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Proposed Regulation Agency Background Document

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-381-10 <i>et seq.</i>
VAC Chapter title(s)	Regulations for the Licensure of Home Care Organizations
Action title	Amend the Regulation after Assessment and Receipt of Public Comment
Date this document prepared	March 8, 2022

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

Brief Summary

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

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 Regulatory language was reviewed and clarified if the content was unclear, inconsistent, or outdated, and was revised to conform to the *Form, Style and Procedure Manual for Publication of Virginia Regulations*.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

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

Acronyms and Definitions

Define all acronyms used in this form, and any technical terms that are not also defined in the “Definitions” section of the regulation.

“Agency” means the Virginia Department of Health.

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

“Board” means Virginia Board of Health.

“HCO” means home care organizations.

“OLC” means the Office of Licensure and Certification.

Mandate and Impetus

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

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

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

Legal Basis

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

Section 32.1-12 of the Code of Virginia gives the Board the responsibility to make, adopt, promulgate, and enforce such regulations as may be necessary to carry out the provisions of Title 32.1 of the Code of Virginia. Section 32.1-162.12 of the Code of Virginia requires the Board to adopt regulations governing the activities and services provided by home care organizations.

Purpose

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

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

Substance

Briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of Changes" section below.

12VAC5-381 is renamed "Home Care Organization Licensure Regulation."

Section 10 Definitions

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

Section 20 License

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

Section 30 Exemption from licensure

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

Section 35 Total geographic area and office location

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

Section 40 License application: initial and renewal

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

Section 45 License expiration and renewal

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

Section 50 Compliance appropriate for all types of HCOs

Repealed as duplicative.

Section 60 Changes to or reissue of a license

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

Section 65 License reinstatement

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

Section 70 Fees

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

Section 80 On-site inspections

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

Section 90 Home visits

Repealed; consolidated with Section 80.

Section 100 Complaint investigations conducted by the OLC

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

Section 105 Plan of correction

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

Section 110 Criminal records checks

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

Section 120 Variances

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

Section 130 Revocation or suspension of a license

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

Section 140 Return of a license

Repealed; consolidated with Section 60.

Section 150 Management and administration

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

Section 160 Governing body

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

Section 170 Administrator

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

Section 180 Written policies and procedures

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

Section 190 Financial controls

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

Section 200 Personnel practices

Renamed "Employee practices." Revised text to more closely align with Section 10's definitions and to clarify that job description requirements apply to all workers, whether 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 more closely align with Section 10's definitions and to reference professional liability insurance instead of malpractice insurance. Revised text to remove statutory reference and replaced with coverage minimums that increase annually.

Section 220 Contract services

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

Section 230 Client rights

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

Section 240 Handling complaints received from clients

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

Section 250 Quality improvement

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

Section 260 Infection control

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

Section 270 Drop sites

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

Section 280 Client record system

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

Section 290 Home attendants

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

Section 300 Skilled services

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

Section 310 Nursing services

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

Section 320 Therapy services

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

Section 330 Home attendants assisting with skilled services

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

Section 340 Medical social services

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

Section 350 Pharmacy services

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

DOCUMENTS INCORPORATED BY REFERENCE (12VAC5-381)

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

Issues

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

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

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

Requirements More Restrictive than Federal

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

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

Agencies, Localities, and Other Entities Particularly Affected

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

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

Economic Impact

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

Impact on State Agencies

<p><i>For your agency:</i> projected costs, savings, fees or revenues resulting from the regulatory change, including:</p> <ul style="list-style-type: none"> a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources 	<p>There are no projected costs, savings, or revenue loss resulting from the regulatory change.</p> <p>The agency estimates that the proposed fees in Section 70 would result in a minimum annual fee revenue of \$2,684,750. This assumes that licensee numbers (1,547), branch office numbers (102), and applicant numbers (approximately 350 annually) remain relatively stable. The number of licensees requesting a material change to their</p>
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	<p>license is highly variable and difficult to predict, making fee revenue projections from that fee equally difficult to predict. Since the agency is proposing to introduce a new reinstatement process that currently has no analog in its other licensure programs, it is difficult to predict what fee revenue may result from HCOs utilizing that process. As explained in the two paragraphs below, this increase in fee revenue is aimed at supporting adequate staff to perform inspections and other oversight functions.</p> <p>The HCO program currently has a team of four FTEs and one wage employee serving as inspectors, in addition to one FTE supervisor and one FTE administrative support. Each FTE inspector can perform an annual average of 65 HCO inspections, which includes biennial licensure inspections, initial licensure inspections, and complaint inspections. Assuming the number of regulants remains relatively stable, if the agency can move forward with the proposed change to a triennial interval for licensure inspections, there would be approximately 906 inspections due every year. This would require a total staff of 14 FTE inspectors, two FTE supervisors, and two FTE administrative supports. Based on current salaries and fringe benefit calculations for these positions, the agency would have a total staffing cost of \$1,951,588.</p> <p>After accounting for the staffing cost, the remaining fee revenue (a minimum of \$733,162) would be utilized to cover the travel expenses of the FTE inspectors. The annual cost of leasing 14 state vehicles is estimated to be \$55,650 (\$331.25 per month per car). Using average fuel costs incurred by FTE inspectors during SFY2019 and adjusting for increased fuel prices since SFY2019, annual cost of fuel is estimated to be \$8,400. Per diem costs (using a blend of \$59/\$69/\$79 per diem to reflect the differing costs of statewide travel) and lodging costs (using a blend of hotel rates and taxes from the DC metro area to represent the high end and hotel rates and taxes from Highland County to represent the low end) consumes the remaining \$669,112 of the minimum fee revenue.</p>
<p><i>For other state agencies:</i> projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.</p>	<p>There are no projected costs, savings, fees, or revenues resulting from the regulatory change for other state agencies.</p>
<p><i>For all agencies:</i> Benefits the regulatory change is designed to produce.</p>	<p>This regulatory action is designed to promote and</p>

