381-170	N/A	Describes the requirements for an HCO administrator	**CHANGE:** The Board is proposing to revise the text to align with Section 10's definitions more closely and for improved clarity. Added language to clarify responsibilities of a designated administrator and requires certain

			training and experience requirements for said administrator. Adds language to require an HCO to notify the OLC given a change of administrator, to provide an administrator's resume or curriculum vitae to OLC, and to appoint a qualified person to act in the absence of an administrator. **INTENT:** The intent of these proposed changes is to: • rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; • clarify the designation of administrators and alternates are to be in writing; and • clarify the respective roles of the administrators and governing bodies. **RATIONALE:** The rationale behind these proposed changes is: • the active voice and the use of subparts are the style preferred and recommended by *The Virginia Register of Regulations*; • by requiring the designation to be written and the qualifications be provided, the agency can easily verify if the administrator requirement has been met; • removing ambiguity about the respective responsibilities of administrators and governing bodies will make it easier for HCOs to comply with regulations. **LIKELY IMPACT:** The likely impact of these proposed changes is improved readability of this section and clarity on how to satisfy the regulatory requirements.
381-180	N/A	Describes an HCO's written policies and procedures.	**CHANGE:** The Board is proposing the following changes: • Renamed "Policies and procedures." • Revised text to better align with the definitions included in Section 10 of this Chapter. • 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. **INTENT:** The intent of these proposed changes is to: • rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; • consolidate the requirements for policies and procedures into a single section; • organize the required policies and procedures by topic; • add additional topics or clarifying language to topics that have been unaddressed or ambiguously addressed; • correct out of date or missing statutory and regulatory references; • strengthen infection prevention policies and procedures; and • provide accommodations for persons with disabilities and persons with limited or no English proficiency. **RATIONALE:** The rationale behind these proposed changes is: • the active voice and the use of subparts are the style preferred and recommended by *The Virginia Register of Regulations*; • housing all policies and procedures in the section entitled “Policies and procedures” makes it easier for regulants and the public to find the requirements; • because of the number of required policies and procedures, readability is increased when organized by topic; • 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; • reducing conflicts between this regulation and statutory and other regulatory language reduces confusion for readers;

			• the COVID-19 pandemic and vaccine hesitancy has highlighted the need for more stringent infection prevention efforts, to protect clients, patients, and employees; and • denying clients and patients information in plain and accessible language interferes with their ability to be informed about and participate in their own care. **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.
381-190	N/A	Describes financial controls of an HCO.	**CHANGE:** The Board is proposing the following changes: • Revised text to better align with the definitions included in Section 10 of this Chapter. • 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. **INTENT:** The intent of these proposed changes is to: • rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; • replaced the audit requirement with a review by an independent CPA; and • keep the agency informed if other state agencies are investigating its regulants **RATIONALE:** The rationale behind these proposed changes is: • the active voice and the use of subparts are the style preferred and recommended by *The Virginia Register of Regulations*; • 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; • 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. **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.
381-200	N/A	Describes personnel practice requirements of HCOs	**CHANGE:** The Board is proposing the following changes: • Renamed "Employee practices." Revised text to align with Section 10's definitions more closely and to clarify that job description requirements apply to all workers, whether compensate or not, whether employed or contracted. • Revised text to require orientation include fraud, abuse, and neglect training. **INTENT:** The intent of these proposed changes is to: • rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; and • removed language about obtaining criminal records checks. **RATIONALE:** The rationale behind these proposed changes is: • the active voice and the use of subparts are the style preferred and recommended by *The Virginia Register of Regulations*; • language about obtaining criminal records checks has been moved in part to section 110, which is entitled "Criminal records checks." **LIKELY IMPACT:** The likely impact of these proposed changes is improved readability of this section.
381-210	N/A	Describes the requirement for indemnity coverage.	**CHANGE:** The Board is proposing the following changes: • Revised text to align with Section 10's definitions more closely and to reference professional liability insurance instead of malpractice insurance. • Revised text to remove statutory reference and replaced with

			coverage minimums that increase annually. **INTENT:** The intent of these proposed changes is to: • rewrite this section in the active voice; • broaden the insurance required to professional liability instead of just malpractice insurance; and • match the professional liability coverage to the maximum recovery amounts for malpractice. **RATIONALE:** The rationale behind these proposed changes is: • the active voice is the style preferred and recommended by *The Virginia Register of Regulations*; • professional liability insurance would cover a broader spectrum of HCO employees than malpractice insurance; and • 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. **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.
381-220	N/A	Describes contract services requirements of HCOs.	**CHANGE:** The Board is proposing to revise text to align with Section 10's definitions more closely. **INTENT:** The intent of these proposed changes is to rewrite this section in the active voice. **RATIONALE:** The rationale behind these proposed changes is the active voice is the style preferred and recommended by *The Virginia Register of Regulations*. **LIKELY IMPACT:** The likely impact of these proposed changes is improved readability of this section.
381-230	N/A	Describes HCO clients' rights.	**CHANGE:** The Board is proposing the following changes: • Renamed "Client and patient rights."

			• Revised text to align with Section 10's definitions more closely and to align with the rights language more closely for home health agency patients. **INTENT:** The intent of these proposed changes is to: • rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; • removed language about policies and procedures; and • more closely align the rights of HCO clients and patients with that of the rights afforded to patients of home health agencies. **RATIONALE:** The rationale behind these proposed changes is: • the active voice and the use of subparts are the style preferred and recommended by *The Virginia Register of Regulations*; • language about policies and procedures has been moved in part to section 180, which is entitled "Policies and procedures"; and • 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. **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.
381-240	N/A	Describes handling of clients' complaints	**CHANGE:** The Board is proposing the following changes: • Renamed "Complaint handling procedures." • Revised text to better align with the definitions included in Section 10 of this Chapter. • Revised text to expand complaint record retention from 3 to 5 years. **INTENT:** The intent of these proposed changes is to rewrite this section in the active voice and break paragraphs with multiple requirements into subparts.

			RATIONALE: The rationale behind these proposed changes is the active voice and the use of subparts are the style preferred and recommended by *The Virginia Register of Regulations*. **LIKELY IMPACT:** The likely impact of these proposed changes is improved readability of this section.
381-250	N/A	Describes HCO quality improvements.	**CHANGE:** The Board is proposing to revise the text to align with Section 10's definitions more closely and for improved clarity. **INTENT:** The intent of these proposed changes is to: • rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; • shift the responsibility for implementing corrective action to the administrator or his designee"; and • 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. **RATIONALE:** The rationale behind these proposed changes is: • the active voice and the use of subparts are the style preferred and recommended by *The Virginia Register of Regulations*; • the administrator is involved in the daily operation and management of an HCO and is better positioned to implement and monitor corrective actions; and • Explicit requirements to include recommended corrective action in 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. **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.
381-260	N/A	Describes HCO infection control requirements.	**CHANGE:** The Board is proposing the following changes:

			• Revised text to align with Section 10's definitions more closely and to add requirement for an employee health program. • Remove infection control activities that are now found in Section 180 **INTENT:** The intent of these proposed changes is to: • rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; • remove language about infection control activities; and • place more explicit requirements on HCOs regarding its care for its employees' health. **RATIONALE:** The rationale behind these proposed changes is: • the active voice and the use of subparts are the style preferred and recommended by *The Virginia Register of Regulations*; • language about infection control activities has been moved to section 180, which is entitled "Policies and procedures"; and • the minimum requirements of the employee health program will reduce likelihood of communicable diseases being transmitted by employees, clients, and patients. **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.
381-270	N/A	Describes requirements governing drop sites.	**CHANGE:** The Board is proposing to revise the text to align with Section 10's definitions more closely and for improved clarity. **INTENT:** The intent of these proposed changes is to rewrite this section in the active voice and break paragraphs with multiple requirements into subparts. **RATIONALE:** The rationale behind these proposed changes is the active voice and the use of subparts are the style preferred and recommended by *The Virginia Register of Regulations*.

			LIKELY IMPACT: The likely impact of these proposed changes is improved readability of this section.
381-280	N/A	Describes the requirement for HCOs to have a client record system.	**CHANGE:** The Board is proposing the following changes: • Renamed "Clinical record system." • Revised text to align with Section 10's definitions more closely and for improved clarity. • Revised to what the medical plan of care or plan of care should include. **INTENT:** The intent of these proposed changes is to: • rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; and • improve clarity about minimum documentation for the medical plans of care and plans of care. **RATIONALE:** The rationale behind these proposed changes is: • the active voice and the use of subparts are the style preferred and recommended by *The Virginia Register of Regulations*; and • 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. **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.
381-290	N/A	Describes requirements for home attendants.	**CHANGE:** The Board is proposing the following changes: • Revised text to better align with the definitions included in Section 10 of this Chapter. • 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. **INTENT:** The intent of these proposed changes is to:

			• rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; and • 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. **RATIONALE:** The rationale behind these proposed changes is: • the active voice and the use of subparts are the style preferred and recommended by *The Virginia Register of Regulations*; and • 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 licensure regulations (12VAC5391-10 et seq.). **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.
381-300	N/A	Description of skilled services an HCO can provide.	**CHANGE:** The Board is proposing the following changes: • Revised text to align with Section 10's definitions more closely for improved clarity. • Revise to specify that pharmaceutical services are a type of skilled services. **INTENT:** The intent of these proposed changes is to: • rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; • remove language regarding drug policies and procedures; and • rewrite this section so as to avoid scope of practice conflicts with health profession regulations. **RATIONALE:** The rationale behind these proposed changes is:

			• the active voice and the use of subparts are the style preferred and recommended by *The Virginia Register of Regulations*; • language about drug policies and procedures has been moved to section 180, which is entitled "Policies and procedures"; and • scope of practice of health care practitioners is the regulatory purview of the Department of Health Professions. **LIKELY IMPACT:** The likely impact of these proposed changes is improved readability of this section.
381-310	N/A	Description of nursing services an HCO can provide.	**CHANGE:** The Board is proposing the following changes: • Revised text to align with Section 10's definitions more closely • Correct a regulatory reference. • Specify that supervision should be at least every 60 calendar days. **INTENT:** The intent of these proposed changes is to: • rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; and • match in-person supervision interval to the update interval for medical plans of care. **RATIONALE:** The rationale behind these proposed changes is: • the active voice and the use of subparts are the style preferred and recommended by *The Virginia Register of Regulations*; and • in-person supervision of nursing services can be conducted at the same time of assessments of patient needs for the medical plan of care. **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.
381-320	N/A	Description of therapy services an HCO can provide.	**CHANGE:** The Board is proposing the following changes: • Revised text to align with Section 10's definitions more closely for improved clarity

