

Rules and Regulations for the Licensure of Home Care Organizations

Chapter 381.

Regulations for the Licensure of Home Care Organizations

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PART I.

DEFINITIONS AND GENERAL INFORMATION.

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12 VAC 5-381-10. Definitions.

“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, and toileting.

“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

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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.

“Board” means the Virginia Board of Health.

“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.

“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.

“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 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.

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“Full-time” means a minimum of a 37- 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 care aide” means an individual who performs basic health-related services in support of medically directed care, such as helping with ambulation or exercises, assisting with normally self-administered medications, reporting changes in the patient=s condition and needs, or providing environmental services essential to the patient=s health in the home.

“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.

“Home care organization” means a public or private organization, whether operated for profit or not for profit, that provides, at the residence of a patient or individual in the Commonwealth of Virginia, one or more of the following services:

1. Home health services, including services provided by or under the direct supervision of any health care professional under a medical plan of care in a patient=s residence on a visit or hourly basis to patients who have or are at risk of injury, illness, or a disabling condition and require short-term or long-term interventions;
2. Personal care services, including assistance in personal care to include activities of daily living provided in an individual=s residence on a visit or hourly basis to individuals who have or are at risk of an illness, injury or disabling condition; or
3. Pharmaceutical services, including services provided in a patient=s residence, which include the dispensing and administration of a drug or drugs, and parenteral nutritional support, associated patient instruction, and such other services as identified by the Board of Health by regulation.

“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.

“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.

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“Organization” means a home care organization.

“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.

“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 adult care residence, 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 aide” means an individual functioning in a supportive relationship to the patient, under appropriate supervision, as a member of the direct care team of a home care organization. The individual may function as an extension of the organization’s professional services with supervision and required guidance of a registered nurse, a licensed practical nurse.

“Personal care services” means the provision of assistance in the five primary activities of daily living, i.e., bathing, toileting, feeding, transferring, and dressing, and may include meal preparation and other supportive services relating to the needs of the patient.

∇Planning district≡ means a contiguous area within the boundaries established by the Virginia Department of Housing and Community Development.

“Primary care physician” means a physician licensed in Virginia, according to Chapter 29 of Title 54.1 (Section 54.1-2901 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.

“Qualified” means meeting current legal requirements of licensure, registration or certification in Virginia or having appropriate training 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.

“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.

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“Surety bond” means a guarantee from a surety (or insurance) company to a home care organization that a contractor will perform a contracted service and assume liability for negligent or criminal acts. A surety bond is the agreement between the contractor, the surety (or insurance) company, and the home care organization on behalf of the patients where the contractor and the insurance company agree to compensate patients for any losses as a result of negligent or criminal acts. The surety bond requirement is 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 home care organization’s liability insurance.

“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 is charged with the responsibility for ensuring that home care organizations provide patient care according to regulations adopted by the Board of Health and any additional requirements that may be specified by the Code of Virginia.

B. The Center for Quality Health Care Services and Consumer Protection (the Center) acts as agent for the Department of Health in administering the licensing program, which includes investigating complaints made by the public against home care organizations.

C. The Code of Virginia requires the Board of Health to adopt standards and regulations for the licensure of home care organizations. The Department of Health is the authorized agent for the Board of Health.

D. In developing or revising licensing regulations for home care organizations, the Department adheres to the requirements of the Administrative Process Act (§ 9-6.14:1 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 public hearings.

12 VAC 5-381-30. License.

A. A license to operate a home care organization is issued to a person or organization. An organization may be a partnership, association, corporation, or public entity.

B. The State Health 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, unless it has been determined that no reciprocal agreement for the licensing of home

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care organizations has been entered into by the Commonwealth with the state in which the applicant resides or with the state in which the applicant=s home care organization is licensed to operate.

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. The services offered by the organization shall be geographically limited to the planning district in which the organization is located.

A home care organization providing services to a patient or patients residing outside the organization=s respective planning district shall have a year from the effective date of the regulation to open an office subject to licensure or to refer those patients to an appropriate home care organization within the planning district in which the patient or patients reside.

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.