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

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

Impact on Other Entities

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

	<p>additional annual cost of \$750 for each branch office they operate.</p> <p>The agency believes that any administrative costs for reporting and recordkeeping required for compliance by small businesses would be incidental to their existing administrative costs. The agency also notes that by requiring a review instead of an audit, licensed HCOs should recognize some cost savings as reviews are typically less expensive than audits.</p> <p>The agency does not predict any projected costs for purchases of equipment or services resulting from the regulatory change for licensed HCOs and persons or entities seeking licensure to operate an HCO.</p> <p>The agency does not anticipate any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change; however, the agency does note that a new requirement mandates that HCO offices (including drop sites and branch offices) be in buildings zoned for business or commercial use, so some HCOs may face a cost to secure a compliant operating space, though the agency does not have sufficient information at this time to predict how many HCOs would be affected. Affected HCOs would have one year from the effective date of the regulatory change to come into compliance.</p>
<p>Benefits the regulatory change is designed to produce.</p>	<p>This regulatory action is designed to promote and ensure the health and safety of clients and patients who receive personal care services and skilled services from HCOs, including ensuring the agency has sufficient fee revenue to support adequate staff to perform inspections and other oversight functions.</p>

Alternatives to Regulation

Describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the regulatory change. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulatory change.

No alternative was considered because the General Assembly required the Board to adopt regulations governing the licensure of home care organizations and amending the regulation is the least burdensome method to accomplish the purpose of this action.

Regulatory Flexibility Analysis

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

In developing the proposed regulations, the Board considered that the affected industry consists primarily of small businesses. Providing a small business exemption would result in the overwhelming HCO being exempt from the requirements, just as establishing performance standards or less stringent requirements specific to small business would have the effect of lowered standards and requirements in nearly every case. Consequently, there are no other alternative regulatory methods to minimizing the adverse impact on small businesses that the Board could utilize without being inconsistent with health, safety, environmental and economic welfare in accomplishing the objectives of the General Assembly mandates.

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

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

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

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

There is a continued need for this regulation because the mandate to regulate home care organizations still exists in the Code of Virginia. 3 public comments were received from a single commenter during the 30-day public comment period following publication of the Notice of Intended Regulatory Action. These comments offered specific recommendations for the regulations, with a general aim of requesting less restrictive regulations. The complexity of the regulation is on par with the complexity of other medical care facility regulations that the Board has promulgated. The regulation does not overlap, duplicate, or conflict with federal or state law or regulation. It has been 6 years since the regulation has been evaluated.

Public Comment

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

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

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

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

The Board is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal, (ii) any alternative approaches, (iii) the potential impacts of the regulation, and (iv) the agency's regulatory flexibility analysis stated in that section of this background document.

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall web site at: <https://townhall.virginia.gov>. Comments may also be submitted by mail, email or fax to **Rebekah E. Allen, Senior Policy Analyst, Virginia Department of Health, Office of Licensure and Certification, 9960 Mayland Drive, Suite 401, Henrico, VA 23233; email: regulatorycomment@vdh.virginia.gov; fax: (804) 527-4502**. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will not be held following the publication of this stage of this regulatory action.

Detail of Changes

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

Table 1: Changes to Existing VAC Chapter(s)

Current chapter-section number	New chapter-section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
381-10	N/A	<p style="text-align: center;">CHAPTER 381 REGULATIONS FOR LICENSURE OF HOME CARE ORGANIZATIONS Part I Definitions and General Information 12VAC5-381-10. Definitions. The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:</p>	<p>CHANGE: The Board is proposing the following changes:</p> <p style="text-align: center;">Chapter 381 REGULATIONS FOR THE LICENSURE OF HOME CARE ORGANIZATIONS ORGANIZATION LICENSURE REGULATION Part I Definitions and General Information 12VAC5-381-10. Definitions. The following words and terms when used in this chapter shall have</p>

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

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

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

			<p><u>§§ 32.1-162.9 and 32.1-162.12 of the Code of Virginia.</u></p> <p>INTENT: The intent of these proposed changes is to:</p> <ul style="list-style-type: none"> (i) write this section in the active voice and break paragraphs with multiple requirements into subparts; (ii) clarify what constitutes total geographic area (iii) clarify that HCO offices, branch offices, and drop sites cannot be in residential spaces; and (iv) giving existing regulants time to comply. <p>RATIONALE: The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> (i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>; (ii) the agency believes that either option for total geographic area in the proposed subsection A represents large swaths of the Commonwealth in which a parent HCO could still reasonably exercise administrative control over its branch offices; (iii) allowing HCOs to conduct their businesses out of residential spaces places the agency's inspectors in potentially dangerous circumstances and is inconsistent with the other licensure programs administered by the agency; and (iv) one year should be sufficient time for an HCO to move locations, if necessary, and to determine what its new total geographic area is. <p>LIKELY IMPACT: The likely impact of these proposed changes is improved readability of the section and improved clarity about the operation of HCO offices, drop sites, and branch offices.</p>
381-40	N/A	<p>12VAC5-381-40. License application; initial and renewal. A. The OLC provides prelicensure consultation and technical assistance regarding</p>	<p>CHANGE: The Board is proposing the following changes:</p>