			• Specify that supervision should in alignment with the therapy licensing board's standards. **INTENT:** The intent of these proposed changes is to: • rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; and • rewrite this section so as to avoid scope of practice conflicts with health profession regulations. **RATIONALE:** The rationale behind these proposed changes is: • the active voice and the use of subparts are the style preferred and recommended by *The Virginia Register of Regulations*; and • scope of practice of health care practitioners is the regulatory purview of the Department of Health Professions. **LIKELY IMPACT:** The likely impact of these proposed changes is improved readability of this section.
381-330	N/A	Describes home attendants assisting clients with skilled services.	**CHANGE:** The Board is proposing the following changes: • Revised text to align with Section 10's definitions more closely for improved clarity • Correct a statutory reference. • Specify that home attendants should be supervised in-person at least once every 60 calendar days. **INTENT:** The intent of these proposed changes is to: • rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; and • specify that home attendants that assist in skilled services are subject to in-person supervision. **RATIONALE:** The rationale behind these proposed changes is: • the active voice and the use of subparts are the style preferred and recommended by *The Virginia Register of Regulations*; and • resolve ambiguity in the current regulation about how frequently home attendants that assist in skilled

			services are subject to in-person supervision. **LIKELY IMPACT:** The likely impact of these proposed changes is improved readability of this section and reduced confusion for regulants on minimum supervision standards.
381-340	N/A	Description of medical social services an HCO can provide.	**CHANGE:** The Board is proposing the following changes: • Revised text to align with Section 10's definitions more closely for improved clarity. • Reduce the minimum experience needed for the licensed clinical social worker or the individual who has master's degree in social work. **INTENT:** The intent of these proposed changes is to: • rewrite this section in the active voice; and • provide clarity and flexibility about who may direct medical social services. **RATIONALE:** The rationale behind these proposed changes is: • the active voice is the style preferred and recommended by *The Virginia Register of Regulations*; and • to make it easier for HCO to find qualified candidates to direct medical social services. **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.
381-350	N/A	Description of pharmacy services an HCO can provide.	**CHANGE:** The Board is proposing the following changes: • Renamed "Pharmaceutical services." • Revised text to better align with the definitions included in Section 10 of this Chapter. • Removed policies and procedures that are now found in Section 180. **INTENT:** The intent of these proposed changes is to: • rewrite this section in the active voice and break paragraphs with multiple requirements into subparts;

			• rewrite this section so as to avoid scope of practice conflicts with health profession regulations; and • remove language regarding home infusion therapy policies and procedures. **RATIONALE:** The rationale behind these proposed changes is: • the active voice and the use of subparts are the style preferred and recommended by *The Virginia Register of Regulations*; • scope of practice of health care practitioners is the regulatory purview of the Department of Health Professions; and • language about home infusion therapy policies and procedures has been moved to section 180, which is entitled "Policies and procedures." **LIKELY IMPACT:** The likely impact of these proposed changes is improved readability of this section.
381-DIBR	N/A	Personal Care Aide Training Curriculum, 2003 Edition, Virginia Department of Medical Assistance Services.	**CHANGE:** The Board is proposing to remove the DIBR for Personal Care Aide Training Curriculum, 2003 Edition, Virginia Department of Medical Assistance Services and add DIBR's for U.S. Centers for Disease Control and Prevention Standard Precautions for All Patient Care, April 3, 2024, and U.S. Centers for Disease Control and Prevention Injection Safety Guidelines, 2007. **INTENT:** The intent of these proposed changes is to accurately reflect current DIBRs . **RATIONALE:** The rationale behind these proposed changes is that there are two documents incorporated by reference in the proposed regulatory text. **LIKELY IMPACT:** The likely impact of these proposed changes is reduced confusion for regulants.

Office of Regulatory Management

Economic Review Form

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12 VAC 5-381
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	10/01/2024
Regulatory Stage (including Issuance of Guidance Documents)	Proposed

Cost Benefit Analysis

Complete Tables 1a and 1b for all regulatory actions. You do not need to complete Table 1c if the regulatory action is required by state statute or federal statute or regulation and leaves no discretion in its implementation.

Table 1a should provide analysis for the regulatory approach you are taking. Table 1b should provide analysis for the approach of leaving the current regulations intact (i.e., no further change is implemented). Table 1c should provide analysis for at least one alternative approach. You should not limit yourself to one alternative, however, and can add additional charts as needed.

Report both direct and indirect costs and benefits that can be monetized in Boxes 1 and 2. Report direct and indirect costs and benefits that cannot be monetized in Box 4. See the ORM Regulatory Economic Analysis Manual for additional guidance.

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

(1) Direct & Indirect Costs & Benefits (Monetized)	Direct Costs: Direct monetized costs resulting from this action are related to increased fees on regulants. This proposed change would increase the initial application fee to $2,000, it would require a $1,500 base application fee for licensure renewals or $2,500 for reinstatements, and it would require an additional $500 fee for each branch office operated by licensees as part of the renewal application fee or $750 as part of the reinstatement application fee. Additional fees included in this change are a processing fee for exemption from licensure ($125) and a fee for material change of license ($250). All persons or entities seeking licensure to operate an HCO would incur a cost of $2,000 for an initial triennial licensure application fee; 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 $1,500 per license renewal application. For each branch office operated by a parent HCO, an additional $500 is added to the renewal fee. A minority of licensed HCOs may incur a cost of $500 for late filing of their license renewal application. Similarly, a minority of HCOs may apply for licensure reinstatement and would incur a cost of at least a $2,500 per license reinstatement application. For each branch office operated by a parent HCO, an additional $750 is added to the reinstatement fee. Direct Benefits: Direct monetized benefits resulting from this action are related to increased fee revenue. Licensure fees for HCOs are issued for a 3 year period. This proposed change would increase the initial application fee to $2,000, it would require a base application fee for licensure renewals or reinstatements, and it would require an additional $500 fee for each branch office operated by licensees as part of the renewal or reinstatement application. Also included in the fee schedule are a processing fee for exemption from licensure ($125) and a fee for material change of license ($250). Currently there are 1,866 HCO licensees and 163 HCO branch offices in the Commonwealth. An average of approximately 200 new initial licensure applications are received by OLC each year, and number of new initial applications is predicted to continue to grow. Additionally, as more HCOs are licensed, triennial license renewals will also increase The agency estimates that the proposed adjustment to the fees in Section 70 would result in a minimum total annual licensure fee revenue (initial licensure application fees, license renewal fees, additional branch office renewal fees) of $1,671,166 beginning in FY26. As the number of licensed HCOs increases, so will fee revenues associated with triennial licenses.

	The number of licensees requesting a material change to their license is highly variable and difficult to predict, making fee revenue projections from that fee equally difficult to predict. Indirect Costs: The indirect costs associated with the proposed regulatory change would be any administrative costs for reporting and recordkeeping required for compliance by HCOs would be incidental to their existing administrative costs. Direct Benefits: The statutory change to require a review instead of an audit may allow licensed HCOs to recognize a direct benefit of some cost savings as reviews are typically less expensive than audits. Indirect Benefits: VDH is not aware of any indirect monetized benefits at this time.

(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) -$1,671,166/year	(b) $1,671,166/year
(3) Net Monetized Benefit	$0	

(4) Other Costs & Benefits (Non-Monetized)	Non-Monetized Benefit: 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. Increases in revenues collected from licensure fees will result in more resources to support personnel who conduct required inspections and other oversight functions. Language amended or added to this regulation is used 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. The resulting non-monetary benefits may be increased compliance with current regulatory standards and decreased confusion of what those standards are by regulants. Non-Monetized Costs: VDH is not aware of any non-monetized costs at this time.
(5) Information Sources	Division of Acute Care Services, Office of Licensure and Certification, Virginia Department of Health

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

(1) Direct & Indirect Costs & Benefits (Monetized)	Direct Costs: Existing direct monetized costs are related to license fees for regulants. All persons or entities seeking licensure to operate an HCO presently incur a cost of $500 fee per initial licensure application and $1,500 per application for renewal triennially. For most applicants, this is a one-time cost. Because there are 1,886 current HCOs licensed in the Commonwealth ($1,500 x 1,866 = $2,799,000), and approximately 200 new, initial licensure applications per year ($500 x 200 x 3 = $300,000), the agency estimates that current licensure fees cost regulants a minimum of approximately $3,099,000 triennially, or approximately $1,033,000 annually. There are currently no additional fees for branch offices, duplicate licenses, or for material changes in licenses. Direct Benefits: Estimated fee revenues Because there are 1,886 current HCOs licensed in the Commonwealth ($1,500 x 1,866 = $2,799,000), and approximately 200 new, initial licensure applications per year ($500 x 200 x 3 = $300,000), the agency estimates that current licensure fees result in a minimum triennial fee revenue of approximately $3,099,000, or $1,033,000 annually. There are currently no additional fees for branch offices, duplicate licenses, or for material changes in licenses. Indirect Costs: VDH is not aware of any indirect monetized costs at this time. Indirect Benefits: VDH is not aware of any direct or indirect monetized benefits at this time	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) -$3,099,000	(b) $3,099,000
(3) Net Monetized Benefit	$0	
(4) Other Costs & Benefits (Non-Monetized)	Non-monetized Benefits: Continued regulatory oversight of HCOs allows VDH 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. Non-monetized costs: The non-monetized costs of keeping the current regulatory language are that unclear regulations hamper regulants' ability to comply and out of date regulations may refer to standards and practices that are not current.	

(5) Information Sources	Division of Acute Care Services, Office of Licensure and Certification, Virginia Department of Health

Table 1c: Costs and Benefits under Alternative Approach(es)

(1) Direct & Indirect Costs & Benefits (Monetized)	An alternative approach to this regulatory action is to codify in the Virginia Administrative Code the existing triennial licensure fee of $1,500, implementing those changes which are statutorily mandated by the Code of Virginia. As those changes increase the HCO initial and renewal license fees from $500 annually to $1,500 triennially, no monetized costs or benefits would result from the alternative change. Direct Costs (monetized): VDH is not aware of any other monetized direct costs at this time. Direct Benefits (monetized): VDH is not aware of any other monetized direct benefits at this time. Indirect Costs (monetized): VDH is not aware of any other monetized indirect costs at this time. Indirect Benefits (monetized): VDH is not aware of any other monetized indirect benefits at this time.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) $0	(b) $0
(3) Net Monetized Benefit	$0	
(4) Other Costs & Benefits (Non-Monetized)	Non-monetized benefits: By only making changes to this regulation that are statutorily mandated, regulants will have fewer discretionary regulatory requirements to meet in order to comply with this regulation. Chapter 105 (2018 Acts of Assembly) introduced statutory provisions regarding branch offices, which are not currently addressed in the regulations for HCO. As an alternative to the proposed regulatory action, promulgation of regulatory text by VDH to address this mandate can provide clarity for HCOs in regulatory compliance and consistency with the Code of Virginia.	