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

A. In accordance with 32.1-162.8 of the Code of Virginia, provision of this regulation is not applicable to:

1. A natural person, acting alone, who provides services to a patient or individual on an individual basis if such person is (i) licensed to provide such services pursuant to Title 54.1 or (ii) retained by the individual or by a person acting on the individual's behalf;

2. Any organization providing only housekeeping, chore or beautician services;

3. Any home care organization located in the Commonwealth which is:

a. Certified by the department under provisions of Title XVIII or Title XIX of the Social Security Act;

b. Approved for payments for home health or personal care by the Department of Medical Assistance Services;

c. Accredited by the Joint Commission on Accreditation for Health Care Organizations, the National League of Nursing or the National Home Caring Council; or

d. Licensed for hospice services under Article 7 (Section 32.1-162.1 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia.

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B. The home care organization must provide documentation and file a request for exemption from licensure in writing.

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 still subject to complaint investigations in keeping with state law.

12 VAC 5-381-50. Licensing process.

A. Upon request, the Center will provide consultation and technical assistance to any person seeking information about obtaining a license. The purpose of such consultation is to explain the regulations and the licensing process and review the potential applicant's proposed program plans, forms, and other documents, as they relate to the regulations. Pre-licensure consultations can be arranged after an applicant has filed an application.

B. Upon request, the Center will provide an application form for a license to operate a home care organization. The Center shall consider the application complete when all requested information and the application fee is submitted with the form required. If the Center finds the application incomplete, the applicant will be notified of receipt of the incomplete application.

An incomplete application shall become inactive six months after it is received by the Center. Applicants must reapply for licensure with a completed application and application fee.

C. The applicant shall complete and submit the initial application along with any required attachments and the application fee to the Center at least 60 days prior to a planned opening date to allow the Center time to act on the application. An application for a license may be withdrawn at any time.

D. The activities and services of each applicant for issuance or renewal of a home care organization license shall be subject to an inspection or examination by the Center to determine if the home care organization is in compliance with the provisions of these regulations and state law.

E. The department shall send an application for renewal of the license to the licensee at least 60 days prior to the expiration date of the current license. Licenses are required to be renewed annually.

F. The home care organization shall submit the completed renewal application form along with any required attachments and the application fee by the date indicated in the cover letter.

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

12 VAC 5-381-60. Modification of a license.

A. Prior to changes in operation which would affect the license, the home care organization must secure a modification to the terms of the license from the Center.

B. Requests to modify a license must be submitted in writing 30 working days in advance of any proposed changes to the Director of the Center for Quality Health Care Services and Consumer Protection.

C. The Center will evaluate written information about any planned changes in operation that affect either 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 modification.

D. If a modification can be granted, the Center shall respond in writing. In the event a new application is needed, the home care organization will receive written notification. When the modification cannot be granted, the home care organization shall be advised by letter.

12 VAC 5-381-70. Fees.

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

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

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

D. A one time processing fee of \$75.00 shall be collected for each exemption for licensure filed and shall accompany the written request for exemption.

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

A. The licensing representative shall make unannounced on-site inspections of the home care organization. The home care 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 licensing representative any necessary records.

C. The home care organization shall also allow the licensing representative to interview the agents, employees, contractors, and any person under its control, direction or supervision.

D. After the on-site inspection, the licensing representative shall discuss the findings of the inspection with the administrator or designee.

E. Upon receipt of the inspection report, the administrator shall submit an acceptable plan for correcting any deficiencies found during an on-site inspection within 10 working days from the date of the deficiency report cover letter. 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 date each correction is expected to be completed;
3. A description of the measures implemented to assure continued compliance with the regulations and prevent a recurrence of the violation; and
4. The signature of the person responsible for the operation.

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

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

H. Time limits for 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 renewal or complaint inspection, the licensing representative may conduct home visits.

B. The home care organization shall be responsible for arranging in-home visits with patients, family members, and care givers for the licensing representative, unless the licensing representative determines otherwise.

12 VAC 5-381-100. Complaint investigation.

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A. The Center has the responsibility to investigate any complaints regarding alleged violations of the regulations or statutes.

B. Complaints may be received in written or oral form and may be anonymous.

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

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

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.

12 VAC 5-381-110. 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 the 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 which will ensure the protection and well-being of patients.

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

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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.

F. The Center shall notify the home care organization of the receipt of the request for a variance. The Center may attach conditions to the granting of the variance in order to protect persons in care.

G. When the decision is to deny a request for a variance, the reason shall be provided in writing to the licensee.

H. When a variance is denied, expires, or is rescinded, routine enforcement of the regulation or portion of the regulation shall be resumed. The home care organization may at any time withdraw a request for a variance.