	<p>the licensure process. The purpose of such consultation is to explain the regulation and the survey process. Prelicensure consultations are arranged after a completed initial application is on file with the OLC.</p> <p>B. Licensure applications are obtained from the OLC. The OLC shall consider an application complete when all requested information and the appropriate fee, stated in 12VAC5-381-70, is submitted. If the OLC finds the application incomplete, the applicant will be notified in writing.</p> <p>C. The activities and services of each applicant and licensee shall be subject to an inspection by the OLC to determine if the organization is in compliance with the provisions of this chapter and state law.</p> <p>D. A completed application for initial licensure must be submitted at least 60 days prior to the organization's planned opening date to allow the OLC time to process the application. An incomplete application shall become inactive six months after it is received by the OLC. Applicants must then reapply for licensure with a completed application and application fee. An application for a license may be withdrawn at any time.</p> <p>E. Licenses are renewed annually. The OLC shall make renewal applications available at least 60 days prior to the expiration date of the current license.</p> <p>F. It is the home care organization's responsibility to complete and return a renewal application to assure timely processing. Should a current license expire before a new license is issued, the current license shall remain in effect provided a complete and accurate application was filed on time.</p> <p>Statutory Authority</p>	<p>12VAC5-381-40. License application; Request for initial license issuance and renewal.</p> <p>A. The OLC provides prelicensure consultation and technical assistance regarding the licensure process. The purpose of such consultation is to explain the regulation and the survey process. Prelicensure consultations are arranged after a completed initial application is on file with the OLC.</p> <p>B. Licensure applications are obtained from the OLC. The OLC shall consider an application complete when all requested information and the appropriate fee, stated in 12VAC5-381-70, is submitted. If the OLC finds the application incomplete, the applicant will be notified in writing.</p> <p>C. The activities and services of each applicant and licensee shall be subject to an inspection by the OLC to determine if the organization is in compliance with the provisions of this chapter and state law.</p> <p>D. A completed application for initial licensure must be submitted at least 60 days prior to the organization's planned opening date to allow the OLC time to process the application. An incomplete application shall become inactive six months after it is received by the OLC. Applicants must then reapply for licensure with a completed application and application fee. An application for a license may be withdrawn at any time.</p> <p>E. Licenses are renewed annually. The OLC shall make renewal applications available at least 60 days prior to the expiration date of the current license.</p> <p>F. It is the home care organization's responsibility to complete and return a renewal application to assure timely processing. Should a current license expire before a new license is issued, the current license shall remain in effect provided a complete and accurate application was filed on time.</p> <p>A. An applicant shall:</p>
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		<p>§§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p>	<p><u>1. Submit an application for initial licensure to the OLC;</u></p> <p><u>2. Identify the services that it intends to perform at its proposed HCO;</u></p> <p><u>3. Identify the total geographic area it intends to serve with its proposed HCO;</u></p> <p><u>4. Disclose to the OLC the ownership interest of the proposed HCO and in the case of corporations, identify by name and address all individuals or entities holding 5.0% or more of total ownership; and</u></p> <p><u>5. Shall pay the fee prescribed by 12VAC5-381-70.</u></p> <p><u>B. Each HCO and any branch office disclose upon each application filed with the OLC:</u></p> <p><u>1. Its legal business name, which shall be distinct; and</u></p> <p><u>2. Any fictitious business name that the HCO or branch office may use.</u></p> <p><u>C. The commissioner shall consider an application complete when all requested information and the nonrefundable application fee are received by the OLC. The commissioner may deny licensure to an applicant whose application has been incomplete for more than 180 calendar days.</u></p> <p><u>D. An applicant shall notify the OLC in writing that it is ready for the initial licensure inspection. The commissioner may deny licensure to an applicant who delays or attempts to delay its initial licensure inspection.</u></p> <p><u>E. The OLC shall notify the applicant of the time and date of the initial licensure inspection. The director of the OLC, at his discretion, may waive the initial licensure inspection for an applicant seeking initial licensure due to a change of ownership of an HCO that is or was licensed.</u></p>
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			<p><u>F. As part of the initial licensure inspection, an applicant shall:</u></p> <ol style="list-style-type: none"><u>1. Make available to an inspector any requested records;</u><u>2. Allow an inspector access to interview the agents, employees, independent contractors, and any person under the applicant's control, direction, or supervision; and</u><u>3. Permit an inspector to enter upon and into the property of any proposed HCO to inspect or investigate as the inspector reasonably deems necessary in order to determine the state of compliance with the provisions of this chapter and all laws administer by the board.</u> <p><u>The commissioner may deny licensure to an applicant who does not comply with this subsection.</u></p> <p><u>G. An applicant may voluntarily terminate an initial licensure inspection at any time during the inspection. The commissioner may deny licensure to any applicant who voluntarily terminates an initial licensure inspection.</u></p> <p><u>H. The OLC shall provide a written inspection report to the applicant after the initial licensure inspection. If the OLC cites one or more licensing violations in the written inspection report, the administrator shall submit a written plan of correction in accordance with the provisions of 12VAC5-381-105. The commissioner may deny licensure to an applicant who does not comply with this subsection.</u></p> <p><u>I. An applicant may:</u></p> <ol style="list-style-type: none"><u>1. Withdraw its application at any time; and</u><u>2. Reapply for licensure, provided that it pays the fee prescribed by 12VAC5-381-70, if:</u><ol style="list-style-type: none"><u>a. It withdraws its application pursuant to</u>
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			<p><u>subdivision 1 of this subsection; or</u></p> <p><u>b. The commissioner denies it initial licensure pursuant to this section, except that if the commissioner has denied an applicant licensure a total of three times, the applicant may not reapply for a license for a period of two years from the date of the third denial.</u></p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p> <p>INTENT: The intent of these proposed changes is to:</p> <ul style="list-style-type: none"> (i) write this section in the active voice and break paragraphs with multiple requirements into subparts; (ii) clarify the initial licensure process; and (iii) clarify the causes for which the State Health Commissioner may deny an initial license. <p>RATIONALE: The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> (i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>; (ii) the initial licensure process is multi-stage and explaining it in greater detail should result in applicants being better prepared for the process; (iii) applicants should be made aware of what action or inaction of theirs may cause the State Health Commissioner to deny them an initial license. <p>LIKELY IMPACT: The likely impact of these proposed changes is improved readability of the section and improved clarity regarding the initial licensure process.</p>
N/A	381-45	N/A	<p>CHANGE: The Board is proposing to add a new section as follows:</p>

