

**REGULATIONS
FOR THE
DESIGNATION AND OPERATION
OF
HOME HEALTH AGENCIES**

Agency of Human Services
Department of Disabilities, Aging and
Independent Living
Division of Licensing and Protection
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I. General Provisions

1.1 It is the purpose of these rules to implement State law governing the designation, re-designation, and designation revocation of, and the establishment of minimum program standards for home health agencies. It is the policy of the state of Vermont to ensure that all residents in every town within the state have access to comprehensive, medically necessary home health services without regard to the patient's ability to pay, including hospice and palliative care services, and to ensure that such services shall be delivered in an efficient and cost-effective manner, consistent with available funding, under a regulatory framework designed to control costs and ensure access to high quality home health services.

1.2 These rules are promulgated pursuant to 33 V.S.A. Chapter 63, Subchapter 1A, and 18 V.S.A. Chapter 221.

1.3 A determination that any provision or application of any provision of these rules is invalid shall not affect the validity of any other provision of these rules or their applicability.

1.4 The Commissioner may grant a variance from any provision of these rules if the Department determines that strict compliance would impose a substantial hardship on the home health agency; the home health agency would otherwise meet the goal of the statutory provision or the rule; and a variance would not result in decreased service to or protections of the health, safety or welfare of the individuals in their designated service area.

(a) Requests for a variance shall include a statement of the regulation for which a variance is requested, an explanation of the reasons why the provisions cannot be met and the variance is being requested, and a description of the alternative method proposed for meeting the intent of the provision in question.

(b) A variance shall not be granted from a statute or regulation pertaining to patient rights.

(c) A home health agency may petition the Commissioner to cease participation in the Choices for Care Medicaid Waiver Program, with 90 days notice, when an agency can demonstrate that losses from the Program threaten the continuing operation of the home health agency, disregarding private donations and municipal and town funds.

(d) A home health agency experiencing financial distress may petition the Commissioner for temporary financial relief. The Commissioner in his discretion may grant such temporary financial relief after a review of the home health agency's need if the Commissioner determines that the Department is able to assist. The temporary financial relief shall be based upon a plan to correct the issues that led to the home health agency's financial distress. The plan of correction shall be developed by the

home health agency and approved by the Department before any financial relief is provided.

1.5 Final interpretation of these rules shall be by the Commissioner.

II. Definitions

2.1 *Acute Care Services* mean medically necessary services provided to address severe, significant or serious illness.

2.2 *Administrator* means an individual, who may also be the supervising physician or registered nurse, who organizes and directs the agency's ongoing functions; maintains ongoing liaison among the governing body, the group of professional personnel, and the staff; employs qualified personnel and ensures adequate staff education and evaluations; ensures the accuracy of public information materials and activities; and implements an effective budgeting and accounting system. A qualified person is authorized in writing to act in the absence of the administrator.

2.3 *Applicant* means the individual who signs the application for a home health agency designation.

2.4 *Branch office* means a location or site from which a home health agency provides or arranges for services within a portion of the total geographic area served by the parent home health agency. The branch office is part of the home health agency and is located sufficiently close to share administration, supervision, and services in a manner that renders it unnecessary for the branch to independently meet the conditions of participation as a home health agency.

2.5 *Chronic Care Services* means a set of health, personal care and social services delivered over a sustained period of time to persons who have lost or never acquired some degree of functional capacity.

2.6 *Clinical note* means a notation of a contact with a patient that is signed and dated by the member of the health team who had the contact, and that describes signs and symptoms, treatment and drugs administered and the patient's reaction, and any changes in physical or emotional condition.

2.7 *Commissioner* means the Commissioner of the Vermont Department of Disabilities, Aging, and Independent Living.

2.8 *Critical Incident* means an unexpected occurrence involving death, patient suicide, poisoning, serious physical or psychological injury related to the provision of home health services, and includes, but is not limited to, loss of limb or function or suspected abuse, neglect or exploitation.

2.9 *Delegation of a nursing service* means the process a registered nurse uses to transfer to an individual with demonstrated competence the authority to perform a selected nursing task in a selected situation. The nurse retains accountability for the delegation.

2.10 *Department* means the Vermont Department of Disabilities, Aging and Independent Living.

2.11 *Family member* means an individual who is related to a person by blood, marriage, civil union, or adoption, or who considers himself or herself to be family based upon bonds of affection, and who currently shares a household with such a person or has, in the past, shared a household with that person. For purposes of this definition, the phrase “bonds of affection” means enduring ties that do not depend on the existence of an economic relationship.

2.12 *For-profit home health agency* means a private home health agency that is not exempt from Federal income tax under section 501 of the Internal Revenue Code of 1954.

2.13 *Home health agency* means a home health care business designated to provide part-time or intermittent skilled nursing services and at least one of the following other therapeutic services in a place of residence used as a patient’s home: physical, speech, or occupational therapy; medical social services; home health aide services. A home health agency may also provide or arrange for other non-nursing therapeutic services, including the services of nutritionists, dieticians, psychologists, and licensed mental health counselors.

2.14 *Home health care services* means the activities and functions that include, but are not limited to, nursing care, personal care, physical, occupational or speech therapy, medical social services, or other non-nursing therapeutic services directly related to care, treatment, or diagnosis of patients in the home.

2.15 *Homemaker Services* means certain activities that help to maintain a safe, healthy environment for persons residing in their homes. These activities include home management services (cooking, cleaning, laundry and related light housework) and/or supportive services (shopping and errands essential to maintain the living quarters).

2.16 *Medically Necessary Services* means physician-ordered treatment, care or therapy that is needed for the diagnosis, direct care, and treatment of a medical condition.

2.17 *Nonprofit home health agency* means a home health agency exempt from Federal income tax under section 501 of the Internal Revenue Code of 1954.

2.18 *Parent home health agency* means the home health agency that develops and maintains administrative controls of sub-units and/or branch offices.