	Non-monetized costs: There are currently points of ambiguity that have caused confusion and inconsistency for regulants, such as the issue of branch offices and changes to existing licenses. Making only statutorily required changes may lead to continued ambiguity and inconsistency for regulants regarding current regulatory language and concerns with compliance
(5) Information Sources	Division of Acute Care Services, Office of Licensure and Certification, Virginia Department of Health

Impact on Local Partners

Use this chart to describe impacts on local partners. See Part 8 of the ORM Cost Impact Analysis Guidance for additional guidance.

Table 2: Impact on Local Partners

(1) Direct & Indirect Costs & Benefits (Monetized)	VDH has no record of local partners owning or operating Home Care Organizations. Therefore, there are no monetized direct or indirect costs or benefits to local partners.	
(2) Present Monetized Values		
	(a) $0	(b) $0
(3) Other Costs & Benefits (Non-Monetized)	Other Costs: There are no non-monetary costs to local partners identified. Other Benefits: The non-monetary benefit to local partners is the consistency in quality home care services provided to individuals in the locality in which the local partner has jurisdiction.	
(4) Assistance	No additional assistance will be required as a result of this regulatory action.	
(5) Information Sources	Division of Acute Care Services, Office of Licensure and Certification, Virginia Department of Health	

Impacts on Families

Use this chart to describe impacts on families. See Part 8 of the ORM Cost Impact Analysis Guidance for additional guidance.

Table 3: Impact on Families

(1) Direct & Indirect Costs & Benefits (Monetized)	There are no monetized direct or indirect costs or benefits to families identified by this regulatory change because the regulation does not place a regulatory burden on families. To the extent that the regulation has requirements about the involvement of family members receiving home care services, those requirements are placed on the home care organization to fulfill.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) $0	(b) $0
(3) Other Costs & Benefits (Non-Monetized)	Other Costs: There are no non-monetary costs to families identified by this regulatory change. Other Benefits: The non-monetized benefits of the current regulation are those incalculable benefits which a family receives from the licensure of home care organizations. For example, the regulations set standards for quality of care which allows families to receive a high quality of home care services. The regulations also create standards for inspections and plans of correction for home care organizations, further protecting the health, safety, and welfare of families in the Commonwealth.	
(4) Information Sources	Division of Acute Care Services, Office of Licensure and Certification, Virginia Department of Health	

Impacts on Small Businesses

Use this chart to describe impacts on small businesses. See Part 8 of the ORM Cost Impact Analysis Guidance for additional guidance.

Table 4: Impact on Small Businesses

(1) Direct & Indirect Costs & Benefits (Monetized)	As of September 20, 2024, there are 1,866 licensed HCOs in Virginia, 1,004 of which are self-reportedly small businesses, and 163 branch offices, 53 of which are owned or operated by a small business. VDH does not validate whether self-reporting as a small business is accurate nor does VDH have the data resources to determine the precise number of applicants that are small businesses. **Direct Costs:** All small businesses seeking licensure to operate an HCO would incur a cost of $2,000 fee per initial licensure application; the agency anticipates that for most applicants, this would be a one-time cost. The agency

	estimates that the triennial fees in would result in a minimum triennial fee revenue increase of $755,500. This assumes that number of licensees that are small businesses (1,004), the number of branch office numbers of small businesses (53), and small business applicant numbers (approximately 486 triennially) remain relatively stable. All small businesses licensed as HCOs would incur a cost of at least a $1,500 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 small businesses licensed as HCOs may incur a cost of $500 for late filing of their license renewal application. The number of small business licensees requesting a material change to their license is highly variable and difficult to predict, making fee revenue projections from that fee equally difficult to predict. The agency is proposing to introduce a new reinstatement process that currently has no analog in its other licensure programs, so it is difficult to predict what fee revenue may result from HCOs utilizing that process. Because the proposed reinstatement process is new, the agency predicts a small minority of small businesses licensed as HCOs would incur a cost of at least a $2,500 fee per license reinstatement application, with an even smaller minority of HCOs incurring an additional annual cost of $750 for each branch office they operate. Indirect Costs: The indirect costs associated with the proposed regulatory change would be any administrative costs for reporting and recordkeeping required for compliance by small businesses licensed as HCOs would be incidental to their existing administrative costs. The agency also notes that by requiring a review instead of an audit, small businesses licensed as HCOs should recognize some cost savings as reviews are typically less expensive than audits. Direct Benefits: VDH notes that by requiring a review instead of an audit, small businesses licensed as HCOs may recognize a direct benefit of some cost savings as reviews are typically less expensive than audits. Indirect Benefits: VDH is not aware of any indirect monetized benefits at this time.

(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) $755,500	(b) $0

(3) Other Costs & Benefits (Non-Monetized)	-$755,500
(4) Alternatives	The State Board of Health has not been able to identify any alternatives for small businesses that would be more equitable while still protecting the health, safety, and welfare of the public. Consideration will be put forth about the burdens of the regulatory requirements that have a cost to regulants while still ensuring the regulations comply with the statutory mandates imposed by the General Assembly.
(5) Information Sources	Division of Acute Care Services, Office of Licensure and Certification, Virginia Department of Health

Changes to Number of Regulatory Requirements

Table 5: Regulatory Reduction

For each individual action, please fill out the appropriate chart to reflect any change in regulatory requirements, costs, regulatory stringency, or the overall length of any guidance documents.

Change in Regulatory Requirements

VAC Section(s) Involved*	Authority of Change	Initial Count	Additions	Subtractions	Total Net Change in Requirements
12VAC5-381-20	**(M/A):**	**3**			
	(D/A):	**1**		**-1**	**-1**
	(M/R):	**3**			
	(D/R):	**3**	**+8**		**+8**
12VAC5-381-30	**(M/A):**	**0**			
	(D/A):	**3**		**-1**	**-1**
	(M/R):	**1**			
	(D/R):	**1**			
12VAC5-381-35	**(M/A):**	**0**			
	(D/A):	**0**			
	(M/R):	**0**			
	(D/R):	**0**	**+5**		**+5**
12VAC5-381-40	**(M/A):**	**1**		**-1**	**-1**
	(D/A):	**5**	**+2**		**+2**
	(M/R):	**0**			
	(D/R):	**3**	**+16**		**+16**
12VAC5-381-45	**(M/A):**	**0**	**+1**		**+1**
	(D/A):	**0**	**+5**		**+5**
	(M/R):	**0**	**+3**		**+3**
	(D/R):	**0**	**+3**		**+3**

12VAC5-381-50	**(M/A):**	**0**			
	(D/A):	**0**			
	(M/R):	**0**			
	(D/R):	**2**		**-2**	**-2**
12VAC5-381-60	**(M/A):**	**0**			
	(D/A):	**3**	**+1**		**+1**
	(M/R):	**0**			
	(D/R):	**3**	**+16**		**+16**
12VAC5-381-65	**(M/A):**	**0**			
	(D/A):	**0**	**+7**		**+7**
	(M/R):	**0**	**+2**		**+2**
	(D/R):	**0**	**+16**		**+16**
12VAC5-381-70	**(M/A):**	**2**			
	(D/A):	**2**		**-2**	**-2**
	(M/R):	**2**	**+6**		**+6**
	(D/R):	**1**			
12VAC5-381-80	**(M/A):**	**2**			
	(D/A):	**2**		**-1**	**-1**
	(M/R):	**1**			
	(D/R):	**6**	**+7**		**+7**
12VAC5-381-90	**(M/A):**	**0**			
	(D/A):	**1**		**-1**	**-1**
	(M/R):	**0**			
	(D/R):	**2**		**-2**	**-2**
12VAC5-381-100	**(M/A):**	**0**			
	(D/A):	**2**	**+9**		**+9**
	(M/R):	**0**			
	(D/R):	**5**		**-4**	**-4**
12VAC5-381-105	**(M/A):**	**0**			
	(D/A):	**0**	**+3**		**+3**
	(M/R):	**0**			
	(D/R):	**0**	**+14**		**+14**
12VAC5-381-110	**(M/A):**	**0**			
	(D/A):	**0**			
	(M/R):	**10**			
	(D/R):	**5**	**+6**		**+6**
12VAC5-381-120	**(M/A):**	**0**			
	(D/A):	**7**		**-2**	**-2**
	(M/R):	**0**			
	(D/R):	**4**			
12VAC5-381-130	**(M/A):**	**1**			
	(D/A):	**4**	**+2**		**+2**
	(M/R):	**1**	**+1**		**+1**
	(D/R):	**0**			
	(M/A):	**0**			

12VAC5-381-140	**(D/A):**	**0**			
	(M/R):	**0**			
	(D/R):	**4**		**-4**	**-4**
12VAC5-381-150	**(M/A):**	**0**			
	(D/A):	**0**			
	(M/R):	**2**		**-1**	**-1**
	(D/R):	**11**	**+12**		**+12**
12VAC5-381-160	**(M/A):**	**0**			
	(D/A):	**0**			
	(M/R):	**0**			
	(D/R):	**5**	**+5**		**+5**
12VAC5-381-170	**(M/A):**	**0**			
	(D/A):	**0**			
	(M/R):	**0**			
	(D/R):	**4**	**+6**		**+6**
12VAC5-381-180	**(M/A):**	**0**			
	(D/A):	**0**			
	(M/R):	**1**	**+1**		**+1**
	(D/R):	**8**	**+13**		**+13**
12VAC5-381-190	**(M/A):**	**1**			
	(D/A):	**0**	**+1**		**+1**
	(M/R):	**2**			
	(D/R):	**5**	**+2**		**+2**
12VAC5-381-200	**(M/A):**	**0**			
	(D/A):	**0**			
	(M/R):	**3**		**-1**	**-1**
	(D/R):	**19**		**-6**	**-6**
12VAC5-381-210	**(M/A):**	**0**			
	(D/A):	**0**			
	(M/R):	**1**			
	(D/R):	**1**	**+2**		**+2**
12VAC5-381-220	**(M/A):**	**0**			
	(D/A):	**0**			
	(M/R):	**0**			
	(D/R):	**4**	**+3**		**+3**
12VAC5-381-230	**(M/A):**	**0**			
	(D/A):	**0**			
	(M/R):	**0**			
	(D/R):	**6**		**-4**	**-4**
12VAC5-381-250	**(M/A):**	**0**			
	(D/A):	**0**			
	(M/R):	**0**			
	(D/R):	**11**	**+1**		**+1**
	(M/A):	**0**			
	(D/A):	**0**			