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

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

			<p><u>and in the case of corporations, identify by name and address all individuals or entities holding 5.0% or more of total ownership; and</u></p> <p><u>5. Shall pay the fee prescribed by 12VAC5-381-70.</u></p> <p><u>The OLC shall consider the submission date of an application to be the date it is postmarked or the date it is received, whichever is earlier.</u></p> <p><u>C. The commissioner shall consider an application complete when all requested information and the nonrefundable application fee are received by the OLC. The commissioner may deny reinstatement of licensure to an HCO whose application has been incomplete for more than 60 calendar days.</u></p> <p><u>D. The OLC may conduct a reinstatement licensure inspection. As part of a reinstatement licensure inspection, an applicant shall:</u></p> <ol style="list-style-type: none"><u>1. Make available to an inspector any requested records;</u><u>2. Allow an inspector access to interview the agents, employees, independent contractors, and any person under the applicant's control, direction, or supervision; and</u><u>3. Permit an inspector to enter upon and into the property of any HCO to inspect or investigate as the inspector reasonably deems necessary in order to determine the state of compliance with the provisions of this chapter and all laws administer by the board.</u> <p><u>The commissioner may deny reinstatement of licensure to an HCO who does not comply with this subsection.</u></p> <p><u>E. An HCO may voluntarily terminate a reinstatement licensure inspection at any time during the inspection. The commissioner may</u></p>
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			<p><u>deny reinstatement of licensure to any HCO who voluntarily terminates a reinstatement licensure inspection.</u></p> <p><u>F. The OLC shall provide a written inspection report to the HCO. If the OLC cites one or more licensing violations in the written inspection report, the administrator shall submit a written plan of correction in accordance with the provisions of 12VAC5-381-105.</u></p> <p><u>G. An HCO may:</u></p> <ol style="list-style-type: none"><u>1. Withdraw its reinstatement application at any time; and</u><u>2. Reapply for licensure pursuant to 12VAC5-381-40, provided that it pays the fee prescribed by 12VAC5-381-70, if:</u><ol style="list-style-type: none"><u>a. It withdraws its application pursuant to subdivision 1 of this subsection; or</u><u>b. The commissioner denies it reinstatement of licensure pursuant to this section, except that if the commissioner has denied an HCO reinstatement of licensure three times, the applicant may not apply for a new license for a period of two years from the date of the third denial.</u> <p><u>H. If the commissioner reinstates a license pursuant to this section, the effective date of the license shall be August 1 of the calendar year in which the HCO's prior license expired.</u></p> <p>Statutory Authority <u>§§32.1-12 and 32.1-162.9 of the Code of Virginia.</u></p> <p>INTENT: The intent of these proposed changes is to:</p> <ol style="list-style-type: none">(i) write this section in the active voice and break paragraphs with multiple requirements into subparts; and(ii) create a new licensure process for those HCOs that fail to timely renew their license and wish to
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			<p>remedy the situation within 30 days of expiration.</p> <p>RATIONALE: The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> (i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>; (ii) a licensure reinstatement process allows for some flexibility when an HCO does not timely renew, but still involves sufficient deterrents (such as the higher fee to reinstate a license) that HCOs should be remain incentivized to timely renew. <p>LIKELY IMPACT: The likely impact of these proposed changes is improved readability of the section and improved clarity about a regulant's options if it fails to timely renew its license.</p>														
381-70	N/A	<p>12VAC5-381-70. Fees.</p> <p>A. The OLC shall collect a fee of \$500 for each initial and renewal license application. Fees shall accompany the licensure application and are not refundable.</p> <p>B. An additional late fee of \$50 shall be collected for an organization's failure to file a renewal application by the date specified.</p> <p>C. A processing fee of \$250 shall be collected for each reissuance or replacement of a license and shall accompany the written request for reissuance or replacement.</p> <p>D. A one time processing fee of \$75 for exemption from licensure shall accompany the written exemption request.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p>	<p>CHANGE: The Board is proposing the following changes:</p> <p>12VAC5-381-70. Fees.</p> <p>A. The OLC shall collect a fee of \$500 for each initial and renewal license application. Fees shall accompany the licensure application and are not refundable. The department shall charge the following fees related to licensure and inspection of HCOs:</p> <table border="1" data-bbox="966 1323 1412 1890"> <tr> <td><u>Application fee for initial licensure</u></td> <td><u>\$2,000</u></td> </tr> <tr> <td><u>Re-application fee for initial licensure</u></td> <td><u>\$2,000</u></td> </tr> <tr> <td><u>Base application fee for renewal of licensure</u></td> <td><u>\$1,250</u></td> </tr> <tr> <td><u>Additional renewal fee for each branch office</u></td> <td><u>\$500</u></td> </tr> <tr> <td><u>Application fee for reinstatement of licensure</u></td> <td><u>\$2,500</u></td> </tr> <tr> <td><u>Additional reinstatement fee for each branch office</u></td> <td><u>\$750</u></td> </tr> <tr> <td><u>Processing fee for exemption from licensure</u></td> <td><u>\$125</u></td> </tr> </table>	<u>Application fee for initial licensure</u>	<u>\$2,000</u>	<u>Re-application fee for initial licensure</u>	<u>\$2,000</u>	<u>Base application fee for renewal of licensure</u>	<u>\$1,250</u>	<u>Additional renewal fee for each branch office</u>	<u>\$500</u>	<u>Application fee for reinstatement of licensure</u>	<u>\$2,500</u>	<u>Additional reinstatement fee for each branch office</u>	<u>\$750</u>	<u>Processing fee for exemption from licensure</u>	<u>\$125</u>
<u>Application fee for initial licensure</u>	<u>\$2,000</u>																
<u>Re-application fee for initial licensure</u>	<u>\$2,000</u>																
<u>Base application fee for renewal of licensure</u>	<u>\$1,250</u>																
<u>Additional renewal fee for each branch office</u>	<u>\$500</u>																
<u>Application fee for reinstatement of licensure</u>	<u>\$2,500</u>																
<u>Additional reinstatement fee for each branch office</u>	<u>\$750</u>																
<u>Processing fee for exemption from licensure</u>	<u>\$125</u>																