2.19 *Personal Care* means providing or assisting an individual with the activities of daily living, such as eating, bathing, dressing, toileting, and transferring, that the individual otherwise would be unable to complete.

2.20 *Sub-unit* means a semi-autonomous organization that serves patients in a geographic area different from that of the parent home health agency; and which independently meets the conditions of participation for home health agencies because geographically it is too far from the parent home health agency to share administration, supervision, and services on a daily basis.

2.21 *Unexpected death* means an untimely death associated with an untoward event, such as an accident, medical error or equipment failure.

III. The Designation Process

3.1 A home health agency designated to provide home health services shall have the obligation and the responsibility of providing or arranging for medically necessary home health and hospice services, including High-Tech and Choices for Care 1115 Medicaid Waiver Program services, which include personal care. The designation shall continue for four years unless suspended or terminated by an enforcement action.

3.2 A home health agency desiring to become a designated home health agency for Vermont must obtain and maintain federal certification. If nationally accredited, the home health agency must provide the Department with documentation of that status, and notify the Department of any change in status and the reason for the change in status.

3.3 Any person, partnership, association or corporation desiring to engage in designated home health care first shall apply for and obtain a Certificate of Need (CON) from the Vermont Department of Banking, Insurance, Securities and Health Care Administration (BISHCA).

3.4 Any person, partnership, association or corporation desiring to engage in home health care services shall file an application with and get approval from the Department prior to the commencement of such operation. Each sub-unit of a home health agency shall be required to have a separate designation in effect.

3.5 A home health agency's application for designation shall be signed by any two officers of the corporation and by its administrator, and shall be submitted upon forms prescribed by the Department.

3.6 A home health agency's application shall contain:

(a) The legal name of the home health agency as registered with the Secretary of State's Office, the name under which it shall be doing business, its physical address;

and, if applicable, the name of the corporation, association or other company responsible for the management of the home health agency;

- (b) A disclosure of ownership form, as provided by the Department;
- (c) A list of all board members, officers, partners, and key administrative staff and their titles, including the names of the administrator and the director of nursing or equivalent; with copies of current licenses;
- (d) Proof of CON for the area where designation is sought;
- (e) Proof of Medicare certification;
- (f) The number of full time equivalent employees by discipline;
- (g) An organizational chart showing all reporting and supervisory relationships;
- (h) Other information, data, statistics or schedules as the Department may request, including, but not limited to information on accounts, salaries, tax status and evidence of financial solvency;
- (i) The name of each person, firm or corporation having direct or indirect ownership interest of 5% or more in the home health agency, and of each physician with financial interest or ownership of any amount in the home health agency, and the amounts of ownerships for all;
- (j) A local community services plan;
- (k) A copy of the most recent accreditation results, if applicable;
- (l) A list of specific home health care services provided by the home health agency, and a list of those services the home health agency obtains by contract; and
- (m) A sample admission packet.

3.7 The Department shall consider each of the following factors in determining whether a home health agency's application or re-application shall be approved:

- (a) CON determination;
- (b) Record of compliance with all relevant regulations and laws;
- (c) Adherence to accepted professional standards and principles in the provision of services;

(d) Financial status and proof of fiscal responsibility, as shown through an annual audit report which includes an unqualified opinion from an independent auditor and indicates that a home health agency is in compliance with general accepted accounting standards and that the financial reports are an accurate representation of the agency's financial condition. In addition, there shall be credit reports, history of tax withholding, no incidences of financial fraud with any third party payer or vendor, no incidences of inappropriate referral arrangements and compliance with the financial terms and conditions of all state contracts;

(e) Current standing with state and federal tax departments; and

(f) Development and implementation of an approved local community services plan.

3.8 Each home health agency shall develop a local community services plan that describes:

(a) The home health care needs within the geographic area for which it is designated or wishes to become designated;

(b) The methods by which the home health agency will meet those needs;

(c) A schedule for the anticipated provision of new or additional services;

(d) The resources needed by and available to the home health agency to implement the plan;

(e) A home health agency's plan for addressing unforeseen interruption of services and for addressing the need for after hours or weekend services to ensure continuity of services;

(f) How public input was obtained and reflected in the plan; and

(g) How the plan shall be made available to the public.

3.9 A home health agency shall revise its local community services plan at least every four years.

3.10 A home health agency shall work in collaboration with the Department to develop and maintain a technological infrastructure that enables the home health agency to cost-effectively collect information, submit data, conduct needs assessments of the geographical area, and perform other required functions. A home health agency shall:

(a) Submit all required information within the requested the timeframes and in the format specified;

(b) Monitor and report costs, outcomes, service provision and service accessibility;

(c) Provide high quality and responsive services with the capacity to monitor the services delivered by contracted service providers;

(d) Provide information on quality assurance, quality improvement and outcome activities; and

(e) Protect confidentiality of consumers when data are transferred in compliance with State and federal laws and regulations.

3.11 A home health agency shall have fiscal management practices that demonstrate cost efficiency and cost controls and that include, at a minimum, the following:

(a) The ability to meet payroll and pay bills in a timely fashion;

(b) Reasonable efforts are made to collect all fees from individuals and third-party payers;

(c) Financial records and accounting practices that are maintained in accordance with generally accepted accounting principles; and

(d) Fire, personal, professional, general liability, and board/officer insurance coverage.

3.12 A home health agency shall provide the Department with the results of its annual and any other financial audits, as well as copies of the home health agency's Medicare cost reports. The annual financial audit shall be performed by an independent public accountant in accordance with generally accepted accounting principles and all applicable State and Federal laws, regulations, policies and procedures.

3.13 A home health agency shall collaborate with the Department in order to provide sufficient financial detail about home health agency services for the purpose of analyzing data, costs and efficiencies of home health agency services paid for by the state.

3.14 A home health agency shall disclose the information required in subsection 3.6 above to the Department at the time of the home health agency's initial request for designation, at the time of every survey, and at the time of any change in ownership or management.

