

## Rules and Regulations for the Licensure of Home Care Organizations

Chapter 381.  
Regulations for the Licensure of Home Care Organizations

PART I.  
DEFINITIONS AND GENERAL INFORMATION.

12 VAC 5-381-10. Definitions.

The following words and terms, when used in this chapter, shall have the following meaning unless the context clearly indicates otherwise.

“Activities of daily living (ADL’s)” means the functions or tasks which are performed either independently or with supervision or assistance, i.e., transferring, bathing, dressing, feeding, toileting, bowel control, and bladder control.

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

“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 a full-time employee. The administrator and the director of nursing may be the same individual if that individual is dually qualified.

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

“Barrier crimes” means certain offenses, specified in § 32.1-162.9:1 of the Code of Virginia, which automatically bar an individual convicted of those offenses from employment with a home care organization.

"Bylaws" means a set of rules adopted by the governing body for governing the organization. Bylaws are the written framework for governance that establishes the roles and responsibilities of a governing body and its members.

“Clinical note” means a written statement contained within a patient’s home care record, dated and signed by the person delivering the care, treatment or service, describing the treatment or services delivered and the effect of the care, treatment or services on the patient’s medical condition.

“Commissioner” means the State Health Commissioner.

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"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.

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

"Department" means the Virginia Department of Health.

"Direction" means the authority to carry out policy and give procedural guidance to accomplish a function or activity.

"Discharge summary" means a final written summary filed in a closed medical record of the service delivered, goals achieved and final disposition at the time of patient's discharge from service.

"Dispense" means to deliver a drug to an ultimate user by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling or compounding necessary to prepare the substance for that delivery as defined in § 54.1-3401 of Title 54.1 of the Code of Virginia.

"Employee" means an individual who has the status of an employee as defined by the U.S. Internal Revenue Service.

"Environmental services" means home maintenance or meal preparation services relating to the needs of the patient.

"Full-time" means a minimum of a 37 1/2 hour work week.

"Governing body" means the individual, group or governmental agency that has legal responsibility and authority over the operation of the home care organization.

"Home attendant" means a non-licensed individual performing personal care and environmental services, under the supervision of the appropriate health professional, to a patient in the patient's residence. Home attendants are also known as home care aides, home health aides, and personal care aides.

"Home care organization" means a public or private organization that provides the services as defined in § 32.1-162.7 in the Code of Virginia, in the residence of a patient or individual in Virginia.

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“Home care record” means a continuous and accurate written account of services provided to a patient, including information that has been dated and signed by the individuals who prescribed or delivered the treatment or care.

“Immediately” means within 24 consecutive hours.

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

“Licensee” means a licensed home care provider.

“Medical plan of care” means a written plan of services, and items needed to treat a patient’s medical condition, that is prescribed, signed and periodically reviewed by the patient’s primary care physician.

“Nursing services” means 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.

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

“Organization” means a home care organization.

“Patient’s residence” means the place where the individual 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 hospital, nursing facility or other extended care facility.

“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.

“Personal care services” means the provision of assistance in the activities of daily living and may include supplemental or complimentary non-medical services related to the needs of the patient to maintain the patient’s health and safety in their home. Personal care services include, but are not limited to, meal preparation, chore, housekeeping and other supportive services.

“Primary care physician” means a physician licensed in Virginia, according to Chapter 29 of Title 54.1 (§ 54.1-2900 et seq.) of the Code of Virginia, or licensed in an adjacent state and identified by the patient as having the primary responsibility in determining the delivery of the patient's medical care.

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

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

"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.

"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.

"Surety bond" a consumer safeguard that directly protects patients from injuries and losses resulting from the negligent or criminal acts of contractors of the home care organization that are not covered under the organization's liability insurance. A fidelity type of surety bond, which covers dishonest acts such as larceny, theft, embezzlement, forgery, misappropriation, wrongful abstraction or willful misapplication, will meet the requirements of surety bond coverage for the purposes of this chapter.

"Sworn disclosure" means a document to be completed, signed, and submitted for employment. The documents discloses an applicant's criminal convictions and pending criminal charges occurring in Virginia or any other state.

"The Center" means the Center for Quality Health Care Services and Consumer Protection of the Virginia Department of Health.

12 VAC 5-381-20. Responsibility of the department.

A. The department, pursuant to Article 7.1 (§ 32.1-162.7 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia, is charged with the responsibility for ensuring that home care organizations provide patient care according to the requirements specified by the Code and the regulations of the Board of Health.