			<table border="1"> <tr> <td><u>Duplicate license fee</u></td> <td><u>\$25</u></td> </tr> <tr> <td><u>Fee for material change of license</u></td> <td><u>\$250</u></td> </tr> <tr> <td><u>Returned check fee</u></td> <td><u>\$50</u></td> </tr> </table> <p>B. An additional late fee of \$50 shall be collected for an organization's failure to file a renewal application by the date specified.</p> <p>C. A processing fee of \$250 shall be collected for each reissuance or replacement of a license and shall accompany the written request for reissuance or replacement.</p> <p>D. A one-time processing fee of \$75 for exemption from licensure shall accompany the written exemption request.</p> <p><u>B. In addition to the fees described in subsection A, the department shall charge a late fee of \$500 for any HCO that applies to renew its license fewer than 60 calendar days in advance of the license's expiration date.</u></p> <p><u>C. Unless otherwise provided, fees may not be refunded.</u></p> <p>Statutory Authority <u>§§ 32.1-12, 32.1-162.9, and 32.1-162.12 of the Code of Virginia.</u></p> <p>INTENT: The intent of these proposed changes is to:</p> <ul style="list-style-type: none"> (i) improve the readability of the fee schedule; (ii) increase fee revenue for the HCO licensure program; and (iii) clarify fees are nonrefundable. <p>RATIONALE: The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> (i) it is easier to identify the correct fees listed in a table rather than described in a narrative paragraph; (ii) the agency does not have sufficient fee revenue to support the staff needed to exercise effective oversight for HCOs and the fee structure should reflect that inspection of branch offices are part of the larger HCO licensure inspection, which 	<u>Duplicate license fee</u>	<u>\$25</u>	<u>Fee for material change of license</u>	<u>\$250</u>	<u>Returned check fee</u>	<u>\$50</u>
<u>Duplicate license fee</u>	<u>\$25</u>								
<u>Fee for material change of license</u>	<u>\$250</u>								
<u>Returned check fee</u>	<u>\$50</u>								

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

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

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

			<p>complainant, if known, will be notified of the findings of the investigation.</p> <p>D. As applicable, the administrator shall submit, within 15 working days of receipt of the complaint report, an acceptable plan of correction for any deficiencies found during a complaint investigation. The plan of correction shall contain:</p> <ol style="list-style-type: none">1. A description of the corrective action or actions to be taken and the personnel to implement the corrective action;2. The expected correction date;3. A description of the measures implemented to prevent a recurrence of the violation; and4. The signature of the person responsible for the validity of the report. <p>E. The administrator will be notified in writing whenever any item in the plan of correction is determined to be unacceptable.</p> <p>F. The administrator shall be responsible for assuring the plan of correction is implemented and monitored so that compliance is maintained.</p> <p><u>D. For any licensing violation cited during a complaint investigation, the administrator shall submit a plan of correction in accordance with 12VAC5-381-105.</u></p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p> <p>INTENT: The intent of these proposed changes is to:</p> <ol style="list-style-type: none">(i) rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; and(ii) give the OLC the flexibility to determine whether a complaint warrants an on-site inspection.
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			<p>RATIONALE: The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> (i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>; and (ii) encourage efficient and effective use of agency resources in responding to complaints. <p>LIKELY IMPACT: The likely impact of these proposed changes is improved readability of the section and a more adaptive and efficient complaint process.</p>
N/A	381-105	N/A	<p>CHANGE: The Board is proposing to add a new section as follows:</p> <p><u>12VAC5-381-105. Plan of correction.</u></p> <p><u>A. Upon receipt of a written inspection report, the administrator or his designee shall prepare a written plan of correction addressing each licensing violation cited at the time of inspection.</u></p> <p><u>B. The administrator shall submit to the OLC a written plan of correction no more than 15 business days after receipt of the inspection report. The plan of correction shall contain for each licensing violation cited:</u></p> <ul style="list-style-type: none"> <u>1. A description of the corrective action or actions to be taken and the position title of the employees to implement the corrective action. If employees share the same position title, the administrator shall assign the employees a unique identifier to distinguish them;</u> <u>2. The expected correction date, not to exceed 45 business days from the exit date of the inspection; and</u> <u>3. A description of the measures implemented to prevent a recurrence of the licensing violation.</u> <p><u>An HCO shall ensure that the person responsible for the validity of</u></p>

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

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

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

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

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

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

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

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

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

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

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

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

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

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

			<p>C. If an HCO operation intends to operate of a drop site as a business office, it shall constitute a separate organization and shall require licensure either be separately licensed as an HCO or be licensed as a branch office of a parent HCO.</p> <p>D. An inspector may inspect Drop a drop sites site shall be subject to inspection at any time pursuant to 12VAC5-381-80 or 12VAC5-381-100.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p> <p>INTENT: The intent of these proposed changes is to rewrite this section in the active voice and break paragraphs with multiple requirements into subparts.</p> <p>RATIONALE: The rationale behind these proposed changes is the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>.</p> <p>LIKELY IMPACT: The likely impact of these proposed changes is improved readability of this section.</p>
381-280	N/A	<p>12VAC5-381-280. Client record system.</p> <p>A. The organization shall maintain an organized client record system according to accepted standards of practice. Written policies and procedures shall specify retention, reproduction, access, storage, content, and completion of the record.</p> <p>B. The client record information shall be safeguarded against loss or unauthorized use.</p> <p>C. Client records shall be confidential. Only authorized personnel shall have access as specified by state and federal law.</p> <p>D. Provisions shall be made for the safe storage of the original record and for accurate and legible reproductions of the original.</p>	<p>CHANGE: The Board is proposing the following changes:</p> <p>12VAC5-381-280. Client <u>Clinical</u> record system.</p> <p>A. The organization <u>An HCO shall maintain an organized client clinical record system according to accepted standards of practice that includes the safe storage of the original record, and the accurate and legible reproductions of the original.</u></p> <p>B. <u>Unless otherwise specified by state or federal requirements, an HCO shall maintain originals or reproductions of clinical records in their entirety:</u></p> <p><u>1. For adult clients or patients, no less than five years from the date of discharge or of last contact; and</u></p>