12VAC5-381-270	**(M/R):**	**0**			
	(D/R):	**8**	**+1**		**+1**
12VAC5-381-280	**(M/A):**	**0**			
	(D/A):	**0**			
	(M/R):	**0**			
	(D/R):	**16**		**-1**	**-1**
12VAC5-381-290	**(M/A):**	**0**			
	(D/A):	**0**			
	(M/R):	**0**			
	(D/R):	**2**	**+3**		**+3**
12VAC5-381-310	**(M/A):**	**0**			
	(D/A):	**0**			
	(M/R):	**1**			
	(D/R):	**1**	**+1**		**+1**
12VAC5-381-320	**(M/A):**	**0**			
	(D/A):	**0**			
	(M/R):	**7**		**-1**	**-1**
	(D/R):	**0**			
12VAC5-381-330	**(M/A):**	**0**			
	(D/A):	**0**			
	(M/R):	**0**			
	(D/R):	**3**	**+1**		**+1**
12VAC5-381-350	**(M/A):**	**0**			
	(D/A):	**0**			
	(M/R):	**2**			
	(D/R):	**3**	**+3**		**+3**
				Grand Total of Changes in Requirements:	**(M/A):0**
					(D/A): +28
					(M/R): +13
					(D/R): +121

Key:

Please use the following coding if change is mandatory or discretionary and whether it affects externally regulated parties or only the agency itself:

(M/A): Mandatory requirements mandated by federal and/or state statute affecting the agency itself

(D/A): Discretionary requirements affecting agency itself

(M/R): Mandatory requirements mandated by federal and/or state statute affecting external parties, including other agencies

(D/R): Discretionary requirements affecting external parties, including other agencies

Cost Reductions or Increases (if applicable)

VAC Section(s) Involved*	Description of Regulatory Requirement	Initial Cost	New Cost	Overall Cost Savings/Increases

12VAC5-391-70	Fees	$500 for each initial license application $1500 for each renewal license application $50 late renewal fee $250 fee for each reissuance or replacement of a license $75 fee for exemption from licensure	$2000 Application fee for initial licensure $2,000 Re-application fee for initial licensure $1,500 Base application fee for renewal of licensure $500 Additional renewal fee for each branch office $2500 Application fee for reinstatement of licensure $750 Additional reinstatement fee for each branch office $125 Processing fee for exemption from licensure $25 Duplicate license fee $250 Fee for material change of license $50 Returned check fee	$1,431,500 increase. This does not include application for reinstatement, branch offices, etc. as those costs are unique to an individual HCO and are difficult to predict.

Other Decreases or Increases in Regulatory Stringency (if applicable)

VAC Section(s) Involved*	**Description of Regulatory Change**	**Overview of How It Reduces or Increases Regulatory Burden**
12VAC5-381	Language additions to the regulatory text to provide clarity to regulants and the role of VDH.	Despite the increase in overall requirements, the changes made provide clarity for regulatory content that is unclear, inconsistent, and outdated as well as to conform with the *Form, Style, and Procedure Manual for*

		Publication of Virginia Regulations.
12VAC5-381-40	Requires VDH to provide regulant with written inspection report within 15 business days following initial license issuance	The requirement on VDH's to provide an expedient written inspection report to the regulant reduces the burden of compliance.
12VAC5-381-50	Describes compliance types for HCOs	Repealed as duplicative and reduction in requirements
12VAC5-381-65	Requires VDH to provide regulant with written inspection report within 15 business days following license reinstatement	The requirement on VDH's to provide an expedient written inspection report to the regulant reduces the burden of compliance.
12VAC5-381-80	Requires VDH to provide regulant with written inspection report within 15 business days following an on-site inspection	The requirement on VDH's to provide an expedient written inspection report to the regulant reduces the burden of compliance.
12VAC5-381-90	Describes home visits an inspector may make as a part of an inspection	This section was repealed and language from this section was incorporated into 12VAC5-381-80(C) with specific and clear language.
12VAC5-381-140	Return of license	Repealed as all active licenses are available online and regulants no longer need to physically mail their licenses back to VDH.

Project 6178 - Proposed

Department of Health

Amend the Regulation after Assessment and Receipt of Public Comment

Chapter 381

~~Regulations for the Licensure of~~ Home Care ~~Organizations~~ Organization Licensure Regulations

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:

"Activities of daily living" ~~or "ADLs"~~ means bathing, dressing, toileting, transferring, bowel control, bladder control and eating/feeding. ~~A person's~~ An individual'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 or patient is unable to complete an activity due to cognitive impairment, functional disability, physical health problems, or safety. The client's or patient'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.

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

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

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

"Barrier ~~crimes"~~ crime" means ~~certain offenses~~ 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 from employment with a home care organization~~.

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

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

"Board" means the State Board of Health.

~~"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.~~

"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.

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

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

~~"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.~~

"Commissioner" means the State Health Commissioner.

~~"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.~~

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

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

"Department" means the Virginia Department of Health.

~~"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.~~

"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.

"Drop site" means a location that HCO ~~staff~~ employees 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~~ clinical records. These locations may also be called charting stations, workstations, or convenience sites.

"Employee" means ~~an individual who has the status of an employee as defined by the U.S. Internal Revenue Service~~ 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. "Employee" shall not include an individual who receives a 1099-NEC from the HCO.

"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 Board of Nursing 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.~~

"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.

"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 residence. Home attendants are also known as certified nurse aides or CNAs, home care aides, home health aides, ~~or~~ personal care aides, or nursing assistants.

"Home Care Organization" or "HCO" or "organization" ~~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.~~ has the same meaning ascribed in § 32.1-162.7 of the Code of Virginia.

"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~~ 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~~.

~~"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.~~

"Independent contractor" means an individual in the service of an HCO under any contract of hire, express or implied, oral or written and who receives a 1099-NEC from the HCO.

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

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

"Instrumental activities of daily living" means meal preparation, ~~housekeeping/light~~ housekeeping or light housework, shopping for personal items, laundry, or using the telephone. A client's or patient's degree of independence in performing these activities is part of determining the appropriate level of care and services.

"Legal representative" means a person legally responsible for representing or standing in the place of the client or patient for the conduct of the client's or patient's 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 agent in a legal document that specifies the scope of the representative's authority to act.

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

"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.

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

"Nursing services" means ~~client~~ patient 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.

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

~~"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.~~

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

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

"Person" has the same meaning ascribed in § 32.1-162.7 of the Code of Virginia. ~~"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.~~

"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.

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

"Personal care services" has the same meaning as ascribed in § 32.1-162.7 of the Code of Virginia. ~~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 or patient, who has or is at risk of an illness, injury or disabling condition. A need for assistance exists when the client or patient is unable to complete an activity due to cognitive impairment, functional disability, physical health problems, or safety. The client's or patient'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.~~

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

~~"Primary care physician"~~ "Physician" means a physician 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 or the District of Columbia 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. ~~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.~~

"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.

"Practitioner" or "health care practitioner" has the same meaning ascribed in § 54.1-2410 of the Code of Virginia.

"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.

"Quality improvement" means ongoing activities designed to objectively and systematically evaluate the quality of client and patient care and services, pursue opportunities to improve client and patient 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, patients, and others.~~

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

"Residence" means the 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.

~~"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.~~

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

"Skilled services director" means a physician actively licensed by the Virginia Board of Medicine or a registered nurse actively licensed by the Virginia Board of Nursing 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.

"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.

"Sworn disclosure ~~statement~~" means a ~~document~~ 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.

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

12VAC5-381-20. License.

A. A person may not establish, conduct, maintain, or operate in this 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 shall first obtain an HCO license.

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

1. The applicant and the applicant's proposed HCO comply with this chapter;

2. The OLC has received the application fee prescribed by subsection A of 12VAC5-381-70; and

3. The applicant and any person having ownership interest in the proposed HCO ~~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.~~

~~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.~~

C. ~~The commissioner may issue a license to a home care organization authorizing the licensee to provide services at~~ 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:

1. The area served by the branch office is located within the same total geographic area as the parent HCO;

2. ~~each~~ Each branch office operates under the supervision and administrative control of the ~~licensee.~~ parent HCO;

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~~.~~;

4. The parent HCO submits policies and procedures demonstrating how it will exercise supervision and administrative control over each branch office; and

5. The parent HCO complies with 12VAC5-381-60.

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

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

E. ~~Licenses~~ An HCO ~~shall~~ may not ~~be transferred~~ transfer or ~~assigned~~ assign the HCO's license.

~~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.~~

F. A change in ownership of an HCO shall require reapplication for initial licensure.

12VAC5-381-30. Exemption from licensure.

~~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 accreditation or federal certification.

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

A. For the purposes of this section, the following words and terms shall have the following meanings:

1. "Beautician services" means assistance to persons with the inability to perform one or more activities of daily living, including assistance with bathing areas the client cannot reach, fastening client's clothing, combing hair, brushing dentures, and shaving with an electric razor.

2. "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; and painting.

3. "Housekeeping services" means assistance to persons with the inability to perform on or more instrumental activities of daily living. Housekeeping services may also include transportation, meal preparation, shopping, light housekeeping, companionship, household

management, and providing stabilization to a client while walking. Housekeeping services do not include feeding, bed baths, transferring, lifting, putting on braces or other supports, cutting nails, or shaving with a blade.

B. This chapter does not apply to:

1. A natural person who provides services to a client or patient on an individual basis if such natural person is:

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

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

2. Organizations providing only housekeeping, chore, or beautician services;

3. An HCO, that after initial licensure as an HCO, is licensed for 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; or

4. An HCO that, after initial licensure as an HCO, receives federal certification as a home health agency or are accredited by an organization recognized by the U.S. Centers for Medicare and Medicaid Services for the purposes of Medicare certification.

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

~~C.~~ D. The OLC ~~home care organization~~ shall ~~be notified~~ notify in writing the person requesting an exemption pursuant to subsection B of this section ~~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.~~

E. An applicant shall first obtain an initial license before submitting an application change for the addition of a branch office.

~~D. Exempted organizations~~ F. An HCO that has been granted an exemption pursuant to subdivision B4 of this section ~~are~~ shall be subject to complaint investigations. ~~in keeping with state law;~~

G. An HCO shall notify the OLC in writing no more than two business days after losing licensure exemption eligibility.

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

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:

1. A single health planning region, as defined by § 32.1-102.1 of the Code of Virginia; or

2. A single planning district and any planning districts that are contiguous to the selected planning district.

B. The location of the parent HCO's office and of any branch office or drop site of an HCO shall be located in the total geographic area it serves. 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.

C. For the purposes of this section, "planning district" means a contiguous area within the boundaries established by the Department of Housing and Community Development as set forth in § 15.2-4202 of the Code of Virginia.

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

~~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.~~

~~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.~~

~~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.~~

~~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.~~

~~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.~~

~~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.~~

A. An applicant for issuance of an HCO license shall:

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

2. Identify the services that the HCO intends to provide;

3. Identify the total geographic area the proposed HCO intends to serve;

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

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

B. An applicant for an HCO shall disclose upon an application filed with the OLC:

1. The HCO's legal business name, which shall be distinct; and

2. Any fictitious business name that the HCO may use.

C. The commissioner shall consider an application complete when the OLC receives all requested information and the nonrefundable application fee. The OLC shall deem an incomplete application to be inactive six months after it is received by the OLC. After six months, an applicant whose application was deemed inactive must submit a new application and application fee.