3.15 A home health agency shall not assign or transfer any authority or designation.

3.16 A home health agency shall apply for a new CON and shall provide the Department with a copy of the new CON when greater than 50% ownership interest in the home health agency is transferred or conveyed.

3.17 A home health agency may enter into collaborative or shared service agreements with other home health agencies. Prior to the implementation of such an agreement, a home health agency shall submit the proposed agreement in writing to the Commissioner for approval.

(a) Collaborative agreements may include, but are not limited to:

(1) Pooling or sharing one or more administrative functions, services or expenses;

(2) Pooling or sharing certain staff, including nurses and other personnel, or services;

(3) Group purchasing arrangements designed to obtain the benefits of volume discounts and achieve other cost savings and efficiencies for the benefit of patients;

(4) Agreements with managed care plans or other third-party payers, at their request and on a nonexclusive basis, to provide their members with prescribed home health services on discounted group-wide or statewide rates, terms, and conditions;

(5) Providing home health services to patients located in the designated service area of another home health agency due to special needs or other exceptional circumstances on an occasional or sporadic basis; or

(6) Sharing of information and technology.

(b) Plans for collaborative agreements shall be submitted to the Commissioner for review prior to implementation and the Commissioner shall have 90 days from receipt of such filing within which to approve or disapprove the plan.

3.18 A home health agency shall respond with at least a telephone call to all referrals within twenty-four (24) hours, or as specified by physician order.

3.19 Whenever a designated home health agency plans to discontinue all or part of its operation or services, including ceasing participation in the Choices for Care Waiver Program pursuant to 1.4(c), or change its ownership or location, and such change in status would necessitate the discontinuation of services or transfer of patients, the administrator shall notify the Department, the Health Care Ombudsman and the State Long-Term Care Ombudsman at least ninety (90) days prior to the proposed date of the change.

(a) No later than sixty (60) days prior to any change which would necessitate the transfer of or discontinuation of services to patients, a home health agency shall provide written notice to all patients or their legal representatives, and place a legal notice in key area newspapers. The notice shall include the date of the intended change, and if the change involves closure of a program or the home health agency, the date upon which the home health agency will no longer accept patients.

(b) No later than forty-five (45) days prior to the change, a home health agency shall provide to the Department, the Health Care Ombudsman and the State Long-Term Care Ombudsman a detailed written plan for how the home health agency intends to provide safe and orderly discontinuations of services for its patients. The plan shall include:

- (1) Assurances that adequate staff and patient care will be provided during the transition;
- (2) Arrangements to ensure the orderly transfer of patients; and
- (3) The disposition of patient files and home health agency records.

(c) No later than thirty (30) days prior to closure or discontinuation of a service, a home health agency shall provide to each patient an individualized plan to ensure continuity of care.

(d) Upon request, the administrator shall provide to the Department any additional information related to the transfer plan as well as follow-up reports regarding specific placement action.

(e) In the event of a home health agency closure or discontinuation of a service, all home health agency rules and regulations shall remain fully applicable until all patients have been transferred.

IV. Re-designation

4.1 A home health agency shall submit to the Department a completed renewal application at least sixty (60) days prior to the expiration of the current designation.

4.2 The Department shall review this renewal application and, based upon its review, inform the home health agency in writing of its decision to:

- (a) Renew the designation for a period of 4 years;
- (b) Grant the home health agency a conditional designation; or
- (c) Deny the application.

4.3 The Department may grant a conditional designation at the time of original application, during the term of designation or at the expiration of a full or provisional designation.

4.4 A conditional designation shall specify the timeframe and terms.

4.5 If a designation is revoked, suspended or not renewed, a home health agency shall advise the public of such action. This public notice shall be in the form of a paid legal notice in the local newspaper(s), published within fifteen (15) days following the suspension or revocation of the designation. The home health agency also shall notify all clients in writing about the action.

V. Requirements for Operation

5.1 A home health agency shall not employ or have a contract with any direct-care personnel without satisfactory results from the Adult Abuse Registry and the Child Abuse Registry and without having conducted a Vermont criminal record check in compliance with the Department's background check policy.

5.2 A home health agency shall conduct business and ensure delivery of services in a way that complies with the Americans with Disabilities Act (ADA).

5.3 A home health agency shall have the staffing and supplies necessary to provide the services it offers. A home health agency shall ensure that services and staff are available to meet the needs of patients who have been accepted for services within the home health agency's specified geographic area and that there are contingency plans for each patient in the event of an unexpected, temporary unavailability of scheduled services.

5.4 A home health agency has the obligation and the responsibility to provide or arrange for all designated services to all eligible patients within their designated geographic area who request its services.

5.5 A home health agency shall develop and maintain a disaster plan describing how the home health agency will continue to provide services in the home health agency's designated service area in times of crisis or disaster. A home health agency shall cooperate and collaborate with Vermont emergency management services (EMS) personnel in their geographic area to develop a protocol regarding details of the plan. A home health agency shall have the capacity to, or contract for the provision of, crisis response and services for eligible patients in the home health agency's specified service area.

5.6 A home health agency shall post its proof of designation on those premises where the home health agency's business operations are conducted in a location where it will be readily visible to visitors.

5.7 A home health agency shall notify the Department of all critical incidents among its current patient population within specified time frames below. Verbal reports shall be followed by a written report that summarizes the occurrence.

(a) A home health agency shall report any suspicion of abuse, neglect or exploitation as defined in 33 V. S. A. §6902 to the Division of Licensing and Protection's Adult Protective Services unit within 48 hours.

(b) A home health agency shall report critical incidents other than abuse, neglect or exploitation to the Division by the next business day after the agency learns of the incident. Such incidents include but are not limited to:

- (1) Any unexpected death;
- (2) Loss of limb or function occurring during the provision of home health services;
- (3) Any serious injury occurring during the provision of home health services that results in or from, among other things:
 - (i) A medication or drug error by home health agency staff;
 - (ii) Use of medical devices or restraints (including bed rails).
- (4) Any patient suicide; and/or
- (5) Any poisoning.