B. The center acts as agent for the department in administering the licensing program, which includes investigating complaints made by the public against home care organizations.

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C. Section 32.1-162.12 of the Code of Virginia requires the Board of Health to adopt standards and regulations for the licensure of home care organizations. The department is the authorized agent for the Board.

D. In developing or revising licensing regulations for home care organizations, the department adheres to the requirements of the Administrative Process Act (Chapter 40 of Title 2.2 of the Code of Virginia) and the public participation process. The department solicits input from licensees, associations of licensees, experts in related fields, advocacy organizations, consumers and the general public in the development or revision of licensing regulations through informal and formal comment periods and, if necessary, public hearings.

12 VAC 5-381-30. License.

A. A license to operate a home care organization is issued to a person. Persons planning to seek federal certification or national accreditation pursuant to § 32.1-162.8 of the Code of Virginia must first obtain state licensure.

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

C. A separate license shall be required for home care organizations maintained at separate locations, even though they are owned or are operated under the same management.

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

E. Licenses shall not be transferred or assigned.

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.

12 VAC 5-381-40. Exemption from licensure.

A. This chapter is not applicable to those individuals and home care organizations listed in § 32.1-162.8 of the Code of Virginia. Organizations planning to seek federal certification or national accreditation must obtain state licensure prior to applying for national accreditation or federal certification.

B. A licensed organization requesting exemption must file a written request and pay the required fee stated in 12 VAC 5-381-70 D of this chapter.

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C. The home care organization shall be notified in writing if the exemption from licensure has been granted and any conditions by which the home care organization must abide.

D. Exempted organizations are subject to complaint investigations in keeping with state law.

12 VAC 5-381-50. License application; initial and renewal.

A. The Center provides pre-licensure consultation and technical assistance regarding the licensure process. The purpose of such consultation is to explain the regulation and review an applicant's proposed program plans, forms, and other documents, as they relate to the regulation. Pre-licensure consultations are arranged after an initial application has been filed.

B. Licensure applications are obtained from the Center. The Center shall consider an application complete when all requested information and the appropriate fee, stated in 12 VAC 5-381-70 of this chapter, is submitted. If the Center finds the application incomplete, the applicant will be notified in writing.

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

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

E. Licenses are renewed annually. The Center shall send a renewal application at least 60 days prior to the expiration date of the current license.

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

12 VAC 5-381-70. Compliance appropriate for type of HCO.

All organizations shall be in compliance with Part I (12 VAC 5-381-10 et seq.) and Part II (12 VAC 5-381-160 et seq.). In addition, organizations shall be in compliance with Part III (12 VAC 5-381-300 et seq.), Part IV (12 VAC 5-381-350 et seq.), or Part V (12 VAC 5-381-360 et seq.) as applicable to the services provided by the organization.

12 VAC 5-381-60. Changes to or re-issue of a license.

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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.

B. An organization shall give written notification 30 working days in advance of any proposed changes that may require the re-issuance of a license as determined by the Center. Notices shall be sent to the attention of the Director of the Center for Quality Health Care Services and Consumer Protection.

The following changes require the re-issuance of a license and payment of a fee:

1. Operator;
2. Organization name; or
3. Address.

C. The Center 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.

D. The organization will be notified in writing whether a license can be re-issued or a new application is needed.

12 VAC 5-381-70. Fees.

A. The Center shall collect a fee of \$500.00 for each initial and renewal license application. Fees shall accompany the licensure application and are not refundable.

B. An additional late fee of \$50.00 shall be collected for an organization's failure to file a renewal application by the date specified.

C. A processing fee of \$250.00 shall be collected for each re-issuance or replacement of a license and shall accompany the written request for re-issuance or replacement.

D. A one time processing fee of \$75.00 for exemption from licensure shall accompany the written exemption request.

12 VAC 5-381-80. On-site inspections.

A. A Center 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 Center.

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B. The home care organization shall make available to the Center'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.

C. After the on-site inspection, the Center's representative shall discuss the findings of the inspection with the administrator or his designee.

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

1. A description of the corrective action or actions to be taken and the personnel to implement the corrective action;
2. The expected correction date;
3. A description of the measures implemented to prevent a recurrence of the violation; and
4. The signature of the person responsible for the validity of the report.

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

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

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

12 VAC 5-381-90. Home visits.

A. As part of any inspection, a Center representative may conduct home visits.

B. The home care organization shall be responsible for arranging in-home visits with patients, family members, and caregivers for the Center's representative.

C. The organization shall explain clearly to the patient, 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 patient's care or other health benefits.