D. An applicant shall notify the OLC in writing that the applicant is ready for the initial licensure inspection. The commissioner, in his discretion, may deny licensure to an applicant who delays or attempts to delay the initial licensure inspection.

E. The OLC shall notify the applicant of the time and date of the initial licensure inspection. The director of the OLC may waive the initial licensure inspection for an applicant seeking initial licensure due to a change of ownership.

F. As part of the initial licensure inspection, an applicant shall comply with the provisions of 12VAC5-381-80.

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.

H. The OLC shall provide a written inspection report to the applicant within 15 business days after the initial licensure inspection. If the OLC cites one or more alleged violations of this chapter 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.

I. An applicant may withdraw an application at any time.

J. An applicant may, at any time, reapply for licensure, provided that the applicant pays the fee prescribed by 12VAC5-381-70, if:

1. The applicant withdraws the application pursuant to subdivision 1 of this subsection; or

2. The commissioner denies 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.

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

A. A license shall expire three years from its effective date and may be renewed triennially, 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.

B. An HCO shall submit a license renewal application to the OLC no fewer than 30 calendar days before the expiration date of the current license. An HCO that submits a license renewal application after 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.

C. An HCO may not make any material change to its licensure record, as defined in 12VAC5-381-60 C on its license renewal application. 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 provided it pays the nonrefundable fee for material change of license prescribed by 12VAC5-381-70.

D. If an active license expires before a new license is issued and the licensee submitted a complete and accurate application before the expiration, the prior active license shall remain in effect until VDH issues a new license.

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

F. 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.

G. 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.

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

12VAC5-381-50. Compliance appropriate for all types of HCOs.

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.

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

A. For the purposes of this section, "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 an HCO.

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

~~B.~~C. An ~~organization~~ HCO shall ~~give written notification~~ notify the director of the OLC by submitting an HCO application electronically 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~~.~~:

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

1. ~~Operator~~ A change of location of a parent HCO or a branch office;
2. ~~Organization name~~ A change of name of a parent HCO or a branch office; ~~or~~
3. ~~Address~~ A change of services being provided~~.~~;
4. A change in operator;
5. A change of total geographic area served;
6. An addition of a new branch office; or
7. A voluntary closure of a parent HCO or a branch office.

D. 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 electronically submitted.

~~C.~~ E. The OLC ~~will evaluate written information about any planned changes in operation that~~ shall determine if changes listed in subsection C of this section 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.

~~D.~~ F. The ~~organization~~ OLC ~~will be notified~~ shall notify ~~in writing~~ the HCO ~~whether a new application is needed~~ if a new application is required if the commissioner deems a change in license is warranted.

G. If an HCO intends to implement a change of ownership, the HCO shall file for a new license, pursuant to 12VAC5-381-40, no less than 30 calendar days in advance of the ownership change, and shall surrender the prior license to the OLC upon receipt of the new license.

H. If an HCO ceases operations, the HCO shall notify clients, patients, and the OLC where all clinical records are to be located no more than five calendar days after the HCO ceases operations.

12VAC5-381-65. License reinstatement.

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.

B. An HCO applying for reinstatement of a license shall:

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

2. Identify the services that the HCO intends to perform;

3. Identify the total geographic area the HCO intends to serve;

4. Disclose to the OLC the ownership interest of the 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

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

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

D. The commissioner shall consider an application complete when the OLC receives all requested information and the nonrefundable application fee. An incomplete application shall become inactive six months after it is received by the OLC. After six months, an applicant shall submit a new application and application fee.

E. The OLC may conduct a reinstatement licensure inspection. As part of a reinstatement licensure inspection, an applicant shall comply with the requirements set forth in 12VAC5-381-80.

F. The commissioner may deny reinstatement of licensure to an HCO that does not comply with the provisions of subsection D of this section.

G. An HCO may voluntarily terminate a reinstatement licensure inspection at any time during the inspection. The commissioner may deny reinstatement of licensure to any HCO that voluntarily terminates a reinstatement licensure inspection.

H. The OLC shall provide a written inspection report to the HCO within 15 business days. If the OLC cites one or more alleged violations of this chapter in the written inspection report, the administrator shall submit a written plan of correction in accordance with the provisions of 12VAC5-381-105.

I. An HCO may withdraw its reinstatement application at any time.

J. An HCO may reapply for licensure pursuant to 12VAC5-381-40, provided that the HCO pays the fee prescribed by 12VAC5-381-70, if:

1. The HCO withdraws the application pursuant to subsection I of this section; or

2. The commissioner denies 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.

K. If the commissioner reinstates a license pursuant to this section, the effective date of the reinstated license shall be one calendar day after the expiration date of the prior license.

12VAC5-381-70. Fees.

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:

Application fee for initial licensure	$2,000

Re-application fee for initial licensure	$2,000
Base application fee for renewal of licensure	$1,500
Additional renewal fee for each branch office	$500
Application fee for reinstatement of licensure	$2,500
Additional reinstatement fee for each branch office	$750
Processing fee for exemption from licensure	$125
Fee for material change of license	$250

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

~~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.~~

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

B. In addition to the fees described in subsection A, the department shall charge a late fee of $500 for an HCO that applies to renew a license fewer than 30 calendar days in advance of the license's expiration date.

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

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

A. ~~An~~ The OLC inspector ~~representative~~ shall make periodic unannounced on-site inspections of each ~~home care organization~~ HCO as necessary but not less often than ~~biennially~~ triennially. ~~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.~~

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

1. 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.

2. Upon request of the inspector and no more than four 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.

3. If the inspector removes copies of records from the premises as part of the inspection, the HCO may redact names and addresses of clients or patients contained in such records prior to removal.

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

C. As part of an inspection, an inspector may conduct home visits pursuant to 12VAC5-381-90 with the consent of the client, patient, or the client's or patient's legal representative.

1.The HCO shall:

a. Arrange the in-home visit pursuant to 12VAC5-381-90 with the client, patient, or legal representative upon the inspector's request;

b. Explain clearly to the client, patient, or legal representative that an in-home visit is voluntary and that refusing an in-home visit will not affect the client's or patient's care; and

c. Obtain signed consent from the client, patient, or legal representative.

2. The HCO may not:

d. Terminate a client or patient if the client, patient, or a legal representative consents to or refuses an in-home visit; and

e. Interfere with or prevent an inspector's or the department's communication with or to a client, patient, or legal representative, either as part of a home visit or as part of the inspection process.

D. After the on-site inspection, the ~~OLC's representative~~ OLC shall ~~discuss the findings of the inspection with~~ provide a written inspection report to the administrator within 15 business days~~or his designee~~. If the OLC cites one or more alleged violations of this chapter in the written inspection report, the administrator shall submit a plan of correction pursuant to 12VAC5-381-105.

~~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:~~

~~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.~~

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

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

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

12VAC5-381-90. ~~Home visits.~~ (Repealed.)

12VAC5-381-90. Home visits.

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

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

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.

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

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

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

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

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

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

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

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

~~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:~~

~~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.~~

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

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

B. The OLC may request records from an HCO to assist in making a determination pursuant to subsection A of this section. The HCO shall provide the requested records no more than 30 calendar days after OLC makes the request.

C. Within 15 business days after the investigation is complete, the OLC shall notify in writing the HCO and the complainant, if known, of the findings of the investigation.

D. The administrator shall submit a plan of correction pursuant to 12VAC5-381-105 for a violation of this chapter and applicable law cited during a complaint investigation.

12VAC5-381-105. Plan of correction.

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

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 violation cited:

1. A description of the corrective action or actions to be taken;

2. The position title of the employees to implement the corrective action;

3. If employees share the same position title, the administrator shall assign the employees a unique identifier to distinguish them;

4. The expected correction date, not to exceed 45 business days from the end date of the inspection; and

5. A description of the measures to be implemented to prevent a recurrence of the violation.

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

D. The OLC shall consider the submission date of a plan of correction to be the date it is received by the OLC.

E. The OLC shall:

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

2. Grant the administrator or designee two opportunities to revise and resubmit a plan of correction that the OLC initially determines to be unacceptable. If the administrator or 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 designee pursuant to subdivision 1 of this subsection.

F. Upon the OLC's request, and no more than 30 calendar days after the OLC's request, an applicant or licensee shall produce additional evidence, that all or part of a plan of correction has been implemented. The OLC may conduct an inspection to verify the implementation of any portion of a plan of correction.

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

H. The commissioner may deny licensure, renewal of licensure, reinstatement of licensure, suspend licensure, or may revoke licensure if an HCO's administrator fails to submit an acceptable plan of correction or fails to implement an acceptable plan of correction.

12VAC5-381-110. Criminal records checks.

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~~ An HCO shall obtain a criminal record report on ~~applicants~~ an applicant for compensated employment from the Virginia Department of State Police no more than 30 calendar days after employment begins. An HCO may not accept a criminal record report dated more than 90 calendar days before 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 organizations provide a sworn disclosure statement regarding their criminal history.~~

~~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.~~

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

~~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~~

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:

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

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

~~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~~.

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

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

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

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

~~E. No employee shall be permitted to~~ C. An HCO 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 or independent contractor 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.

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

~~G.~~ D. An HCO shall obtain ~~A~~ a new criminal record report and a new sworn ~~statement~~ disclosure ~~shall be required when~~ if an individual:

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, in whole or in part, 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:~~

~~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~~ 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.~~

~~H.~~ E. An HCO shall:

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

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

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

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

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

3. Five years have elapsed since the conviction.

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

~~J.~~ H. 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 the entirety of employment from the date of employment with the HCO or as otherwise provided by law.

~~K.~~ I. 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.

12VAC5-381-120. ~~Variances~~ Allowable variances.

A. The ~~OLC~~ commissioner ~~can~~ may authorize ~~variances~~ a variance only to ~~its own licensing regulations~~ a specific requirement of this chapter, not to regulations of another agency or to any requirements in federal, state, or local laws. An HCO requesting a variance shall request advance written approval from the commissioner.

B. A variance may not be extended to general applicability and may not endanger the health, safety, or well-being of clients, patients, or the public.

~~B. A home care organization~~ C. A licensee may request a variance at any time. ~~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~~ shall ~~describe~~ include:

1. ~~how~~ How compliance with the current ~~regulation~~ 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

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

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

~~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.~~ E. 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, protect the health, safety, and well-being of clients, patients, and the public.

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

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

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

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

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

~~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.~~

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

G. If a variance is denied, expires, or is rescinded, the commissioner or the commissioner's designee shall ~~routine enforcement of~~ enforce the ~~regulation or portion of the regulation shall be resumed~~ requirement to which the variance was granted.

~~H. The home care organization~~ H. The governing body of an HCO shall develop written 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~~ a variance.