5.8 A home health agency shall not discriminate based on age, sex, race, sexual orientation, country of origin, disability, source of payment, geography, or any other basis specified by law.

5.9 A home health agency shall comply with all applicable state and federal policies, guidelines, laws and regulations. In the event that State and federal regulations differ, the more stringent shall apply.

5.10 A home health agency shall inform each of its participants in the Choices for Care 1115 Medicaid Waiver Program in writing of their right to contact and receive assistance from the State Long-Term Care Ombudsman. The notice shall include the address and telephone number for the local Long-Term Care Ombudsman.

5.11 A home health agency shall ensure that representatives of the State Long-Term Care Ombudsman have:

(a) Appropriate access to review the clinical records of a patient receiving Choices for Care services if:

- (1) The ombudsman has the permission of the patient or the permission of the patient's legal representative; or
- (2) The patient is unable to consent to the review and has no legal representative.

(b) Access to the record as is necessary to investigate a complaint by a patient in those instances in which:

- (1) The legal representative or the legal guardian of the patient refuses to give the permission;
- (2) The ombudsman has reasonable cause to believe that the legal guardian is not acting in the best interests of the patient; and
- (3) The regional ombudsman has obtained the approval of the State Long-Term Care Ombudsman.

5.12 A home health agency shall ensure that representatives of the Health Care Ombudsman have:

(a) Appropriate access to review the clinical records of a patient (other than one receiving Choices for Care services) if:

- (1) The ombudsman has the permission of the patient or the permission of the patient's legal representative; or
- (2) The patient is unable to consent to the review and has no legal representative.

(b) Access to the record as is necessary to investigate a complaint by a patient in those instances in which:

- (1) The legal representative or the legal guardian of the patient refuses to give the permission; and
- (2) The ombudsman has reasonable cause to believe that the legal guardian is not acting in the best interests of the patient.

VI. Organization, Services and Administration

6.1 A governing body or its designee(s) shall assume full legal authority and responsibility for the operation of the home health agency. The governing body shall

appoint a qualified administrator, arrange for professional advice, adopt and periodically review written bylaws or an acceptable equivalent, and oversee the management and fiscal affairs of the home health agency.

6.2 The board of each not-for-profit designated home health agency shall be representative of the demographic makeup of the area or areas served by the agency or by the health facility governed by the board.

(a) A majority of the members of the board shall be composed of individuals who have received or currently are receiving services from the agency or from the health care facility governed by the board and family members of individuals who have received or currently are receiving such services.

(b) The board president shall survey board members annually and certify to the Commissioner that the composition of the board meets the requirements of this subsection.

(c) The composition of the board shall be confirmed by the home health agency's annual independent audit.

(d) The board shall have overall responsibility and control of the planning and operation of a home health agency, including development of the local community services plan.

6.3 A for-profit home health agency shall have an advisory board that is representative of the demographic makeup of the area or areas served by the home health agency.

(a) A majority of the members of the advisory board shall be composed of individuals who have received or currently are receiving services from the home health agency and family members of individuals who have received or currently are receiving such services.

(b) The advisory board president shall survey board members annually and certify to the commissioner that the composition of the board meets the requirements of this subsection.

(c) The composition of the board shall also be confirmed by the home health agency's annual independent audit.

(d) The advisory board shall meet at least twice per year and shall advise the home health agency's board of directors with respect to planning and operation of the home health agency, patient needs, and development of the local community services plan.

6.4 A home health agency shall establish a professional group of advisors to advise the home health agency on professional issues, to participate in the evaluation of the

agency's program(s) and to assist the agency with the maintenance of liaisons with other health care providers in the community and with the home health agency's community information program. At a minimum, the professional advisors group shall:

(a) Include at least one physician and one registered nurse, with appropriate representation from other professional disciplines, and at least one member who shall not be an owner or an employee of the agency;

(b) Establish and annually review the agency's policies governing scope of services offered, admission, discontinuation of services, transfer, medical supervision and plans of care, emergency care, clinical records, personnel qualifications, and program evaluation;

(c) Advise a home health agency on professional issues, participate in the evaluation of the home health agency's programs, and assist the home health agency in maintaining liaisons with other health care providers in the community; and

(d) Meet no less frequently than every six months, and document each meeting with dated minutes.

6.5 A home health agency shall have an administrator, who may also be the supervising physician or registered nurse, and who shall:

(a) Organize and direct a home health agency's ongoing functions; maintain ongoing liaisons among the governing body, the group of professional personnel, and the staff;

(b) Employ qualified personnel and ensure adequate staff education and evaluations; ensure the accuracy of public information materials and activities; and

(c) Implement an effective budgeting and accounting system.

6.6 A home health agency shall ensure that skilled nursing and other therapeutic services are provided under the supervision and direction of a physician or a registered nurse who has at least 1 year of nursing experience. This individual, or other qualified designee, shall be available at all times during operating hours.

6.7 A home health agency shall develop, maintain, and upon request provide to the Department, policies and procedures for, but not limited to the following:

(a) Admission, transfer and discontinuation of services to patients;

(b) Medical supervision and plans of care;

(c) Emergency care;

(d) Clinical records;

(e) Personnel, including but not limited to qualifications, credentialing verification, staff orientation, training and evaluation, and as applicable, policies pertaining to students and volunteers;

(f) Program evaluations;

(g) Confidentiality, including the storage, use, removal and release of patient information and clinical records;

(h) Quality improvement;

(i) Handling complaints and grievances; and

(j) Involuntary transfers or discontinuation of services.

6.8 A home health agency shall develop a fee schedule which shall be provided to all patients or their legal representatives and to the public upon request.

6.9 A home health agency shall conduct an overall evaluation of the home health agency's total program at least once a year, with input from the professional advisory group, home health agency staff, and consumers and their representatives.

(a) The evaluation shall consist of an overall policy and administrative review, shall include the results of clinical record reviews, and shall assess the extent to which the home health agency's programs are appropriate, adequate, effective, and efficient.