12 VAC 5-381-100. Complaint investigation.

A. The Center has the responsibility to investigate any complaints regarding alleged violations of this chapter and applicable law.

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



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

D. As applicable, the administrator shall submit an acceptable plan of correction for any deficiencies found during a complaint investigation.

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

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

12 VAC 5-381-110. Criminal records checks.

A. Section 32.1-162.9:1 of the Code of Virginia requires home care providers, as defined in § 32.1-162.7 of the Code, to obtain a criminal record report on applicants for compensated employment from the Virginia Department of State Police. Section 32.1-162.9:1 also requires that all applicants for employment in home care organizations provide a sworn disclosure statement regarding their criminal history.

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

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

D. 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:

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.

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

F. 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 organization. The following exceptions are permitted:

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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. A criminal record report for an individual who takes a leave of absence 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.

G. The 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.

H. 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.

I. All criminal records reports shall be confidential and maintained in locked files accessible only to the administrator or designee.

J. 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.

12 VAC 5-381-120. Variances.

A. The Center 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.

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

C. The Center shall have the authority to waive, either temporarily or permanently, the enforcement of one or more of these regulations provided safety, patient care and services are not adversely affected.

D. The Center may rescind or modify a variance if: (i) conditions change; (ii) additional information becomes known which alters the basis for the original decision; (iii) the organization

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fails to meet any conditions attached to the variance; or (iv) results of the variance jeopardize the safety, comfort, or well-being of patients.

E. Consideration of a variance is initiated when a written request is submitted to the Director, Center for Quality Health Care Services and Consumer Protection. The Center shall notify the home care organization in writing of the receipt of the request for a variance. The Center may attach conditions to a variance to protect the safety and well being of the patient.

F. When the decision is to deny a variance, the licensee shall be notified in writing.

G. If a variance is denied, expires, or is rescinded, routine enforcement of the regulation or portion of the regulation shall be resumed.

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 center.

12 VAC 5-381-130. Revocation or suspension of a license.

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.

B. If a license is revoked, the commissioner may issue a new license when the conditions upon which revocation was based have been corrected and compliance with all provisions of the law and this chapter has been achieved.

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

D. Suspension of a license shall in all cases be for an indefinite time. The suspension may be lifted and rights under the license fully or partially restored at such time as the commissioner determines that the rights of the licensee appear to so require and the interests of the public will not be jeopardized by resumption of operation.

12 VAC 5-381-140. Surrender of a license.

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

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B. The licensee shall notify its patients and the Center, in writing, 30 days before discontinuing services.

C. If the organization is no longer operational, or the license has been suspended or revoked, the license shall be returned to the Center within five working days. The licensee shall notify the organization's patients and the Center where all home care records will be located.

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PART II.  
ADMINISTRATIVE SERVICES.

12 VAC 5-381-150. Management and Administration.

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

B. The organization must comply with:

1. This chapter (12 VAC 5-381-10 et seq.);
2. Other applicable federal, state or local laws and regulations; and
3. The organization's own policies and procedures.

C. The organization shall submit, or make available, reports and information necessary to establish compliance with this chapter and applicable law.

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

1. Verify application information;
2. Determine compliance with this chapter;
3. Review necessary records and documents; and
4. Investigate complaints.

E. The organization shall notify the Center 30 days in advance of changes effecting the organization, including the:

1. Service area;
2. Mailing address of the organization;
3. Ownership;
4. Services provided;
5. Operator;
6. Administrator;
7. Organization name; and
8. Closure of the organization.

F. The current license from the department shall be posted for public inspection.

G. Service providers or community affiliates under contract with the organization must comply with the organization's policies and this chapter.

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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.

I. The organization shall have regular posted business hours and be fully operational during business hours. Services shall be available on an emergency basis 24 hours a day, seven days a week.

J. The organization shall accept a patient only when the organization can adequately meet that patient's medical, rehabilitation, or medical social service needs in the patient's place of residence.

K. The organization must have a prepared plan for emergency operations in case of inclement weather or natural disaster to include contacting and providing essential care to patients, coordinating with community agencies to assist as needed, and maintaining a current list of patients who would require specialized assistance.

12 VAC 5-381-160. 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 adopt, and review periodically review but not less often than every 2 years, to organization's written by-laws. The governing body shall describe the organizational structure, including the:

1. Organization's objectives;
2. Scope of services;
3. Relationship of the organization's services to other services operated by the governing body; and
4. Establishment of 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.