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

A. The commissioner ~~is authorized to~~ may deny, revoke, or suspend ~~any~~ the license to operate an HCO if the commissioner determines that an applicant ~~the~~ or licensee is:

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

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

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

~~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.~~ C. 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:

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

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.

D. The HCO shall submit evidence relevant to subdivisions C1 and C2 of this section that is satisfactory to the commissioner or the commissioner's designee. The commissioner or the commissioner's designee may conduct an inspection before making a determination.

~~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.~~

~~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.~~ E. The commissioner may restore a suspended license to an HCO if the commissioner determines that:

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

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

F. To request the commissioner consider lifting the suspension, the HCO shall submit evidence relevant to subdivisions E1 and E2 of this section that is satisfactory to the commissioner or the commissioner's designee. The commissioner or the commissioner's designee may conduct an inspection before making a determination. The OLC shall not require an additional fee for restoring a license pursuant to subsections E and F of this section.

G. 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).

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

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

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

~~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.~~

12VAC5-381-150. Management and administration.

Part II
Administrative Services

~~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.~~

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

1. This chapter (~~12VAC5-381~~);

2. Other applicable ~~federal, state or local~~ laws and regulations administered by the board; and

3. The ~~organization's~~ HCO's own policies and procedures.

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

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

~~1. Verify application information;~~

~~2. Determine compliance with this chapter;~~

~~3. Review necessary records and documents; and~~

~~4. Investigate complaints.~~

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

~~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.~~

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 one of the following:

1. The HCO's bylaws, if the HCO is a corporation;

2. An operating agreement, if the HCO is a limited liability company;

3. A governing instrument, if the HCO is a business trust;

4. A statement of partnership authority, if the HCO is a partnership; or

5. Another written document, if the HCO is a sole proprietorship.

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

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

~~H.~~ F. ~~The organization~~ 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.

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

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

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

~~J. The organization~~ H. 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.

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

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

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

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

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

12VAC5-381-160. Governing body.

A. ~~The organization~~ An 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. The governing body of a hospital that operates ~~a home care organization~~ an HCO shall include in ~~its~~ the hospital's 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~~ the HCO will provide;

2. ~~Ensure that the organization is staffed and adequately equipped to provide the services it offers to clients~~ Provide the employees and other resources that are necessary to meet client, patient, and program needs, whether provided directly by the ~~organization~~ HCO or ~~through~~ by contract; and

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

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

3. Establish and maintain an organizational plan with written bylaws that clearly set forth organization, duties and responsibilities, accountability, and relationships of management, clinical employees, and other employees.

~~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.~~

12VAC5-381-170. Administrator.

A. The governing body shall ~~appoint as~~ 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.~~

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

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

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

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

~~3.~~ 2. Employing qualified ~~personnel~~ employees;

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

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

5. ~~Implementing~~ Ensuring an effective budgeting and accounting system is implemented;

6. Maintaining compliance with applicable laws and regulations and implementing corrective action ~~in response to reports of organization committees and regulatory agencies~~; and

7. Arranging and negotiating services provided through contractual agreement~~; and~~.

~~8. Implementing the policies and procedures approved by the governing body.~~

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 preceding designation as the administrator of supervisory or administrative management experience in home health care or a related health program.

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 the notice of change of administrator.

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

~~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.~~

~~D.~~ E. An HCO shall ensure that ~~The~~ the administrator or ~~his~~ the administrator's designee ~~shall be~~ is readily available on the premises or by telecommunications at all times during operating hours and for emergency situations.

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

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

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~~.~~;

2. Review all policies and procedures at least triennially with the administrator and appropriate clinical employees;

3. Update the policies and procedures, as the governing body deems necessary; and

4. Document in writing the triennial review process and recommendations for changes or updates.

~~B. All policies and procedures shall be reviewed at least annually, with recommended changes submitted to the governing body for approval, as necessary.~~

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

1. Administrative records, including granted variances;

~~2. Admission and discharge or termination from service criteria;~~

~~3.~~ 2. Informed signed consent;

~~4.~~ 3. ~~Advance~~ Providing information regarding advance directives, including Durable Do Not Resuscitate Orders;

~~5. Client rights;~~

~~6.~~ 4. Contract services;

~~7. Medication management, if applicable~~ 5. If applicable, an actively licensed nurse's monitoring of medication taken by a patient, to confirm that the patient is complying with a medication regimen, while also ensuring that the patient avoids potentially dangerous drug interactions and other complications;

~~8.~~ 6. Quality improvement;

~~9.~~ 7. Mandated reporting of abuse, neglect, and exploitation pursuant to § 63.2-1606 or § 63.2-1509 of the Code of Virginia;

~~10. Communicable and reportable diseases~~ 8. Reporting diseases and conditions to the local health department in accordance with the Regulations for Disease Reporting and Control (12VAC5-90);

~~11. Client~~ 9. Clinical records, including confidentiality;

~~12.~~ 10. Record retention of adult and pediatric clients and patients, including termination of services;

~~13.~~ 11. Supervision and delivery of services;

~~14.~~ 12. Emergency and on-call services;

~~15. Infection control;~~

~~16.~~ 13. Handling ~~consumer~~ the complaints of clients, patients, clients' and patients' family members, employees, and the public that meets the requirements of 12VAC5-381-240;

~~17.~~ 14. Telemonitoring; ~~and~~

~~18. Approved variances~~ 15. Identification of the administrator and methods established by the governing body for holding the administrator responsible and accountable~~.~~;

16. An emergency management plan;

17. Provisions regarding electronic health record and electronic signature, if applicable;

18. Protocols to prevent the occurrence of pressure sores or decubitus ulcers;

19. Identification of the prescription drugs and nonprescription drugs that the HCO permits to be self-administered; and

20. Provisions regarding the use of 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.

C. Client and patient rights policies and procedures shall include:

1. A process by which clients and patients are informed of their rights under 12VAC5-381-230; and

2. A requirement to provide timely information in plain language to all clients and patients and in a manner that is accessible to a client or patient:

a. With disabilities, including accessible websites and the provision of auxiliary aids and services at no cost to the client or patient; or

b. With limited English proficiency through the provision of language services at no cost to the client or patient, including oral interpretation and written translations.

D. Financial policies and procedures shall include~~, but are not limited to~~:

1. Admission agreements;

2. Data collection and verification of services delivered;

3. Methods of billing for services by the ~~organization~~ HCO and by independent contractors;

4. Client and patient notification of changes in fees and charges;

5. Correction of billing errors and refund policy; and

6. Collection of delinquent client and patient accounts.

E. ~~Personnel~~ Employee policies and procedures shall include~~, but are not limited to a~~:

1. Written job ~~description~~ descriptions that ~~specifies authority, responsibility, and qualifications for each job classification~~ meet the requirements of 12VAC5-381-200;

~~2. Process for maintaining an accurate, complete and current personnel record for each employee;~~

~~3. Process for verifying~~ 2. Verifying ~~current~~ active professional licensing or certification and training of employees, volunteers, or independent contractors;

~~4. Process for annually evaluating~~ 3. Evaluating at least annually employee performance and competency;

~~5. Process for verifying~~ 4. Verifying that independent contractors and their employees meet the ~~personnel~~ employee qualifications of the ~~organization~~ HCO;

~~6. Process for obtaining~~ 5. 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~~ 6. Reporting licensed and certified medical ~~personnel~~ employees, volunteers, and independent contractors for violations of their licensing or certification to the appropriate board within the Department of Health Professions~~.~~;

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;

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;

9. Employee participation in annual infection prevention in-service training and the process by which training is documented;

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

11. Employee 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.

F. Admission and discharge or termination from service policies and procedures shall include~~, but are not limited to~~:

1. Criteria for accepting clients and patients for services offered;

2. The process for obtaining a medical plan of care or ~~service~~ plan of care;

3. Admissions, including criteria for evaluating the client or patient before admission;

4. Criteria for determining discharge or termination from each service and referral to other agencies or community services; and

~~4.~~ 5. Process for notifying clients and patients of intent to ~~discharge/terminate~~ discharge, terminate, or refer, including:

a. Oral and written notice and explanation of the reason for ~~discharge/termination~~ discharge, termination, or referral;

b. The name, address, telephone number and contact name at the referral organization; and

c. Documentation in the ~~client~~ clinical record of the referral or notice.

G. A clinical employee 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:

1. 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:

a. Correct hand-washing technique, including indications for use of soap and water, and use of alcohol-based hand rubs;

b. Compliance with bloodborne pathogen requirements of the U.S. Occupational Safety and Health Administration found in 29 CFR 1910.1030; and

c. Use of personal protective equipment;

2. Use of safe injection practices recommended by the U.S. Centers for Disease Control and Prevention;

3. Monitoring employee, volunteer, and independent contractor adherence to standard precautions;

4. Access to hand-washing equipment and adequate supplies such as alcohol-based hand rubs or disposable towels;

5. Handling, storing, and transporting clean or sterile supplies and equipment;

6. Handling, storing, processing, and transporting regulated medical waste in accordance with 9VAC20-121;

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:

a. The level of cleaning, disinfecting, or sterilizing to be used for each type of equipment;

b. The process by which cleanliness, disinfection, or sterilization is achieved; and

c. The method for verifying that the recommended level of cleanliness, disinfection, or sterilization has been achieved;

8. Maintenance, repair, and disposal of equipment and supplies in accordance with manufacturer recommendations;

9. Cleaning of environmental surfaces with appropriate cleaning products;

10. Other infection prevention procedures necessary to prevent or control transmission of an infectious agent between clients, patients, and employees; and

11. Monitoring employee, volunteer, and independent contractor performance in infection control practices.

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

1. Developing a medical plan of care;

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;

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 patient's response to therapy, any other patient specific needs, and any significant change in the patient's condition;

5. Communication with the patient's provider pharmacy concerning problems or needed changes in a patient's medication;

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;

7. Educating or instructing the patient, family members, or other caregivers involved in the administration of infusion therapy in the proper storage of medication, proper handling of supplies and equipment, any applicable safety precautions, recognizing potential problems with the patient, and actions to take in an emergency; and

8. Initial training and retraining of all employees, including on procedures for first dosing of infusion therapy.

~~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.

~~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.

12VAC5-381-190. Financial controls.

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

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

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

~~1.~~ a. Cash;

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

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

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

B. The OLC shall accept as ~~Proof of funds sufficient~~ satisfactory evidence that an applicant has met the requirements of subdivision A2 of this section:

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.

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

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

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

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

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 the HCO is the subject of a Medicaid fraud investigation.

12VAC5-381-200. ~~Personnel~~ Employee practices.

A. An HCO shall ensure that:

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

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

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

1. ~~a~~ Design and implement a staffing plan that reflects the types of services offered by the HCO;

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

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

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

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

~~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.~~

~~G.~~ C. An HCO shall have a written job description for each employee, independent contractor, and volunteer description ~~Each employee position shall have a written job description~~ that includes:

1. ~~Job~~ the position title, authority, specific responsibilities, and minimum qualifications.