		<p>E. Policies shall specify arrangements for retention and protection of records if the organization discontinues operation and shall provide for notification to the OLC and the client of the location of the records.</p> <p>F. An accurate and complete client record shall be maintained for each client receiving services and shall include, but shall not be limited to:</p> <ol style="list-style-type: none"> 1. Client identifying information; 2. Identification of the primary care physician; 3. Admitting information, including a client history; 4. Information on the composition of the client's household, including individuals to be instructed in assisting the client; 5. An initial assessment of client needs to develop a plan of care or services; 6. A plan of care or service that includes the type and frequency of each service to be delivered either by organization personnel or contract services; 7. Documentation of client rights review; and 8. A discharge or termination of service summary. <p>In addition, client records for skilled and pharmaceutical services shall include:</p> <ol style="list-style-type: none"> 9. Documentation and results of all medical tests ordered by the physician or other health care professional and performed by the organization's staff; 10. A medical plan of care including appropriate assessment and pain management; 11. Medication sheets that include the name, 	<p><u>2. For minor clients or patients, no less than five years after the minor reaches 18 years of age.</u></p> <p>Written policies and procedures shall specify retention, reproduction, access, storage, content, and completion of the record.</p> <p>B. C. An HCO shall safeguard <u>The client clinical record information shall be safeguarded</u> against loss or unauthorized use.</p> <p>C. D. An HCO shall ensure that Client clinical records shall be <u>are confidential and that Only only authorized personnel employees shall</u> have access as specified by state and federal law.</p> <p>D. Provisions shall be made for the safe storage of the original record and for accurate and legible reproductions of the original.</p> <p>E. Policies shall specify arrangements for retention and protection of records if the organization discontinues operation and shall provide for notification to the OLC and the client of the location of the records.</p> <p>F. E. An HCO shall maintain <u>An an accurate and complete client clinical record shall be maintained</u> for each client <u>or patient</u> receiving services and shall include, but shall not be limited to:</p> <ol style="list-style-type: none"> 1. Client <u>or patient</u> identifying information; 2. Identification of the primary care physician; 3. Admitting information, including a client <u>or patient</u> history; 4. Information on the composition of the client's <u>or patient's</u> household, including individuals to be instructed in assisting the client <u>or patient</u>; 5. An initial <u>and all subsequent</u> assessment of client <u>or patient</u> needs to develop a <u>medical plan of care or services plan of care</u>;
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		<p>dosage, frequency of administration, possible side effects, route of administration, date started, and date changed or discontinued for each medication administered; and</p> <p>12. Copies of all summary reports sent to the primary care physician.</p> <p>G. Signed and dated notes on the care or services provided by each individual delivering service shall be written on the day the service is delivered and incorporated in the client record within seven working days.</p> <p>H. Entries in the client record shall be current, legible, dated and authenticated by the person making the entry. Errors shall be corrected by striking through and initialing.</p> <p>I. Originals or reproductions of individual client records shall be maintained in their entirety for a minimum of five years following discharge or date of last contact unless otherwise specified by state or federal requirements. Records of minors shall be kept for at least five years after the minor reaches 18 years of age.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p>	<p>6. A <u>medical plan of care or service plan of care</u> that includes:</p> <ul style="list-style-type: none"> a. the <u>The</u> type and frequency of each service to be delivered <u>furnished</u>; b. <u>Who shall furnish the services and when either by organization personnel or contract services</u>; c. <u>Prescription drugs or nonprescription drugs to be administered and the route of administration, including if self-administered</u>; d. <u>Documentation of supervisory visits, including date, time, review of the medical plan of care or plan of care, services provided to date, and client or patient assessments; and</u> e. <u>Interruptions in service and an explanation for any such interruption</u>; <p>7. Documentation of client <u>and patient</u> rights review; and</p> <p>8. A <u>written</u> discharge or termination of service summary <u>that records the service delivered and final disposition at the time of client's or patient's discharge or termination from service</u>.</p> <p>E. In addition, <u>An HCO shall include in client clinical records for skilled and pharmaceutical services shall include:</u></p> <ul style="list-style-type: none"> 9. <u>1.</u> Documentation and results of all medical tests ordered by the physician or other health care professional practitioner and performed by the organization's staff <u>HCO employees</u>; 10. <u>2.</u> A medical plan of care including appropriate assessment and pain management;
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			<p>41. 3. Medication sheets that include the name, dosage, frequency of administration, possible side effects, route of administration, date started, and date changed or discontinued for each medication administered; and</p> <p>42. 4. Copies of all summary reports sent to the primary care physician <u>who signed the medical plan of care.</u></p> <p>G. <u>An HCO shall ensure that:</u></p> <p>1. Signed and dated notes on the care or services provided by each individual delivering service shall be <u>are</u> written on the day the service is delivered;</p> <p>2. and incorporated <u>Signed and dated notes on the care or services provide are incorporated</u> in the <u>client clinical</u> record within seven <u>working calendar days</u>;</p> <p>H. 3. Entries in the <u>client clinical</u> record shall be <u>are</u> current, legible, dated and authenticated by the person making the entry; <u>and</u></p> <p>4. Errors shall be <u>are</u> corrected by striking through and initialing.</p> <p>I. Originals or reproductions of individual client records shall be maintained in their entirety for a minimum of five years following discharge or date of last contact unless otherwise specified by state or federal requirements. Records of minors shall be kept for at least five years after the minor reaches 18 years of age.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p> <p>INTENT: The intent of these proposed changes is to:</p> <p>(i) rewrite this section in the active voice and break paragraphs with</p>
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			<p>multiple requirements into subparts; and</p> <p>(ii) improve clarity about minimum documentation for the medical plans of care and plans of care.</p> <p>RATIONALE: The rationale behind these proposed changes is:</p> <p>(i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>; and</p> <p>(ii) requiring medical plans of care and plans of care to only address type and frequency of service provides an incomplete accounting of care to be provided, which can complicate inspections, particularly of complaints.</p> <p>LIKELY IMPACT: The likely impact of these proposed changes is improved readability of this section and clearer documentation for the client, the patient, the HCO, and the agency to review when there is a complaint.</p>
381-290	N/A	<p>12VAC5-381-290. Home attendants.</p> <p>Home attendants shall be able to speak, read and write English and shall meet one of the following qualifications:</p> <ol style="list-style-type: none"> 1. Have satisfactorily completed a nursing education program preparing for registered nurse licensure or practical nurse licensure; 2. Have satisfactorily completed a nurse aide education program approved by the Virginia Board of Nursing; 3. Have certification as a nurse aide issued by the Virginia Board of Nursing; 4. Be successfully enrolled in a nursing education program preparing for registered nurse or practical nurse licensure and have currently completed at least one nursing course 	<p>CHANGE: The Board is proposing the following changes:</p> <p>12VAC5-381-290. Home attendants.</p> <p>A. An HCO shall ensure that its Home home attendants shall be <u>are</u> able to speak, read, and write English and shall meet one of the following qualifications:</p> <ol style="list-style-type: none"> 1. Have satisfactorily completed a nursing education program preparing for registered nurse licensure or practical nurse licensure; 2. Have satisfactorily completed a nurse aide education program approved by the Virginia Board of Nursing; 3. Have <u>active</u> certification as a nurse aide issued by the Virginia Board of Nursing; 4. Be successfully enrolled in a nursing education program preparing for registered nurse