12 VAC 5-381-170. Administrator.

A. The governing body shall appoint as administrator an individual who has evidence of at least 1 year of training and experience in health service administration with at least one year,

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within the last five years, of supervisory or administrative experience in home health care or a related health program.

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

1. Organizing and supervising the administrative function of the organization;
2. Maintaining an on-going 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 action in response to reports of organization committees and regulatory agencies;
7. Arranging and negotiating services provided through contractual agreement; and
8. Implementing the policies and procedures approved by the governing body.

C. An individual who meets the qualifications of subsection A of this section shall be designated to perform the duties of the administrator when the administrator is absent from the organization.

Organizations shall have one year from the effective date of this chapter to ensure that individuals currently designated meet the qualifications of subsection A of this section.

D. The administrator or his designee shall be available at all times during operating hours and for emergency situations.

12 VAC 5-381-180. 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 changes submitted to the governing body for approval, as necessary.

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

1. Administrative records;
2. Admission and discharge criteria;
3. Informed consent;
4. Advance directives, including Durable Do Not Resuscitate Orders;
5. Patient rights;

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6. Contract services;
7. Medication management;
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. Home care records, including confidentiality;
12. Record retention, including termination of services;
13. Supervision and delivery of services;
14. Emergency and after-hour care;
15. Infection control
16. Handling consumer complaints; and
17. Approved variances.

D. Financial policies and procedures shall include, but are not limited to:

1. Admission agreements;
2. Data collection and verification of services delivered;
3. Methods of billing for services by the organization and by contractors;
4. Patient notification of changes in fees and charges;
5. Correction of billing errors and refund policy; and
6. Collection of delinquent patient accounts.

E. Personnel policies and procedures shall include a, but are not limited to:

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
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.

F. Admission and discharge policies and procedures shall include, but are not limited to:

1. Criteria for accepting patients for services offered;
2. The process for obtaining a plan of care;



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3. Criteria for determining discharge from each service and referral to other agencies or community services; and

4. Process for notifying patients of intent to discharge or refer, including:

a. Oral and written notice and explanation of the reason for discharge or referral;

b. The name, address, telephone number and contact name at the referral organization; and

c. Documentation in the home care record of the referral or notice.

G. Policies shall be made available for review, upon request, to patients and their designated representatives.

H. Policies and procedures shall be readily available for staff use at all times.

12 VAC 5-381-190. Financial controls.

A. The organization shall document financial resources to operate its services or shall have a line of credit sufficient to cover 90 days of operating expenses.

B. All financial records shall be kept according to generally accepted accounting principles (GAAP).

C. All financial records shall be audited at least triennially by an independent Certified Public Accountant (CPA) or audited as otherwise provided by law.

D. The organization shall have documented financial controls to minimize risk of theft or embezzlement.

12 VAC 5-381-200. Personnel practices.

A. Personnel management and employment practices shall comply with applicable state and federal laws and regulations.

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 patients.

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

D. The organization shall design and implement a mechanism to verify professional credentials.

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

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

G. Each employee position shall have a written job description that includes:

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.

H. Employees shall have access to their current position description. There shall be a mechanism for advising employees of changes to their job responsibilities.

I. New employees and contract individuals shall be oriented commensurate with their function or job-specific responsibilities. Orientation shall include:

1. Objectives and philosophy of the organization;
2. Practices of confidentiality;
3. Practices that assure patient rights;
4. Mandated reporting of abuse, neglect, and exploitation;
5. Applicable personnel policies;
6. Emergency preparedness procedures;
7. Infection control practices and measures; and
8. Applicable laws, regulations, and other policies and procedures that apply to specific positions, specific duties and responsibilities.

J. The organization shall develop and implement a policy for evaluating employee performance.

K. Individual staff development needs and plans shall be a part of the performance evaluation.

L. The organization shall provide opportunities for and record participation in staff development activities designed to enable staff to perform the responsibilities of their positions.

M. All individuals who enter a patient's home for or on behalf of the organization shall be readily identifiable by employee nametag, uniform or other visible means.

N. The organization shall maintain an organized system to manage and protect the confidentiality of personnel files and records.

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O. Employee personnel records, whether hard copy or electronic, shall include:

1. Identifying information;
  2. Education and training history;
  3. Employment history;
  4. Results of the verification of applicable professional licenses or certificates;
  5. Results of reasonable efforts to secure job-related references and reasonable verification of employment history;
  6. Results of performance evaluations;
  7. A record of disciplinary actions taken by the organization, if any;
  8. A record of adverse action by any licensing bodies and organizations, if any;
  9. A record of participation in staff development activities, including orientation;
- and
10. The criminal record check and sworn affidavit.

