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detail for certain processes and requirements, (ii) update existing regulatory language that is inconsistent or outdated, (iii) revise language to conform to the *Form, Style, and Procedure Manual for Publication of Virginia Regulations*, (iv) adjust HCO licensure fees.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.

<u>Section 240 Handling complaints received from clients</u>
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.

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

<u>Section 260 Infection control</u>
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.

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

<u>Section 280 Client record system</u>
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”.

<u>Section 290 Home attendants</u>
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.

<u>Section 300 Skilled services</u>
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.

<u>Section 310 Nursing services</u>
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.

<u>Section 320 Therapy services</u>
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.

<u>Section 330 Home attendants assisting with skilled services</u>
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.

<u>Section 340 Medical social services</u>
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.

<u>Section 350 Pharmacy services</u>
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.

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

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 • Decreases 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.