(b) Results of the evaluation shall be reported to and acted upon by those responsible for the operation of the home health agency and shall be maintained separately as administrative records.

6.10 A home health agency shall establish mechanisms for the collection of data to be reported to the Department. Data to be collected and reported shall include, but not be limited to:

(a) Information on complaints, waiting lists, numbers of individuals ineligible for services, numbers of individuals eligible but not provided services, numbers of patients served under and over the age of 65, total number of visits and hours provided to patients, charitable and subsidized programs and services for uninsured or low income persons, and any other quality indicators or data deemed relevant by the Commissioner to monitor and evaluate access to and the cost and quality of home health services provided by each home health agency.

(b) In addition, home health agencies shall provide the Department with the results of patient surveys, data from federal and State surveys, scoring by any national accrediting organizations, audited annual financial statements and annual cost reports.

6.11 A home health agency shall investigate complaints made by a patient, the patient's family or a legal guardian regarding treatment or care that is (or that fails to be) furnished, or regarding the lack of respect for the patient's property, by the agency or by anyone furnishing services on behalf of the home health agency, and must document both the existence of the complaint and the resolution of the complaint. The home health agency shall furnish patients with the toll-free number for the Home Health Hotline.

6.12 A home health agency shall keep a log of all complaints. The log shall include the date of the complaint, name of complainant, subject of the complaint, person assigned and the date and resolution of the complaint.

(a) The home health agency shall respond to all complaints, whether received orally or in writing, within 2 business days.

(b) A home health agency shall report any quality of care or service-related complaint not resolved to the satisfaction of the patient within 7 days to the Department's Division of Licensing and Protection and shall notify the complainant in writing of the right to request assistance from the Health Care Ombudsman or, if applicable, the State Long-Term Ombudsman and include information on how to do so. If a resolution is pending or in progress and both the home health agency and the patient are actively seeking resolution but the final resolution will take more than 7 days, the home health agency shall report the complaint within 30 days if no final resolution is reached. The home health agency shall notify the patient in writing that he or she may complain to the Department during that time.

(c) The complaint log shall be made available upon request for inspection by authorized reviewers from the Department.

6.13 A home health agency shall have written agreements for clinical or direct care services provided by contract or sub-contract, which shall be dated and signed by a representative of the home health agency and by the person or other agency providing the service, and which shall specify each party's responsibilities, functions and objectives during the time which services shall be provided, the financial arrangements and charges, and the duration of the agreement. Additionally, the agreement shall:

(a) Specify that the home health agency shall retain an administrative responsibility for services rendered, including subcontracted services;

(b) Require that services shall be provided in accordance with these rules and that personnel providing services meet licensing, training and experience requirements, and be supervised in accordance with these rules; and

(c) Require the provision of written documentation to the home health agency regarding the amount and type(s) of services provided.

VII. Discontinuation of Services

7.1 A home health agency shall have policies and procedures regarding the discontinuation of services to patients. Planning for the discontinuation of services shall be initiated at the time of admission to the home health service and shall be provided as part of the ongoing assessment of a patient's continuing care needs and in accordance with expected patient care outcomes.

7.2 A home health agency may discontinue services to a patient when the home health agency determines:

- (a) The patient has requested that the services be discontinued;
- (b) Treatment objectives are met and skilled services are no longer medically needed as determined by the physician;
- (c) The patient has moved out of the service area or chooses another provider;
- (d) After attempting to resolve the situation, that the patient's needs cannot be adequately met in the home by the home health agency;
- (e) The patient, primary caregiver or other person in the home has exhibited behavior that is a safety risk to agency staff such as physical abuse, sexual harassment, threatening behavior or verbal abuse; or
- (f) The patient has failed to pay for services for which he or she is responsible.

7.3 When a home health agency identifies a need to discontinue or reduce services to a patient, the home health agency shall provide a verbal notice, followed by a written notice, accessible to the patient.

(a) If services will be reduced or discontinued, the home health agency shall give written notice as follows:

- (1) In general, written notice shall be provided by the home health agency at least 14 days prior to the discontinuation or reduction of services.
- (2) When skilled services are discontinued pursuant to a physician's order, when the patient has terminated services or when the patient has moved out of the service area, the home health agency shall give written notice at least 2 days prior to the discontinuation of services.

(3) Prior to discontinuing services for safety reasons to a patient or staff, the home health agency shall: notify the physician, if applicable, or the case manager; advise a patient that a discontinuation of services for safety reasons is being considered; make a serious effort to resolve the problem(s) presented by the patient's behavior or situation; ascertain that the proposed discontinuation of services to the patient is not due to the patient's use of necessary home health agency services; and document the problem(s) and efforts made to resolve the problem(s) in the patient's clinical record.

(4) If there is an emergency basis to terminate services and advance notice cannot reasonably be given, services may be reduced or discontinued immediately. The home health agency shall provide immediate verbal (when possible) and written notice of the nature of the emergency, the basis for the discontinuation of services, the reason why advance notice was not given and what steps, if any, the patient may take to allow services to be restored.

(b) All notices shall include the reason for the discontinuation of services, the date services will be discontinued and information regarding the patient's right to appeal, if applicable, and where to file an appeal, the name and address of the Health Care Ombudsman or, if applicable, the State Long-Term Care Ombudsman and a statement that the patient may request that services continue while the appeal is pending, if applicable.

(c) A home health agency shall develop and implement policies and procedures that set forth the steps that the home health agency will follow if the services are being discontinued for one of the reasons listed in subsection (d), (e) or (f) above.

7.4 When a home health agency determines that a patient will require continuing care after services are discontinued, the agency shall arrange or assist the patient to arrange for such services and shall provide sufficient clinical information to the receiving entity to assure continuity of care and services. The home health agency shall educate the patient about how to obtain further care, treatment and services to meet his or her identified needs, if applicable.

7.5 When a home health agency discontinues services to a patient for any of the circumstances specified in this section, the circumstances must be documented in the patient record.