P. Each employee personnel record shall be retained in its entirety for a minimum of three years after termination of employment.

Q. Personnel record information shall be safeguarded against loss and unauthorized use.

R. Employee health-related information shall be maintained separately within the employee's personnel file.

12 VAC 5-381-210. Indemnity coverage.

A. The governing body shall ensure the organization and its contractors have appropriate indemnity coverage to compensate patients for injuries and losses resulting from services provided.

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

1. Blanket 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 liable and slander of at least \$1,000,000 comprehensive general liability per occurrence;
3. Surety bond coverage of \$50,000 minimum.

12 VAC 5-381-220. Contract services.

A. There shall be a written agreement for the provision of services not provided by employees of the organization.

## Rules and Regulations for the Licensure of Home Care Organizations

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

1. The services to be furnished by each party to the contract;
2. The contractor's responsibility for participating in developing plans of care;
3. The manner in which services will be controlled, coordinated, and evaluated by the primary home care organization;
4. The procedures for submitting clinical and progress notes, scheduling of visits, and periodic patient evaluation;
5. The process for payment for services furnished under the contract; and
6. Adequate liability insurance and surety bond coverage.

C. The organization shall have a written plan for provision of services when a contractor is unable to deliver services.

D. The contractor shall conform to applicable organizational policies and procedures as specified in the contract, including the required affidavit and criminal record check.

12 VAC 5-381-230. Patient Rights.

A. The organization shall establish and implement written policies and procedures regarding the rights of patients.

B. Patient rights shall be reviewed with patients or patient designees upon admission to the organization. The review shall be documented in the patient's record.

C. Written procedures to implement the policies shall ensure that each patient is:

1. Treated with courtesy, consideration and respect and is assured the right of privacy;
2. Assured confidential treatment of his medical and financial records as provided by law;
3. Free from mental and physical abuse, neglect, and property exploitation;
4. Assured the right to participate in the planning of the patient'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 patient;
8. Advised orally and in writing of any changes in fees for services that are the patient's responsibility. The home care organization shall advise the patient of these changes as

## Rules and Regulations for the Licensure of Home Care Organizations

soon as possible, but no later than 30 calendar days from the date the home care organization became aware of the change;

9. Provided with advance directive information prior to start of services; and

10. Given at least 5 days written notice when the organization determines to terminate services.

D. Before care is initiated, the home care organization shall inform the patient, orally and in writing, of:

1. The nature and frequency of services to be delivered and the purpose of the service;

2. Any anticipated effects of treatment, as applicable;

3. A schedule of fees and charges for services;

4. The method of billing and payment for services, including the:

a. Services to be billed to third party payers;

b. Extent to which payment may be expected from third party payers known to the home care organization;

c. Charges for services that will not be covered by third party payers;

5. The charges that the individual may have to pay;

6. The requirements of notice for cancellation or reduction in services by the organization and the patient; and

7. The refund policies of the organization.

12 VAC 5-381-240. Complaints.

A. The organization shall establish and maintain complaint handling procedures which specify the:

1. System for logging receipt, investigation and resolution of complaints;

2. Format of the written record of the findings of each complaint investigated;

3. Method in which the local social services department Adult Protective Services unit is to be informed and for what complaints; and

4. Description of the appeal rights if a complainant is not satisfied with the resolution.

B. The organization shall designate staff responsible for complaint resolution, including:

1. Complaint intake, including acknowledgment of complaints;

2. Investigation of the complaint;

3. Review of the investigation of findings and resolution for the complaint; and

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

## Rules and Regulations for the Licensure of Home Care Organizations

C. The patient or his designee shall be given a copy of the complaint procedures at the time of admission to service. The organization shall provide each patient or his designee with the name, mailing address, and telephone number of the:

1. Organization contact person;
2. State Ombudsman; and
3. Center for Quality Health Care Services and Consumer Protection.

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 3 years.

12 VAC 5-381-250. Quality Improvement.

A. An organization providing home care services shall implement an on-going, comprehensive, integrated, self-assessment program of the quality and appropriateness of care provided, including services provided under contract or agreement. The quality improvement program shall address actual patient outcomes (results of care), clinical, administrative, and cost-of-care issues. 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 that influence patient outcomes (results of care):

1. Staffing patterns and clinical performance to assure adequacy and appropriateness of services delivered;
2. Unexpected results of admissions and discharges;
3. Supervision appropriate to the level of service;
4. Emergency preparedness plan;
5. Home care records for appropriateness of services including: i) complications, ii) admissions to inpatient facilities, iii) follow-up on abnormal findings and laboratory test results, iv) medication errors, and v) specific diagnoses;
6. Patient satisfaction;
7. Complaint resolution;
8. Infections;
9. Staff concerns regarding patient care; and
10. Provision of services appropriate to the patients' needs.