12 VAC 5-381-120. 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 (Section 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 upon application therefore if, when, and after the conditions upon which revocation was based have been corrected and all provisions of the law and this regulation have been complied with.

C. Whenever a license is 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 providing services.

D. Suspension of a license shall in all cases be for an indefinite time and 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 5-381-130. Surrender of a license.

A. Upon revocation or suspension of a license, the licensee must surrender its license to a representative of the Center.

B. Other circumstances under which a license must be surrendered include transfer of ownership and discontinuation of services. The licensee shall notify the Center, in writing, 30 days before discontinuing services.

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C. If, at any time, the organization is no longer operational, the license shall be returned to the Center within five working days. The organization's owner is responsible for notifying its patients and the Center where all home care records will be located.

PART II.
ADMINISTRATIVE SERVICES.

12 VAC 5-381-140. Management and administration.

12 VAC 5-381-150. Governing body.

12 VAC 5-381-160. Administrator.

12 VAC 5-381-170. Written policies and procedures.

12 VAC 5-381-180. Financial resources.

12 VAC 5-381-190. Personnel practices.

12 VAC 5-381-200. Insurance.

12 VAC 5-381-210. Contract services.

12 VAC 5-381-220. Patient rights.

12 VAC 5-381-230. Quality improvement.

12 VAC 5-381-240. Home care record system.

12 VAC 5-381-140. 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. These regulations (12 VAC 5-381 et seq.);
2. Other applicable federal, state or local laws and regulations; and
3. The organization's own policies.

C. The organization shall submit, or make available, reports and information necessary to establish compliance with these regulations and applicable statutes.

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

1. Verify application information;
2. Determine compliance with these regulations;
3. Review necessary records; and
4. Investigate complaints.

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

1. Geographic location or mailing address of the organization;
2. Ownership;
3. Services provided;
4. Operator;
5. Administrator;
6. Organization name; and
7. 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 these regulations.

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 be required to 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 a 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 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 during a disaster.

12 VAC 5-381-150. Governing body.

A. The organization shall have a governing body that is legally responsible for the management, operation and fiscal affairs of the organization.

B. The governing body shall adopt, and periodically review, written by-laws. The governing body shall describe the organizational structure, including the:

1. Organization's objectives;

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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 approve the written policies and procedures of the organization.

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

12 VAC 5-381-160. 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, 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 12 VAC 5-381-160 A shall be designated to perform the duties of the administrator when the administrator is absent from the organization.

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

12 VAC 5-381-170. Written policies and procedures.

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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;
5. Patient rights;
6. Contract services;
7. Quality improvement;
8. Home care records, including confidentiality;
9. Record retention, including termination of services;
10. Supervision and delivery of services;
11. Emergency and after-hour care;
12. Infection control; and
13. Handling consumer complaints.

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, but are not limited to:

1. Written job descriptions that specify 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; and

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5. Process for verifying that contractors and their employees meet the personnel qualifications of the organization.

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;
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 5-381-180. 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) or those standards promulgated by the Virginia Department of Accounts and the Virginia Auditor of Public Accounts.

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 5-381-190. Personnel practices.

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

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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.

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 affidavit 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. Applicable personnel policies;
5. Emergency preparedness procedures;
6. Infection control practices and measures; and
7. Other policies and procedures that apply to specific positions and 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.

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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 name tag, uniform or other visible means.

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

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. Verification of the criminal record check.

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

Q. Personnel records 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 5-381-200. Insurance.

A. The governing body shall ensure the organization and its contractors have appropriate insurance 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 insurance coverage at all times:

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1. Blanket malpractice insurance for all nursing and medical professional employees:
 - a. At least \$1,000,000 per incident; and
 - b. At least \$3,000,000 aggregate;
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 5-381-210. Contract services.

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

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

1. Patients accepted for care only by the primary home care organization;
2. The services to be furnished;
3. The necessity to conform to all applicable organization policies, including personnel qualifications;
4. The responsibility for participating in developing plans of care;
5. The manner in which services will be controlled, coordinated, and evaluated by the primary home care organization;
6. The procedures for submitting clinical and progress notes, scheduling of visits, and periodic patient evaluation;
7. The process for payment for services furnished under the contract; and
8. 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 5-381-220. 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.

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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 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 soon as possible, but no later than 30 calendar days from the date the home care organization became aware of the change; and
9. Provided with advance directive information prior to start of 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.