VIII. Skilled Nursing Services

8.1 A home health agency shall furnish skilled nursing services by or under the supervision of a registered nurse (RN) and in accordance with the patient's plan of care.

8.2 The registered nurse shall:

(a) Make the initial evaluation visit;

- (b) Regularly re-evaluate the patient's nursing needs;
- (c) Initiate the plan of care and necessary revisions;
- (d) Furnish those services requiring substantial and specialized nursing skill;
- (e) Initiate appropriate preventive and rehabilitative nursing procedures;
- (f) Prepare clinical and progress notes;
- (g) Coordinate services;
- (h) Inform the physician and other personnel of changes in the patient's condition and needs in a timely manner;
- (i) Counsel the patient and family in meeting nursing and related needs;
- (j) Participate in in-service programs;
- (k) Supervise and teach other nursing personnel; and
- (l) Teach the patient and, as appropriate, the patient's family or primary caregiver self-care techniques.

8.3 The registered nurse may delegate selected nursing tasks in selected patient-specific situations to licensed nursing assistants (LNAs) or unlicensed caregivers.

8.4 The registered nurse shall perform supervisory visits of LNA services.

(a) The registered nurse shall make a home visit to the patient who is receiving skilled nursing as well as LNA services no less frequently than every 2 weeks to observe and assist, assess relationships, determine whether goals are being met, evaluate the appropriateness of the plan of care, and make changes as appropriate.

(b) The registered nurse shall make a home visit to the patient who is receiving long-term care home health agency services no less frequently than every 60 days to observe and assist, assess relationships, determine whether goals are being met, evaluate the appropriateness of the plan of care, and make changes as appropriate.

(c) The registered nurse shall provide direct supervision as necessary and be readily available at other times by telephone.

- (d) The registered nurse shall evaluate on an ongoing basis the LNA's ability to:
 - (1) Carry out assigned duties;

- (2) Relate to the patient; and
- (3) Work effectively as a member of the health care team.

IX. Licensed Practical Nurse Services

9.1 A home health agency shall provide licensed practical nursing (LPN) services, if applicable, under the supervision of a registered nurse, in accordance with the patient's plan of care.

9.2 The licensed practical nurse shall:

- (a) Furnish services in accordance with the home health agency's policies;
- (b) Prepare clinical and progress notes;
- (c) Assist the physician and registered nurse in performing specialized procedures;
- (d) Prepare equipment and materials for treatments observing aseptic technique as required; and
- (e) Assist the patient and, as appropriate, the patient's family or primary caregiver with self-care techniques.

X. Licensed Nursing Assistant Services

10.1 For purposes of these regulations, licensed nursing assistant (LNA) services and home health aide services shall be considered equivalent and the terms interchangeable.

10.2 Licensed nursing assistant services shall be assigned to a particular patient pursuant to that patient's plan of care and shall be supervised by a registered nurse or appropriate therapist, who shall prepare written patient care instructions for the licensed nursing assistant.

10.3 A home health agency shall require and document that LNAs receive at least twelve (12) hours of in-service training annually. Documentation of on-the-job training may be applied to the required hours of in-service training.

10.4 The duties of a licensed nursing assistant include the provision of hands-on personal care, the performance of simple procedures such as an extension of therapy or nursing services, and assistance in ambulation or exercises. Duties include, but shall not be limited to:

- (a) Assisting a patient with activities of daily living;

- (b) Assisting a patient in and out of bed and assisting with ambulation;
 - (c) Assisting with health care treatment as determined in a patient's plan of care;
 - (d) Performing selected nursing tasks for specific patients if delegated by a registered nurse;
 - (e) Reporting changes in a patient's condition and needs and assisting in emergency situations; and
 - (f) Completing appropriate records and signing full name, title and date.
- 10.5 When a patient receives therapy services but does not receive skilled nursing care, a qualified therapist may provide supervision of the LNAs. The supervising therapist shall make an on-site visit to the patient's home no less frequently than every 2 weeks to observe and assist, assess relationships, determine whether goals are being met, evaluate the appropriateness of the plan of care, and make changes as appropriate.

XI. Therapy Services

11.1 A home health agency shall offer therapy services (physical, speech and occupational therapy) directly or under arrangement by a licensed therapist, or by a qualified therapy assistant under the supervision of a licensed therapist, in accordance with the patient's plan of care.

11.2 The duties of a licensed therapist shall include, but are not limited to:

- (a) Providing those services requiring substantial and specialized therapy skills;
- (b) Making an initial visit to assess the patient's level of function;
- (c) Regularly re-assessing the patient's therapy needs;
- (d) Initiating appropriate preventive and rehabilitative therapeutic procedures;
- (e) Coordinating services and documenting case management meetings;
- (f) Informing the physician and other personnel of the patient's condition and needs;
- (g) Advising and consulting with the patient and the patient's family, if appropriate, and with other home health agency personnel;
- (h) Participating in in-service programs;
- (i) Supervising qualified therapy assistants; and

- (j) Teaching qualified therapy assistants and other personnel.

11.3 The duties of a qualified therapy assistant shall include, but are not limited to:

- (a) Preparing clinical notes and progress reports;
- (b) Participating in educating the patient and family;
- (c) Participating in in-service programs; and
- (d) Following the plan of care as developed by the therapist.

11.4 A qualified, licensed therapist shall provide supervision if services are furnished by qualified a therapy assistant.

11.5 A therapist may provide supervision of LNAs if a patient is receiving therapy services but not receiving skilled nursing care. The supervising therapist shall make an on-site visit to the patient's home no less frequently than every 2 weeks to observe and assist, assess relationships, determine whether goals are being met, evaluate the appropriateness of the plan of care, and make changes as appropriate.

11.6 Speech therapy services shall be furnished only by or under supervision of a qualified speech pathologist or audiologist.

XII. Medical Social Services

12.1 A home health agency shall provide or arrange for medical social services by a qualified social worker or by a qualified social work assistant under the supervision of a qualified social worker, in accordance with the patient's plan of care.