C. The administrator or governing body shall appoint or designate a quality improvement committee, which is responsible for the oversight and supervision of the program. The committee shall consist of:

1. A physician with association to the organization;

## Rules and Regulations for the Licensure of Home Care Organizations

2. A member of the administrative staff;
3. Representatives from each of the services provided by the organization, including contracted services; and
4. An individual with demonstrated ability to represent the rights and concerns of patients. The individual may be a member of the organization staff, a patient, or a patient's family member.

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 patients.

D. Measures shall be implemented to resolve important problems or concerns that have been identified. Health care practitioners as well as administrative staff shall participate in the resolution of the problems or concerns that are identified.

E. Results of the quality improvement program shall be reported annually to the governing body, 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.

12 VAC 5-381-260. Infection control.

A. The organization shall implement a program to reduce the risk of infection.

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

1. Staff education regarding infection risk-reduction behaviors;
2. Use of universal precautions;
3. Handling, storing, processing and transporting of regulated medical waste according to applicable procedures;
4. Handling, storing, processing and transporting supplies and equipment in a manner that prevents the spread of infections; and
5. Monitoring staff performance in infection control practices.

C. 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.

12 VAC 5-381-270. Home care record system.

A. The organization shall maintain an organized home care record system according to accepted standards of practice. Written policies and procedures shall specify retention, reproduction, access, storage, content, and completion of the record.

B. The home care record information shall be safeguarded against loss or unauthorized use.

## Rules and Regulations for the Licensure of Home Care Organizations

C. Home care records shall be confidential. Only authorized personnel shall have access as specified by state and federal law.

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

E. Policies shall specify arrangements for retention and protection of records if the organization discontinues operation and shall provide for notification to the Center and the patient of the location of the records.

F. An accurate and complete home care record shall be maintained for each patient receiving home care services and shall include, but shall not be limited to:

1. Patient identifying information;
2. Identification of the primary care physician;
3. Admitting information, including a patient history;
4. Information on the composition of the patient's household, including individuals to be instructed in assisting the patient;
5. Documentation and results of all medical tests ordered by the physician or other health care professional and performed by the organization's staff;
6. A medical plan of care including appropriate assessment and management of pain;
7. An initial assessment of patient care needs to develop a plan of treatment;
8. A plan of care that includes the type and frequency of each service to be delivered either by organization personnel or contract services;
9. Medication sheets, when applicable, which include the name, dosage, frequency of administration, possible side effects, route of administration, date started, changed or discontinued for each medication administered;
10. Copies of all summary reports sent to the primary care physician;
11. Reports of case reviews;
12. Documentation of patient rights review; and
13. A discharge summary.

G. Signed and dated progress notes by each individual delivering service shall be written on the day the service is delivered and incorporated in the home care record within seven working days.

H. Entries in the home care record shall be current, legible, dated and authenticated by the person making the entry. Errors shall be corrected by striking through and initialing.

I. Originals or reproductions of individual patient home care records shall be maintained in their entirety for a minimum of five years following discharge or date of last contact unless



## Rules and Regulations for the Licensure of Home Care Organizations

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.

12 VAC 5-381-250. Home attendants.

Home attendants shall be able to speak, read and write English and shall meet one of the following qualifications:

1. Have satisfactorily completed a nursing education program preparing for registered nurse licensure or practical nurse licensure;
2. Have satisfactorily completed a nurse aide education program approved by the Virginia Board of Nursing;
3. Have 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 which includes clinical experience involving direct patient care; or
5. Have satisfactorily passed a competency evaluation program that meets the criteria of § 484.36 (b) of Title 42 of the Code of Federal Regulations.

## Rules and Regulations for the Licensure of Home Care Organizations

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PART III.  
HOME CARE SERVICES.

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12 VAC 5-381-280. Home care services.

A. The organization shall provide a program of specific services that shall include one or more of the following:

1. Nursing services;
2. Home attendant services;
3. Physical therapy services;
4. Occupational therapy services;
5. Speech therapy services;
6. Respiratory therapy services; or
7. Medical social services.

B. All 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 home care 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 patient's primary care physician.

C. Verbal orders shall be immediately documented in the health care record by the health care professional receiving the order and shall be countersigned by the prescribing person.