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

	<p>C. Verbal orders shall be documented within 24 consecutive hours in the client's record by the health care professional receiving the order and shall be countersigned by the prescribing person.</p> <p>D. The primary care physician shall be notified immediately of any changes in the client's condition that indicates a need to alter the medical plan of care.</p> <p>E. The medical plan of care shall be reviewed, approved, and signed by the primary care physician at least every 60 days.</p> <p>F. There shall be a director of skilled services, who shall be a physician licensed by the Virginia Board of Medicine or a registered nurse, responsible for the overall direction and management of skilled services including the availability of services, the quality of services and appropriate staffing. The individual shall have the appropriate experience for the scope of services provided by the organization.</p> <p>G. The organization shall develop and implement policies and procedures for the handling of drugs and biologicals, including procurement, storage, administration, self-administration, and disposal of drugs and shall allow clients to procure their medications from a pharmacy of their choice.</p> <p>H. All prescription drugs shall be prescribed and properly dispensed to clients according to the provisions of Chapters 33 (§ 54.1-3300 et seq.) and 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia and the regulations of the Virginia Board of Pharmacy, except for prescription drugs authorized by § 54.1-3408 of the Drug Control Act, such as epinephrine for emergency administration, normal saline and heparin flushes for the maintenance of IV lines, and adult immunizations, which</p>	<p>4. Orders for medications, when applicable; and</p> <p>5. Orders for special dietary or nutritional needs, when applicable.</p> <p><u>An HCO shall ensure The the medical plan of care shall be is approved and signed by the client's primary care patient's physician.</u></p> <p><u>C. An HCO shall ensure Verbal oral orders shall be are:</u></p> <ol style="list-style-type: none"> <u>1. documented Documented within no more than 24 consecutive hours in the client's clinical record by the actively licensed health care professional practitioner receiving the order; and</u> <u>2. shall be countersigned Countersigned by the prescribing person actively licensed health care practitioner.</u> <p><u>D. An HCO shall immediately notify a patient's The primary care physician shall be notified immediately of any changes in the client's patient's condition that indicates a need to alter the medical plan of care.</u></p> <p><u>E. An HCO shall ensure The the medical plan of care shall be is reviewed, approved, and signed by the patient's primary care physician at least every 60 calendar days.</u></p> <p><u>F. An HCO shall appoint in writing There shall be a director of skilled services, who shall:</u></p> <ol style="list-style-type: none"> <u>1. be Be a physician actively licensed by the Virginia Board of Medicine or a registered nurse actively licensed by the Virginia Board of Nursing;:</u> <u>2. Be responsible for the overall direction and management of skilled services including the availability of services, the quality of services and appropriate staffing; and</u> <u>3. The individual shall have Have the appropriate</u>
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		<p>may be given by a nurse pursuant to established protocol.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p>	<p>experience for the scope of services provided by the organization <u>HCO</u>.</p> <p>G. The organization shall develop and implement policies and procedures for the handling of drugs and biologicals, including procurement, storage, administration, self-administration, and disposal of drugs and shall allow clients to procure their medications from a pharmacy of their choice.</p> <p>H. All prescription drugs shall be prescribed and properly dispensed to clients according to the provisions of Chapters 33 (§ 54.1-3300 et seq.) and 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia and the regulations of the Virginia Board of Pharmacy, except for prescription drugs authorized by § 54.1-3408 of the Drug Control Act, such as epinephrine for emergency administration, normal saline and heparin flushes for the maintenance of IV lines, and adult immunizations, which may be given by a nurse pursuant to established protocol.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p> <p>INTENT: The intent of these proposed changes is to:</p> <ul style="list-style-type: none"> (i) rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; (ii) remove language regarding drug policies and procedures; and (iii) rewrite this section so as to avoid scope of practice conflicts with health profession regulations. <p>RATIONALE: The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> (i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>; (ii) language about drug policies and procedures has been moved to
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			<p>section 180, which is entitled “Policies and procedures”; and</p> <p>(iii) scope of practice of health care practitioners is the regulatory purview of the Department of Health Professions.</p> <p>LIKELY IMPACT: The likely impact of these proposed changes is improved readability of this section.</p>
<p>381-310</p>	<p>N/A</p>	<p>12VAC5-381-310. Nursing services.</p> <p>A. All nursing services shall be directly provided by an appropriately qualified registered nurse or licensed practical nurse, except for those nursing tasks that may be delegated by a registered nurse according to 18VAC90-20-420 through 18VAC90-20-460 of the regulations of the Virginia Board of Nursing and with a plan developed and implemented by the organization.</p> <p>B. Supervision of services shall be provided as often as necessary as determined by the client’s needs, the assessment by the registered nurse, and the organization’s written policies not to exceed 90 days.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p>	<p>CHANGE: The Board is proposing the following changes:</p> <p>12VAC5-381-310. Nursing services.</p> <p>A. <u>An HCO shall ensure that All all nursing services shall be are:</u></p> <ol style="list-style-type: none"> <u>1. directly</u> Directly provided by an <u>actively licensed and</u> appropriately qualified registered nurse or licensed practical nurse;<u>;</u> <u>or</u> <u>2. By a person to whom except for those nursing tasks that may be are</u> delegated by a registered nurse <u>according to in accordance with 18VAC90-20-420 through 18VAC90-20-460 of the regulations of the Virginia Board of Nursing Part VI (18VAC90-19-240 et seq.) of the Regulations Governing the Practice of Nursing</u> and with a plan developed and implemented by the organization <u>HCO.</u> <p>B. <u>An HCO shall ensure that nursing services are supervised in person in the patient’s residence</u> <u>Supervision of services shall be provided as often as necessary, but not less often than every 60 calendar days,</u> as determined by:</p> <ol style="list-style-type: none"> <u>1. the The client’s patient’s needs;</u> <u>2. the The assessment by the registered nurse;</u> and <u>3. the The organization’s HCO’s written policies not to exceed 90 days.</u> <p>Statutory Authority</p>