12.2 The duties of the social worker shall include, but are not limited to:

- (a) Determining the significant social and emotional factors related to patient care, and relaying that information to physicians and other team members;
- (b) Participating in the development of the plan of care;
- (c) Preparing clinical and progress notes;
- (d) Working with the family;
- (e) Using appropriate community resources;
- (f) Participating in planning for the discontinuation of services and in-service programs;

- (g) Acting as a consultant to other home health agency personnel; and
- (h) Helping patients with advance directives and other long-term care issues.

XIII. Unlicensed Caregiver Services

13.1 If a home health agency provides or arranges for unlicensed caregiver services, those services shall be provided pursuant to a patient's plan of care in accordance with State and federal program standards, and shall include, but not be limited to, personal care services and homemaker services.

13.2 A home health agency may permit unlicensed caregivers to assist patients with chore services, companionship and personal care in accordance with the patient's plan of care.

13.3 A home health agency shall train and determine the competency of unlicensed caregivers employed by the agency to perform specific tasks for specific patients and shall ensure that the caregiver is appropriately supervised.

XIV. Clinical Records

14.1 A home health agency shall maintain a clinical record containing pertinent past and current findings in accordance with accepted professional standards for every patient receiving home health services.

14.2 A home health agency shall retain clinical records for 5 years after the month the cost report to which the records apply is filed with the intermediary, unless State or federal law stipulates a longer period of time. A home health agency shall retain the records even if the home health agency discontinues operations. If a patient is transferred to a health care facility, the home health agency shall send a copy of the record or abstract with the patient.

14.3 A home health agency shall maintain the confidentiality of all clinical records and shall safeguard clinical record information against loss or unauthorized use. A home health agency shall develop written procedures governing the use and removal of records and the conditions for release of information pursuant to state and federal law. The home health agency shall obtain the patient's written consent for release of information not authorized by law.

14.4 A home health agency's patient clinical records, whether written or electronic, shall contain at a minimum:

- (a) Identifying information about the patient, household members and caretakers, medical history, health status, living arrangements and psychosocial history;

(b) A care plan for the patient, developed by the interdisciplinary team with input from the patient;

(c) All medications taken by the patient, with signature and start and stop dates for those prescribed by the physician, and documentation of patient education regarding medication side effects and contraindications;

(d) All patient functional, cognitive, health and psychosocial assessments;

(e) Signed and dated clinical notations made at each patient visit by each health care staff person who renders a service to the patient;

(f) Reports of all patient care conferences;

(g) Written summary reports containing home health care services provided, the patient's status, recommendations for revision of the plan of treatment, and the need for initiation, continuation or termination of services;

(h) Where appropriate, a dated and signed summary after services are discontinued giving a brief review of service, patient status, reason(s) for the discontinuation of services, and plans for the subsequent needs of the patient;

(i) A copy of appropriate patient transfer information, if the patient is transferred to a health care facility or other home health agency;

(j) Evidence of contingency provisions made in cooperation with the patient or patient representative to provide for a continuum of care in the event of the temporary unavailability of services provided by the home health care agency;

(k) Documentation showing patient receipt of Patient Rights provisions, Home Health Hotline information, complaint or grievance procedures, abuse prevention information, advanced directives information and contact information for the State Long-Term Care Ombudsman, if applicable, and/or the HealthCare Ombudsman;

(l) A copy of any advanced directive, Do Not Resuscitate Order (DNR) or Clinician's Order for Life Sustaining Treatment (COLST), if applicable.

14.5 The clinical note shall be written and incorporated into the patient's clinical record within a timeframe that will ensure that the patient's status is communicated to other caregivers and in accordance with the home health agency's policies and procedures. The clinical note shall include, but not be limited to a written description of signs and symptoms, treatment and medications administered; and the patient's response and any changes in physical or mental status.

14.6 A physician's electronic or rubber stamp signature for plan of care documentation is permitted if authorized by the home health agency's policy. A signed statement from

the physician is required attesting that he or she is the only one who has the electronic signature or stamp and may use it. This statement shall be on file and available in the administrative offices of the home health agency.

14.7 At least quarterly, appropriate health professionals, representing the scope of the program, shall review a sample of both active and closed clinical records to determine whether established policies are followed in furnishing services directly or under arrangement. There shall be a continuing review of the plan of care for each 60-day period that a patient receives home health services to determine adequacy of the plan of care and appropriateness of continuation of care.

14.8 A home health agency shall develop written policies and procedures, including plans for implementation and maintenance of, electronic information systems which shall address data integrity, confidentiality of patient records, security, authentication, non-repudiation, encryption as warranted and ability to be audited, as appropriate to the system and types of information.

14.9 A home health agency shall develop written policies and procedures pertaining to the release of records to a patient or other authorized individual or entity. The policy shall establish a reasonable cost, consistent with state record copying costs, for the provision of copies of patient records.

14.10 A home health agency shall ensure that each patient is assured confidential treatment of his or her personal and medical records, and shall not release a patient's record without the patient's consent to any individual outside the home health agency, except in the case of his or her transfer to another health care institution, or as required by law, survey or third-party payment contract.

(a) Upon an oral or written request, each patient shall be given access to all current records pertaining to him or herself within 24 hours (excluding weekends and holidays). Archived records shall be provided within 5 working days of the request.

(b) After receipt of his or her records for inspection, a patient may purchase, at a cost not to exceed the community standard, photocopies of the records or any portions of them, upon request and with 2 working days advance notice to the agency.

14.11 The home health agency shall ensure that any advanced directive, including a DNR or COLST, is accessible and that staff are familiar with the patient's wishes and with the requirement that the patient's wishes and preferences shall be honored.

XV. Patient Assessment

15.1 A home health agency shall complete an assessment that shall accurately identify the patient's need for home care services, including the patient's medical, nursing, rehabilitative, social, planning for discontinuation of services, and other needs. In

addition, the assessment shall include a review of all medications the patient is currently using in order to identify any potential adverse effects and drug reactions.