D. The primary care physician shall be notified immediately of any changes in the patient's condition that indicates a need to alter the medical plan of care.

E. The medical plan of care shall be reviewed, approved, and signed by the primary care physician at least every 60 days.

F. There shall be a director of patient care services, who shall be a physician licensed by the Virginia Board of Medicine or a registered nurse licensed by the Virginia Board of Nursing, responsible for the overall direction and management of patient care 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.

## Rules and Regulations for the Licensure of Home Care Organizations

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 patients to procure their medications from a pharmacy of their choice.

H. All prescription drugs shall be prescribed and properly dispensed to patients according to the provisions of Chapters 33 and 34 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.

12 VAC 5-381-290. Nursing services.

A. All nursing services shall be provided directly or under the supervision of a qualified registered nurse currently licensed by the Virginia Board of Nursing. Nursing services shall include, but are not limited to:

1. Assessing a patient's needs and admission for service as appropriate;
2. Implementing the medical plan of care and revising as necessary;
3. Providing those services requiring substantial and specialized nursing skill;
4. Educating the patient and patient's family regarding the disease process, self-care techniques and prevention strategies;
5. Initiating appropriate preventive and rehabilitative nursing procedures;
6. Coordinating and communicating with the patient's primary care physician and other care providers regarding the patient's needs;
7. Preparing clinical notes; and
8. Supervising licensed practical nurses and home health aides providing delegated nursing services.

B. If nursing duties are delegated, the organization shall develop and implement an organizational plan pursuant to 18 VAC 90-20-420 through 18 VAC 90-20-460 of the Virginia Administrative Code.

C. Licensed practical nurses shall be currently licensed by the Virginia Board of Nursing. The services provided by a licensed practical nurse may include, but are not limited to:

1. Delivering nursing services according to the organization's policies and standard nursing practices;
2. Assisting the registered nurse in performing specialized procedures;
3. Assisting the patient with activities of daily living, including the teaching of self-care techniques;
4. Supervising home care aides; and

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5. Preparing clinical notes.12 VAC 5-381-310. Home attendant services.A. Services of the home attendant may include, but are not limited to:

1. Assisting patients with: i) activities of daily living; ii) ambulation and prescribed exercise; and iii) other special duties with appropriate training and demonstrated competency;
2. Assisting with oral or topical medications that the patient can normally self-administer;
3. Measuring and recording fluid intake and output;
4. Taking and recording blood pressure, pulse and respiration;
5. Recording and reporting to the appropriate health care professional changes in the patient's condition;
6. Documenting services and observations in the home care record; and
7. Performing any other duties that the aide is qualified to do by additional training and demonstrated competency, within state and federal guidelines.

B. Prior to the initial delivery of services, the home attendant shall receive specific written instructions for the patient's care from the appropriate health care professional responsible for the care.

C. Home attendants shall work under the supervision of the appropriate health care professional responsible for the patient's care.

D. The nurse or therapist responsible for the supervision of the home attendant shall make visits to the patient's home as frequently as necessary, but not less than once every 30 calendar days. The results of the supervisory visit shall be documented in the home care record.

E. Relevant in-service education or training for home attendant shall consist of at least 12 hours annually. In-service training may be in conjunction with on-site supervision.

12 VAC 5-381-320. Therapy services.

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 or certified as required in Virginia.

B. The therapy services shall be provided according to the medical plan of care by or under the direction of an appropriately qualified therapist and may include, but are not limited to:

1. Assessing patient needs or admission for service as appropriate;
2. Implementing a medical plan of care and revising as necessary;

## Rules and Regulations for the Licensure of Home Care Organizations

3. Initiating appropriate preventive, therapeutic, and rehabilitative techniques according to the medical plan of care;
4. Educating the patient 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 patient's needs;
7. Supervising therapy assistants and home attendants as appropriate; and
8. Preparing clinical notes.

C. Therapy assistants may be used to provide therapy services.

1. The occupational therapy assistant shall be currently certified by the American Occupational Therapy Association and shall practice under the supervision of a certified 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.

D. Duties of therapy assistants shall be within the scope of practice and may include, but are not limited to:

1. Performing services planned, delegated, and supervised by the appropriately licensed therapist; and
2. Preparing clinical notes.

12 VAC 5-381-330. Medical social services.

A. Medical social services shall be provided according to the medical plan of care by or under the direction of a qualified social worker who holds, at a minimum, a bachelor's degree with major studies in social work, sociology, or psychology from a four 4 year college or university accredited by the Council on Social Work Education and has at least 3 years experience in case work or counseling in a health care or social services delivery system.