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.~~

D. An HCO shall review the job description at least annually, update as the HCO deems necessary, and shall give a copy to each employee, independent contractor, and volunteer when assigned to the position and when revised.

~~H. Employees shall have access to their current position description. There shall be a mechanism for advising employees of changes to their job responsibilities.~~

~~I.~~ E. 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~~. Orientation~~, which shall include:

1. Objectives and philosophy of the ~~organization~~ HCO;

2. Confidentiality;

3. Client and patient rights;

4. Mandated reporting of abuse, neglect, and exploitation;

5. Applicable ~~personnel~~ policies and procedures, including administrative and employee policies and procedures;

6. Emergency preparedness procedures;

7. Infection control practices and measures;

8. Cultural awareness;

9. How to report suspected Medicaid fraud; and

~~9.~~ 10. Applicable laws, regulations, and other policies and procedures that apply to specific positions~~,~~ and specific duties and responsibilities.

~~J. The organization~~ F. 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.

~~K. Individual staff development needs and plans shall be a part of the performance evaluation.~~

~~L. The organization~~ G. An HCO shall provide or arrange opportunities for and record participation in staff development activities designed to enable staff to perform the responsibilities of their positions.

~~M.~~ H. An HCO shall ensure that ~~All~~ all ~~individuals~~ employees, contractors, and volunteers who enter a client's home for or on behalf of the ~~organization~~ HCO ~~shall be~~ are readily identifiable by employee nametag, uniform or other visible and conspicuous means.

~~N. The organization shall maintain an organized system to manage and protect the confidentiality of personnel files and records.~~

~~O.~~ I. For each ~~Employee personnel records~~ employee file, ~~whether hard copy or electronic,~~ an HCO shall ~~include~~:

1. ~~Identifying information~~ Ensure the employee file is complete and accurate;

2. ~~Education and training history~~ Make the employee file readily available, including by electronic means;

3. ~~Employment history~~ Systematically organize the employee file to facilitate the compilation and retrieval of information;

4. ~~Results of the verification of applicable professional licenses or certificates~~ Safeguard the employee file against loss and unauthorized use;

5. ~~Results~~ Document results of reasonable efforts to secure job-related references and reasonable verification of employment history;

6. Maintain employee health information separately within the employee file;

~~6.~~ 7. ~~Results of performance evaluations~~ 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;

~~7.~~ 8. ~~A record of~~ Record performance evaluations and disciplinary actions, if any, taken by the ~~organization, if any~~ HCO;

~~8.~~ 9. ~~A record of~~ Record adverse action by ~~any licensing bodies and organizations~~ a licensing body or organization, if any; and

~~9. A record of participation in staff development activities, including orientation; and~~

10. Maintain documentation of ~~The~~ the criminal record ~~check~~ report and sworn affidavit as required in 12VAC5-381-110.

~~P.~~ J. An HCO shall report ~~All~~ 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~~.

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

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

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

12VAC5-381-210. Indemnity coverage.

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

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

1. Malpractice insurance consistent with § 8.01-581.15 of the Code of Virginia or professional liability insurance consistent with the amount of malpractice insurance required by § 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.

12VAC5-381-220. Contract services.

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

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

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~~ HCO;

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 general and professional liability insurance and third-party crime insurance or a blanket fidelity bond, as prescribed by 12VAC5-381-210.

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

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

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

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

~~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.~~

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

~~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;~~

~~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;~~

~~9. Provided with advance directive information prior to start of services; and~~

~~10. Given at least five days written notice when the organization determines to terminate services.~~

~~D. Before care is initiated, the home care organization shall inform the client, orally and in writing, of:~~

~~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:~~

~~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 the organization and the client; and~~

~~7. The refund policies of the organization.~~

A. A client or patient has the right to:

1. Have his property and person treated with respect;

2. Be free from verbal, mental, sexual, and physical abuse, including injuries of unknown source, neglect and misappropriation of property;

3. Make complaints to the HCO regarding (i) treatment or care that the HCO provides or fails to provide, and (ii) the lack of respect for property or person by anyone who is providing services on behalf of the HCO;

4. Receive services from individuals who are properly trained and competent to perform their duties;

5. Be informed about, and consent to or refuse treatment in advance of and during treatment, with respect to the following:

a. Completion of assessments;

b. The care to be provided, based on the comprehensive assessment;

c. Establishing and revising the medical plan of care;

d. The types of care that will be provided;

e. The frequency of visits;

f. Expected outcomes of care, including client- or patient-identified goals, and anticipated risks and benefits;

g. The factors that could impact treatment effectiveness; and

h. Changes in the care to be provided;

6. Receive all services outlined in the medical plan of care or plan of care;

7. Have a confidential clinical record and financial record as provided by law;

8. Be provided with advance directive information prior to the initiation of services;

9. Be advised before services are initiated, orally and in writing, of:

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;

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;

c. The charges the client or patient may have to pay before care is initiated; and

d. 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 the 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;

10. Receive written notice, at least five business days in advance of a specific service being provided, if the HCO believes that the service may be non-covered care, or at least five business days in advance of the HCO reducing or terminating on-going care;

11. 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, including:

a. Agency on Aging;

b. Center for Independent Living; and

c. disAbility Law Center of Virginia;

12. Be free from any discrimination or reprisal for exercising his rights or for voicing grievances to the HCO or an outside entity; and

13. Receive a written copy of the HCO's refund policies and receive written notice of changes to those policies, at least five business days in advance of the change.

B. An HCO shall review client and patient rights with clients, patients, or their legal representatives upon admission to the HCO, and said review shall be documented in the clinical record.

12VAC5-381-240. ~~Handling complaints received from clients~~ Complaint handling procedures.

A. ~~The organization~~ An HCO shall establish and maintain complaint handling procedures that specify the:

1. System for logging receipt, investigation and resolution of complaints; and

2. Format of the written record of the findings of each complaint investigated.

~~B. The organization shall designate~~ 3. The ~~staff~~ position title of the employees responsible for complaint resolution, including:

~~1.~~ a. Complaint intake, including acknowledgment of complaints;

~~2.~~ b. Investigation of the complaint;

~~3.~~ c. Review of the investigation of findings and resolution for the complaint; and

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

~~C.~~ B. An HCO shall give ~~The~~ the client, patient, or legal representative ~~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, patient, or ~~his~~ designee with the name, mailing address, and telephone number of the:

1. ~~Organization~~ HCO's contact person;

2. State Long-Term Care Ombudsman and the ombudsman for their locality; and

3. Complaint Unit of the OLC.

~~D. The organization~~ C. An HCO shall maintain documentation of ~~all~~ the complaints the HCO has 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~~ five years from the date of receipt.

12VAC5-381-250. Quality improvement.

A. ~~The organization~~ An HCO 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. The HCO shall use the findings ~~shall be used~~ to correct identified problems and revise policies and practices, as necessary.

2. ~~Exclusive concentration on~~ The HCO may not limit the scope of the program to only administrative or cost-of-care issues ~~does not fulfill this requirement~~.

B. To identify unacceptable or unexpected trends or occurrences, an HCO ~~The following data~~ shall ~~be evaluated~~ evaluate ~~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~~ Clinical records for appropriateness of services provided;

5. Client and patient satisfaction;

6. Complaint resolution;

7. Infections;

8. ~~Staff~~ Employee concerns regarding client or patient care; and

9. Provision of services appropriate to the ~~clients'~~ client's or patient's needs.

C. ~~A~~ An HCO shall establish a quality improvement committee ~~responsible for the oversight and supervision of the program,~~ which shall consist of:

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

2. ~~A member of the~~ An administrative ~~staff~~ employee;

3. Representatives from each of the services provided by the ~~organization~~ HCO, including contracted services; and

4. ~~An individual with demonstrated ability to represent the rights and concerns of clients. The individual~~ 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.

D. In selecting members of ~~this~~ the quality improvement committee, consideration shall be given to a candidate's abilities and sensitivity to issues relating to quality of care and services provided to clients and patients.

~~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.~~

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

1. At least annually, the ~~Results~~ results of the quality improvement program ~~shall be reported annually to the governing body and the administrator and available in the organization~~, which shall include the deficiencies the quality improvement committee has identified and the recommendations for corrections and improvements and for maintaining compliance~~.~~; and

2. Immediately, in writing, a deficiency the quality improvement committee has identified that jeopardize client and patient safety.

F. The administrator or the administrator's designee shall implement corrective action for a deficiency identified by the quality improvement committee and ~~The report shall be acted upon by the governing body and the organization. All corrective actions shall be documented~~ shall document the corrective actions in writing.

12VAC5-381-260. Infection control.

A. ~~The organization~~ 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.

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

~~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.~~

~~C.~~ B. An HCO shall ensure that ~~Accumulated~~ accumulated waste, including all contaminated sharps, dressings, or similar infectious waste materials, ~~shall be~~ are disposed of in a manner compliant with the OSHA Bloodborne Pathogens standard (enumerated in 29 CFR 1910.1030).

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

1. Access to or referrals for vaccines, including influenza, hepatitis B, and SARS-CoV-2;

2. Procedures for ensuring that employees with a communicable disease are identified and prevented from work activities that could result in transmission to other employees, clients, or patients;

3. An exposure control plan for bloodborne pathogens;

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

5. Compliance with requirements of the U.S. Occupational Safety and Health Administration for reporting of workplace-associated injuries or exposure to infection.

12VAC5-381-270. Drop sites.

A. ~~The organization~~ An HCO may operate one or more drop sites for the convenience of ~~staff~~ employees providing direct client and patient care or service. ~~However, such sites shall~~ An HCO may not:

1. ~~Have staff~~ Assign an employee to a drop site ~~assigned~~;

2. Accept referrals at a drop site;

3. Operate a drop site as a branch office; or

~~3. Be advertised~~ 4. Advertise a drop site as part of the ~~organization~~ HCO.

B. An HCO shall safeguard against loss or unauthorized use ~~Any client~~ clinical records located at ~~the~~ a drop site ~~shall be safeguarded against loss or unauthorized use~~. An HCO shall ensure that only

~~Only~~ authorized ~~personnel~~ employees ~~shall~~ have access to ~~client~~ clinical records as specified by state and federal law~~.~~ and

~~It shall be the responsibility of the organization to assure that records~~ that records maintained at ~~the~~ a drop site are readily available and accessible for ~~inspection staff~~ inspectors.

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

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.

12VAC5-381-280. ~~Client~~ Clinical record system.