			<p>§§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p> <p>INTENT: The intent of these proposed changes is to:</p> <ul style="list-style-type: none"> (i) rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; and (ii) match in-person supervision interval to the update interval for medical plans of care. <p>RATIONALE: The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> (i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>; and (ii) in-person supervision of nursing services can be conducted at the same time of assessments of patient needs for the medical plan of care . <p>LIKELY IMPACT: The likely impact of these proposed changes is improved readability of this section and reduce burden to the HCOs who can combine medical plan of care updates and in-person supervision into a single visit.</p>
381-320	N/A	<p>12VAC5-381-320. Therapy services.</p> <p>A. Physical therapy, occupational therapy, speech therapy, or respiratory therapy services shall be provided according to the medical plan of care by or under the direction of an appropriately qualified therapist currently licensed in Virginia and may include, but are not limited to:</p> <ul style="list-style-type: none"> 1. Assessing client needs or admission for service as appropriate; 2. Implementing a medical plan of care and revising as necessary; 3. Initiating appropriate preventive, therapeutic, and rehabilitative 	<p>CHANGE: The Board is proposing the following changes:</p> <p>12VAC5-381-320. Therapy services.</p> <p>A. <u>An HCO shall ensure that Physical physical</u> therapy, occupational therapy, speech therapy <u>language pathology</u>, or respiratory therapy services shall be <u>are</u> provided according to the medical plan of care by or under the direction of an appropriately qualified therapist currently <u>actively</u> licensed in Virginia and may shall <u>shall</u> include, but are not <u>limited to:</u></p> <ul style="list-style-type: none"> 1. Assessing client <u>the patient's</u> needs or admission for service as appropriate;

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

	<p>A. Home attendants assisting with providing skilled services may:</p> <ol style="list-style-type: none"> 1. Assist clients with (i) activities of daily living, (ii) ambulation and prescribed exercise, and (iii) other special duties with appropriate training and demonstrated competency; 2. Administer normally self-administered drugs as allowed by § 54.1-3408 of the Virginia Drug Control Act (Chapter 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia); 3. Measure and record fluid intake and output; 4. Take and record blood pressure, pulse and respiration; 5. Record and report to the appropriate health care professional changes in the client's condition; 6. Document services and observations in the client's record; and 7. Perform any other duties that the attendant is qualified to do by additional training and demonstrated competency as allowed by state or federal guidelines. <p>B. Prior to the initial delivery of services, the home attendant shall receive specific written instructions for the client's care from the appropriate health care professional responsible for the care.</p> <p>C. Home attendants shall work under the supervision of the appropriate health care professional responsible for the client's care.</p> <p>D. Relevant in-service education or training for home attendants shall consist of at least 12 hours annually. In-service</p>	<p>12VAC5-381-330. Home attendants assisting with skilled services.</p> <p>A. <u>An HCO that employs or contracts with Home home attendants assisting to assist with providing skilled services may permit home attendants, consistent with the medical plan of care, to:</u></p> <ol style="list-style-type: none"> 1. Assist clients <u>patients</u> with (i) activities of daily living, (ii) ambulation, and prescribed restorative <u>restorative</u> exercise, and (iii) other special duties with appropriate training and demonstrated competency; 2. Administer normally self-administered drugs as allowed by § 54.1-3408 of the Virginia Drug Control Act (Chapter 34 (§ 54.1-3400 et seq.) <u>(§ 54.1-3400 et seq. of Title 54.1 of the Code of Virginia)</u>); 3. Measure and record fluid intake and output; 4. Take and record blood pressure, pulse and respiration; 5. Record and report to the appropriate <u>actively licensed</u> health care professional <u>practitioner</u> changes in the client's <u>patient's</u> condition; 6. Document services and observations in the client's <u>clinical</u> record; and 7. Perform any other duties that the attendant is qualified to do by additional training and demonstrated competency as allowed by state or federal guidelines. <p>B. Prior to the initial delivery of services, <u>an HCO shall ensure that the home attendant</u> shall receive <u>receives</u> specific written instructions for the client's <u>patient's</u> care from the appropriate <u>actively licensed</u> health care professional <u>practitioner</u> responsible for the care.</p> <p>C. <u>An HCO shall ensure that a Home attendants</u> <u>home attendant:</u></p>
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		<p>training may be in conjunction with on-site supervision.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p>	<p>1. shall work Works under the supervision of the appropriate <u>actively licensed</u> health care professional <u>practitioner</u> responsible for the client's <u>patient's</u> care, with supervision being conducted in-person at least once every 60 calendar days; and</p> <p>D. Relevant in service education or training for home attendants shall consist of at least <u>2. Completes no less than 12 hours annually of in-service education or training, which in-service training may be in conjunction with on-site supervision.</u></p> <p>Statutory Authority §§ 32.1-12 and 32.1-162.12 of the Code of Virginia.</p> <p>INTENT: The intent of these proposed changes is to:</p> <ul style="list-style-type: none"> (i) rewrite this section in the active voice and break paragraphs with multiple requirements into subparts; and (ii) specify that home attendants that assist in skilled services are subject to in-person supervision. <p>RATIONALE: The rationale behind these proposed changes is:</p> <ul style="list-style-type: none"> (i) the active voice and the use of subparts are the style preferred and recommended by <i>The Virginia Register of Regulations</i>; and (ii) resolve ambiguity in the current regulation about how frequently home attendants that assist in skilled services are subject to in-person supervision. <p>LIKELY IMPACT: The likely impact of these proposed changes is improved readability of this section and reduced confusion for regulants on minimum supervision standards.</p>
381-340	N/A	<p>12VAC5-381-340. Medical social services.</p>	<p>CHANGE: The Board is proposing the following changes:</p>

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

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