E. 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;

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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.

F. 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.

G. 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.

H. The organization shall maintain documentation of all complaints received and the status of each complaint from date of receipt through its final resolution.

12 VAC 5-381-230. Quality Improvement.

A. The organization 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;

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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 tests 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=s 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;
2. A member of the administrative staff;
3. Nursing and representatives of other services provided; and
4. An individual with demonstrated ability to represent the rights and concerns of patients, who 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 are implemented to resolve important problems or concerns that have been identified. Health care practitioners as well as administrative staff 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 5-381-240. 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.

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C. Home care records shall be confidential. Only authorized personnel shall have access as specified in § 32.1-127.1:03 of the Code of Virginia. Written procedures shall govern the use and removal of records and the conditions of release of information. The patient's written consent shall be required for release of information not authorized by 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;
7. An initial assessment of patient needs to carry out the plan of treatment;
8. A plan of care that includes each service to be delivered either by organization employee or contract services;
9. Medication sheets, when applicable, which include the name, dosage, frequency of administration, 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
12. 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.

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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 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.

PART III.
HOME CARE SERVICES.

12 VAC 5-381-250. Home care services.

12 VAC 5-381-260. Nursing services.

12 VAC 5-381-270. Licensed practical nurses.

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

12 VAC 5-381-290. Therapy services.

12 VAC 5-381-300. Medical social services.

12 VAC 5-381-250. Home Care Services.

A. Specific services which shall be provided in a home care program shall include one or more of the following:

1. Nursing services;
2. Home care aide 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.

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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 which 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 62 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.

12 VAC 5-381-260. 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.

B. 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.

C. 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.

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12 VAC 5-381-270. Licensed practical nurses.

A. Licensed practical nurses shall be currently licensed by the Virginia Board of Nursing and shall practice under the supervision of a registered nurse.

B. 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, when delegated; and
5. Preparing clinical notes.

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

A. Services of the home care aide may include, but are not limited to:

1. Assisting or providing patients with: i) personal hygiene; ii) transferring, ambulation and exercise; iii) self-administration of medications; iv) meal preparation and feeding, when required; and v) prescribed exercises and other special duties with appropriate training and demonstrated competency;
2. Measuring and recording fluid intake and output;
3. Taking and recording blood pressure, pulse and respiration;
4. Recording and reporting to the health care professional changes in the patient=s condition;
5. Documenting services and observations in the home care record; and
6. Performing any other duties which 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 care aide shall receive specific written instructions for the patient=s care from the appropriate health care professional responsible for the care.

C. Home care aides 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 care aide shall make visits to the patient=s home as frequently as necessary, but not less than once every 14 calendar days. The results of the supervisory visit shall be documented in the home care record.

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

F. Home care aides shall be able to speak, read and write English and shall meet one of the following qualifications:

1. Have 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 Board of Nursing;
3. Be registered as a certified nurse aide with the Board of Nursing;
4. Be enrolled in a nursing education program preparing for registered nurse or practical nurse licensure and have completed at least one nursing course which includes clinical experience involving patient care; or
5. Have passed a competency evaluation program that meets the criteria of Section 484.36 (b) of Title 42 of the Code of Federal Regulations.

12 VAC 5-381-290. 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 services of a therapist 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;
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 care aides as appropriate; and
8. Preparing clinical notes.

C. 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.

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The physical therapy assistant shall be currently licensed by the Virginia Board of Medicine and shall practice under the supervision of a licensed physical therapist.

D. Duties of therapy assistants shall include, but are not limited to:

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

12 VAC 5-381-300. 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 shall meet one of the following requirements:

1. Currently licensed by the Virginia Board of Social Work;
2. Holds a masters degree from a school of social work accredited by the Council on Social Work Education and has 1 year social work experience in a health care or social services delivery system;
3. Holds a bachelor=s degree in social work from an accredited 4 year college or university and has 2 years of experience in a health care delivery system; or
4. Holds a bachelor=s degree with major studies in social work, sociology, or psychology from an accredited 4 year college or university and has at least 3 years experience in case work or counseling in a health care or social service delivery system.

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

Rules and Regulations for the Licensure of Home Care Organizations

PART IV.
PHARMACEUTICAL SERVICES.