A. ~~The organization~~ 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.

B. Unless otherwise specified by state or federal requirements, an HCO shall maintain originals or reproductions of clinical records in their entirety:

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

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

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

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

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

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

~~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.~~

~~F.~~ E. 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~~:

1. Client or patient identifying information;

2. Identification of the client's or patient's ~~primary care~~ physician;

3. Admitting information, including a client or patient history;

4. Information on the composition of the client's or patient's household, including individuals to be instructed in assisting the client or patient;

5. An initial and all subsequent assessment of client or patient needs to develop a medical plan of care or ~~services~~ plan of care;

6. A medical plan of care or ~~service~~ plan of care that includes:

a. ~~the~~ The type and frequency of each service to be ~~delivered~~ provided:

b. Who will provide the services and when ~~either by organization personnel or contract services~~;

c. Prescription drugs or nonprescription drugs to be administered and the route of administration, including if self-administered;

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

e. Interruptions in service and an explanation for any such interruption;

7. Documentation of client and patient rights review; and

8. A written discharge or termination of service summary that records the service delivered and final disposition at the time of client's or patient's discharge or termination from service.

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

~~9.~~ 1. Documentation and results of all medical tests ordered by the physician or other health care ~~professional~~ practitioner and performed by the ~~organization's staff~~ HCO employees;

~~10.~~ 2. A medical plan of care including appropriate assessment and pain management;

~~11.~~ 3. Medication sheets that include the name, dosage, frequency of administration, possible side effects, route of administration, date started, and date changed or discontinued for each medication administered; and

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

G. An HCO shall ensure the medical plan of care is approved and signed by the patient's physician.

~~G.~~ H. An HCO shall ensure that:

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

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

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

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

~~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.~~

12VAC5-381-290. Home attendants.

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

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 active 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 experience involving direct client care;

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

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

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

1. Include education addressing:

a. Goals of personal care;

b. Personal care and rehabilitative services;

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

d. Documentation requirements for Medicaid recipients;

e. Reading and recording temperature, pulse, and respiration;

f. Prevention of skin breakdown, including recognizing and reporting changes in skin condition such as pressure ulcers;

g. Physical and biological aspects of aging;

h. Orientation to types of physical disabilities;

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, privacy, and property;

j. Body mechanics, including normal range of motion and positioning;

k. Basic elements of body functioning and changes in body function that must be reported to a home attendant's or volunteer's supervisor;

l. Home management, including maintenance of a clean, safe, and healthy environment;

m. Basic infection control policies and procedures;

n. Safety and accident prevention in the home, including safe transfer techniques and ambulation;

o. Policies and procedures regarding accidents or injuries;

p. Recognizing emergencies and knowledge of emergency policies and procedures;

q. Food, nutrition, and meal preparation, including adequate nutrition and fluid intake;

r. Special considerations in preparation of special diets;

s. Appropriate and safe techniques in personal hygiene and grooming that include nail and skin care, oral hygiene, toileting and elimination, and bathing and hair care of clients and patients with limited mobility; and

t. Care of the home and personal belongings.

2. Be conducted by a registered nurse who meets the requirements in 18VAC90-26-30.

3. Issue and maintain certificates of completion containing:

a. The instructor’s printed name and signature;

b. The participant’s printed name; and

c. The date of completion of the program.

Part III

Skilled Services and Personal Care Services

12VAC5-381-300. Skilled services.

A. ~~The organization~~ An HCO ~~shall~~ may provide a program of home health skilled services that ~~shall include~~ includes ~~one or more of the following~~:

1. Nursing services;
2. Physical therapy services;
3. Occupational therapy services;
4. Speech ~~therapy~~ language pathology services;
5. Respiratory therapy services; ~~or~~
6. Medical social services~~.~~; or
7. Pharmaceutical services.

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

1. Diagnosis and prognosis;
2. Functional limitations;
3. Orders for all skilled services, including:
   ~~(i) specific~~ a. Specific procedures~~,~~
   ~~(ii) treatment~~ b. Treatment modalities~~,~~; and
   ~~(iii) frequency~~ c. 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 primary care physician.~~

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

1. ~~documented~~ Documented ~~within~~ in the clinical record by the actively licensed healthcare professional within 24 consecutive hours ~~in the client's clinical record by the health care professional~~ of receiving the order; and
2. ~~shall be countersigned~~ Countersigned by the prescribing ~~person~~ actively licensed health care practitioner.

D. An HCO shall immediately notify a patient's ~~The primary care~~ physician ~~shall be notified immediately~~ of ~~any changes~~ a change in the ~~client's~~ patient's condition that indicates a need to alter the medical plan of care.

E. 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.

F. An HCO shall appoint in writing ~~There shall be~~ a ~~director of~~ skilled services director, who shall:

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~~,~~;
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

~~The individual shall have~~ 3. Have the appropriate experience for the scope of services provided by the ~~organization~~ HCO.

~~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.~~

~~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~~.

12VAC5-381-310. Nursing services.

A. An HCO shall ensure that ~~All~~ all nursing services ~~shall be~~ are:

1. ~~directly~~ Directly provided by an actively licensed and appropriately qualified registered nurse or licensed practical nurse~~,~~; or

2. By a person to whom ~~except for those~~ nursing tasks ~~that may be~~ are delegated by a registered nurse ~~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 and with a plan developed and implemented by the ~~organization~~ HCO.

B. An HCO shall ensure that nursing 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 every 60 calendar days, as determined by:

1. ~~the~~ The ~~client's~~ patient's needs~~,~~;

2. ~~the~~ The assessment by the registered nurse~~,~~; and

3. ~~the~~ The ~~organization's~~ HCO's written policies ~~not to exceed 90 days~~.

12VAC5-381-320. Therapy services.

A. An HCO shall ensure that ~~Physical~~ physical therapy, occupational therapy, speech ~~therapy~~ language pathology, or respiratory therapy services ~~shall be~~ are provided according to the medical plan of care by or under the direction of an appropriately qualified therapist ~~currently~~ actively licensed in Virginia and ~~may~~ shall include~~, but are not limited to~~:

1. Assessing ~~client~~ the patient's 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~~ patient and family regarding treatment modalities and use of equipment and devices;

5. Providing consultation to other actively licensed health care ~~professionals~~ practitioners, as applicable;

6. Communicating with the physician and other actively licensed health care ~~professionals~~ practitioners regarding changes in the ~~client's~~ patient's needs;

7. Supervising therapy assistants and home attendants as appropriate; and

8. Preparing clinical notes.

B. An HCO may employ or contract with ~~Therapy~~ therapy assistants ~~may be used~~ to provide therapy services. An HCO shall ensure that:

1. ~~The~~ An occupational therapy assistant ~~shall be~~ is ~~currently~~ actively certified by the National Board for Certification in Occupational Therapy and ~~shall practice~~ practices under the supervision of ~~a~~ an actively licensed occupational therapist~~.~~; and

2. ~~The~~ A physical therapy assistant ~~shall be~~ is ~~currently~~ actively licensed by the Virginia Board of Physical Therapy and ~~shall practice~~ practices under the supervision of ~~a~~ an actively licensed physical therapist.

~~C. Duties of therapy assistants shall be within their scope of practice and may include, but are not limited to:~~

~~1. Performing services planned, delegated, and supervised by the appropriately licensed therapist; and~~

~~2. Preparing clinical notes.~~

~~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 licensing board, as determined by:

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~~.

12VAC5-381-330. Home attendants assisting with skilled services.

A. An HCO that employs or contracts with ~~Home~~ home attendants ~~assisting~~ to assist with providing skilled services may permit home attendants, consistent with the medical plan of care, to:

1. Assist ~~clients~~ patients with ~~(i)~~ activities of daily living, ~~(ii)~~ ambulation, and ~~prescribed~~ restorative exercise~~, and (iii) other special duties with appropriate training and demonstrated competency~~;

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.)~~ (§ 54.1-3400 et seq. ~~of Title 54.1~~ of the Code of Virginia);

3. Measure and record fluid intake and output;

4. Take and record blood pressure, pulse and respiration;

5. Record and report to the ~~appropriate~~ actively licensed health care ~~professional~~ practitioner changes in the ~~client's~~ patient's condition;

6. Document services and observations in the ~~client's~~ clinical record; and

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.

B. Prior to the initial delivery of services, an HCO shall ensure that the home attendant ~~shall receive~~ receives specific written instructions for the ~~client's~~ patient's care from the ~~appropriate~~ actively licensed health care ~~professional~~ practitioner responsible for the care.

C. An HCO shall ensure that a ~~Home attendants~~ home attendant:

1. ~~shall work~~ Works under the supervision of the ~~appropriate~~ actively licensed health care ~~professional~~ practitioner responsible for the ~~client's~~ patient's care~~.~~, with supervision being conducted in-person at least once every 60 calendar days; and

~~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.

12VAC5-381-340. Medical social services.

A. An HCO shall ensure that ~~Medical~~ medical social services ~~shall be~~ are provided according to the medical plan of care by or under the direction of ~~a qualified~~ an actively licensed clinical social worker 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 ~~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~~ one year's experience in case work or counseling in a health care or social services delivery system.

~~The organization shall have one year from January 1, 2006, to ensure the designated individual meets the qualifications of this standard.~~

B. An HCO may assign ~~The~~ duties ~~of~~ to a social worker, including ~~may include, but are not limited to~~:

1. Assessing the ~~client's~~ patient'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 patient's ~~primary care~~ physician and other actively licensed health care ~~professionals~~ practitioners regarding changes in the ~~client's~~ patient's needs;

5. Preparing notes on the care or services provided; and

6. Participating in discharge planning.

~~Part IV~~

~~Pharmaceutical Services~~

12VAC5-381-350. ~~Pharmacy~~ Pharmaceutical services.

A. An HCO shall ensure that ~~All~~ all prescription drugs ~~shall be~~ are prescribed and properly dispensed to the ~~client~~ patient 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~~.

B. An HCO may permit ~~Home~~ home attendants ~~may~~ to administer normally self-administered drugs as 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.~~

~~C. The organization shall develop written policies and procedures for the administration of home infusion therapy medications that include, but are not limited to:~~

~~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 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~~

~~8. Initial and retraining of all organization staff providing infusion therapy.~~

~~D.~~ C. ~~The organization~~ An HCO 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:

1. ~~supervise~~ Supervise medication administration by ~~staff~~ employees consistent with the type of medication being administered~~.~~;

2. ~~This person shall be responsible for ensuring~~ Ensure employee compliance with applicable laws and regulations~~,~~;

3. Ensure adherence to the policies and procedures related to administration of medications~~,~~; and

4. ~~conducting~~ Conduct ~~periodic~~ annual assessments of ~~staff~~ employee competency in performing infusion therapy.

~~Part V~~

~~Personal Care Services~~

Documents Incorporated by Reference (12VAC5-381)

~~Personal Care Aide Training Curriculum, 2003 Edition, Virginia Department of Medical Assistance Services.~~

U.S. Centers for Disease Control and Prevention Injection Safety Guidelines, 2007.

U.S. Centers for Disease Control and Prevention Standard Precautions for All Patient Care, April 3, 2024.

OTHER BUSINESS

ADJOURN