The organization shall have one year from the effective date of this chapter to ensure the designated individual meets the qualifications of this standard.

B. The duties of a social worker may include, but are not limited to:

1. Assessing the patient's psychological status;
2. Implementing a medical plan of care and revising, as necessary;
3. Providing social work services including: i) short-term individual counseling, ii) community resource planning, and iii) crisis intervention;
4. Providing consultation with the primary care physician and other health care professionals regarding changes in the patient's needs;

Rules and Regulations for the Licensure of Home Care Organizations

5. Preparing clinical notes; and
6. Participating in discharge planning.

## Rules and Regulations for the Licensure of Home Care Organizations

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PART IV.  
PHARMACEUTICAL SERVICES.

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12 VAC 5-381-340. Pharmacy services.

A. All prescription drugs shall be prescribed and properly dispensed to the patient according to the provisions of the Chapters 33 and 34 of Title 54.1 of the Code of Virginia and the regulations of the Virginia Board of Pharmacy, except for prescription drugs authorized by § 54.1-3408 of the Drug Control Act, such as epinephrine for emergency administration, normal saline and heparin flushes for the maintenance of IV lines, and adult immunizations, which may be given by a nurse pursuant to established protocol.

B. Home attendants may assist only with those topical and oral medications that the patient would normally self administer. Any other drug shall be administered only by a licensed nurse or physician assistant.

C. The organization shall develop written policies and procedures for the administration of home infusion therapy medications, that include, but are not limited to:

1. Developing a plan of care;
2. Initiation of medication administration based on a prescriber's order and monitoring of the patient for response to the treatment and any adverse reactions or side effects;
3. Assessment of any factors related to the home environment that may affect the prescriber's decisions for initiating, modifying, or discontinuing medications;
4. Communication with the prescriber concerning assessment of the patient's response to therapy, any other patient specific needs, any significant change in the patient's condition;
5. Communication with the patient's provider pharmacy concerning problems or needed changes in a patient's medication.
6. Maintaining a complete and accurate record of medications prescribed, medication administration data, patient assessments, any laboratory tests ordered to monitor response to drug therapy and results, and communications with the prescriber and pharmacy provider;
7. Educating or instructing the patient, family members, or other caregivers involved in the administration of infusion therapy in the proper storage of medication, 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
8. Initial and retraining of all organization staff providing infusion therapy.

D. The organization shall employ a registered nurse, who holds a current active license with the Virginia Board of Nursing, 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

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performing infusion therapy.



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PART V.  
PERSONAL CARE SERVICES.

12 VAC 5-381-350. Personal care services.

A. An organization may provide personal care services in support of the patient's health and safety in their home. The organization shall designate a registered nurse, who holds a current license with the Virginia Board of Nursing, responsible for the supervision of personal care services.

B. The personal care services shall include:

1. Assistance with the five primary activities of daily living;
2. Taking and recording vital signs, if indicated in the personal care plan;
3. Recording, and reporting to the supervisor, any changes regarding the patient's condition, behavior or appearance; and
4. Documenting the services delivered in the patient's record.

Other services related to the needs of the patient may include:

5. Meal preparation;
6. Housekeeping;
7. Shopping; or
8. Laundry.

C. Such services shall be delivered based on a written plan developed by a registered nurse, in collaboration with the patient and patient's family. The plan shall include at least the following:

1. Assessment of the patient's needs;
2. Functional limitations of the patient;
3. Activities permitted;
4. Special diet needs;
5. Specific personal care services to be performed; and
6. Frequency of service.

D. The plan shall be retained in the patient's record. Copies of the plan shall be provided to the patient receiving services and reviewed with the assigned home attendant prior delivering services.

E. Home attendants shall receive on-site supervision by a registered nurse or a licensed practical nurse, holding a current license with the Virginia Board of Nursing, and shall be delivering services to the patient at the time of on-site supervisory visits.

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F. The on-site supervisory nurse shall visit the patient's home to evaluate the personal care aide, the patient's needs and the personal care plan as frequently as necessary, but at least once every 30 days. The personal care aide shall be delivering services to the patient at the time of on-site supervisory visits.

G. A registered nurse or licensed practical nurse shall be available during all hours that personal care services are being provided.

H. Home attendants providing personal care services shall receive at least 12 hours annually of in-service training and education. In-service training may be in conjunction with on-site supervision.

I certify that this regulation is full, true, and correctly dated.

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Robert B. Stroube, M.D., M.P.H.

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Date