12 VAC 5-381-310. PHARMACEUTICAL SERVICES.12 VAC 5-381-310. Pharmaceutical services.

A. The organization shall develop written policies and procedures for the provision of pharmaceutical services that shall include, but are not limited to:

1. Initiation;
2. Medication administration;
3. Monitoring; and
4. Discontinuation.

B. Pharmaceutical services shall be under the direct supervision of a:

1. Physician currently licensed by the Virginia Board of Medicine; or
2. Pharmacist currently licensed by the Virginia Board of Pharmacy.

C. The supervising individual shall be responsible for ensuring that the organization complies with all state and federal laws and regulations related to pharmaceutical services. The individual shall be responsible for ensuring that the organization employs licensed professionals who follow the accepted standard of care including, but not limited to:

1. Dispensing medications and monitoring the treatment provided as ordered and approved by the primary care physician;
2. Evaluating the patient's infusion therapy service needs, and the home environment in order to make recommendations to the primary care physician and to assist the physician in ordering services based on the patient's specific needs;
3. Developing a plan of care;
4. Coordinating care and ensuring communication between the individuals providing and administering infusion services;
5. Assessing the patient's response to the therapy prescribed and reporting pertinent findings regarding the patient's condition to the primary care physician and organization staff involved in the patient's care and documenting this information in the patients's record;
6. Notifying the primary care physician of any change in the patient's condition which indicates a need to alter the medical plan of care;

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7. Advising, consulting with, and instructing when necessary the patient or care giver and other organization personnel involved in the patient's care about the patient's infusion therapy program;

8. Ensuring that the patient or care giver, and organization staff involved in the administration of the infusion therapy, are instructed in the proper storage of medications and handling of supplies and equipment, handling and disposal of waste, safety precautions and actions to be taken in case of emergency; and

9. Participating in in-service training to organization staff involved in the provision of infusion therapy services.

D. An organization shall employ a registered nurse, licensed by the Board of Nursing, who has completed training in infusion therapy and has the requisite skills, competencies, and knowledge to administer infusion therapy as ordered in a patient's medical plan of care. The registered nurse shall supervise organization staff involved in direct patient care involving the administration of infusion therapies.

E. Orders shall be given for home infusion therapy by a person lawfully authorized to give the order. Documentation of the order in the record shall include:

1. The medication prescribed;
2. The specific dose, frequency, and route of medication administration;
3. The duration of the therapy, if determined; and
4. Related lab orders as appropriate to monitor the patient's response to the infusion therapy.

Verbal orders shall be documented in the patient's record by the health care professional receiving the orders and shall be countersigned by the prescribing person.

F. An ongoing assessment of the staff's competency in performing infusion therapy related procedures shall be done at periods specified by organization policies.

G. A plan for parenteral nutrition therapy, based on the needs of the patient, shall be developed by a registered dietitian, nutritionist, or physician, for patients receiving parenteral nutritional therapy.

PART V.

PERSONAL CARE SERVICES.

12 VAC 5-381-320. PERSONAL CARE SERVICES.

12 VAC 5-381-320. Personal Care Services.

Rules and Regulations for the Licensure of Home Care Organizations

A. All personal care services shall be delivered based on a written plan developed by a registered nurse. 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.

B. The personal plan of care shall be retained in the patient's record. Copies of the plan shall be provided to the patient receiving services and given to the assigned personal care aide.

C. The organization shall designate a registered nurse, currently licensed by the Board of Nursing, to be responsible for the supervision of personal care services.

D. Personal care aides shall receive on-site supervision by a registered nurse or a licensed practical nurse, licensed by the Board of Nursing.

E. 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 60 days. The personal care aide shall be delivering services to the patient at the time of on-site supervisory visits.

F. Prior to the initial delivery of services, the personal care plan shall be reviewed with the assigned personal care aide.

G. Personal care aides shall be able to speak, read and write English and shall meet one of the following qualifications:

1. Have 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 Board of Nursing;
3. Be registered as a certified nurse aide with the Board of Nursing;
4. Be enrolled in a nursing education program preparing for registered nurse or practical nurse licensure and have completed at least one nursing course which includes clinical experience involving patient care; or
5. Have passed a competency evaluation program that meets the criteria of 484.36 (b) of Title 42 of the Code of Federal Regulations.

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H. The services of the personal care aide shall include:

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

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

J. Personal care aide in service training and education shall consist of at least 12 hours annually. In service training may be in conjunction with on-site supervision.