15.2 A registered nurse shall conduct an initial assessment visit to determine the immediate care and support needs of the patient. When therapy is the only service ordered by the physician, a physical therapist, speech-language pathologist or occupational therapist may complete the assessment.

15.3 The initial assessment visit shall be held either within 48 hours of referral, or within 48 hours of the patient's return home, or on the date the physician ordered care to start. The assessment shall be completed in a timely manner, consistent with the patient's immediate needs, but no later than 5 calendar days after the start of care, unless otherwise ordered by the physician.

15.4 The assessment shall be updated and revised as frequently as the patient's condition warrants due to a major decline or improvement in the patient's health status, but not less frequently than:

(a) The last five days of every sixty (60) days beginning with the date the care starts, unless there is a:

- (1) Beneficiary-elected transfer;
- (2) Significant change in condition; or
- (3) Discontinuation of services and return to the same home health agency during the 60-day episode.

(b) Within 48 hours of the patient's return to the home from a hospital admission of 24 hours or more for any reason other than diagnostic tests; and

(c) When services are discontinued.

XVI. Plan of Care

16.1 A home health agency shall accept patients for treatment on the basis of a reasonable expectation that the patient's medical, nursing and social needs can be met adequately by the home health agency in the patient's place of residence. A home health agency shall initiate each patient's plan of care within three (3) business days or in accordance with physician orders.

16.2 A home health agency shall develop the plan of care in consultation with the physician and the patient and/or the patient's representative. The plan of care shall cover all pertinent diagnoses, including mental status, types of services and equipment required, frequency of visits, prognosis, rehabilitation potential, functional limitations, activities permitted, nutritional requirements, medications and treatments, any safety

measures to protect against injury, instructions for timely discontinuation of services or referral, shall be consistent with any advanced directive, if applicable, and include any other appropriate items. The home health agency shall submit the treatment plan to the patient's physician for approval and signature.

16.3 A patient's plan of care shall be in a format accessible to the patient.

16.4 The plan of care shall be family-directed if the patient is under 18 years old.

16.5 A home health agency shall respond to a patient's request for a care conference or a meeting or to change provider, case manager or direct care staff, in a timely manner.

16.6 A home health agency shall consider a patient's preferences for services and care givers and shall collaborate with the patient's other services persons, service agencies or service systems if appropriate and desired by the patient.

16.7 A home health agency and the patient's physician shall review the plan for skilled care at least once every 60 days or as required by a specific program. A home health agency's professional staff shall promptly alert the physician to any changes that suggest a need to alter the plan of care.

(a) If a physician refers a patient with a specific plan of care that cannot be completed until after an evaluation visit, the physician shall be consulted to approve additions or modifications to the ordered plan. Orders for therapy services shall include the type, modality, frequency and duration of therapy.

(b) All plans of care for patients requiring nursing services shall be written, coordinated and completed by a registered nurse who has made an initial visit to the residence of the patient to assess and evaluate the care and/or services, required.

(c) All plans of care for patients requiring only the services of therapists, or medical social workers shall be written, coordinated and completed by these licensed health care professionals who have made an initial visit to the residence of the patient to assess and evaluate the care and/or services required.

(d) Visit ranges may be permitted but shall not begin with zero (0). PRN visits shall be documented and shall include the rationale for the PRN visit.

(e) The home health agency staff shall administer drugs and treatments only as ordered by the physician with the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered pursuant to a home health agency's policy developed in consultation with a physician, and after an assessment for contraindications.

(f) The home health agency shall put verbal orders in writing, signed and dated by the individual who took the verbal order. Verbal orders shall be accepted only by

personnel authorized to do so by applicable State and federal laws and regulations as well as by the home health agency's policies. All verbal orders shall be counter-signed by the physician. A facsimile order (fax) is acceptable.

XVII. Patient Rights

17.1 A patient has the right to be fully informed of all of his or her rights and responsibilities by the home health agency and to receive written notice from the home health agency of these rights during the initial visit or before care is furnished.

17.2 A patient has the right to have his or her property and person respected by the home health agency.

17.3 A patient has the right to participate in care planning and in that care, to be informed by the home health agency in advance of changes in care and to be informed of the disciplines that will provide care and the frequency of visits.

17.4 A patient has the right to confidentiality of his or her protected health information and the right to review the written record upon request.

17.5 A patient has the right to be advised by the home health agency of the number and availability of the toll-free home health hotline, the hours of operation and that the purpose of the hotline is to receive complaints or questions about local home health agencies.

17.6 A patient has the right to receive from the home health agency an admission packet that shall include relevant information, including information on the right to contact the Health Care Ombudsman or the State Long-Term Care Ombudsman (if the patient receives services under the Choices for Care 1115 Medicaid Waiver), with information on how to do so.

17.7 A patient has the right to appropriate and professional care in accordance with appropriate standards of care.

17.9 A patient has the right to receive a timely response from the home health agency to his or her request for service.

17.10 A patient has the right to refuse treatment within the confines of the law and to be informed of the consequences of that action.

17.11 A patient has the right to be informed of his or her right to formulate advanced directives.

17.12 A patient has the right to be fully informed of home health agency policies and charges for services, including eligibility for third-party reimbursements. Before care is initiated, a home health agency shall inform a patient of the extent to which payment for

the services may be expected from Medicare or other sources, and the extent to which payment may be required from the patient. Before the care is initiated, the home health agency shall inform the patient, verbally and in writing, of:

(a) The extent to which payment may be expected from Medicare, Medicaid, any other federally funded program, or any State or private insurance known to the home health agency;

(b) The charges for services that will not be covered by Medicare or Medicaid;
and

(c) The charges that the individual may have to pay.

17.13 A patient has the right to voice grievances and request changes in services or staff without fear of retaliation or discrimination by the home health agency. In the case of a patient adjudicated incompetent by a court, the rights of the patient shall be exercised by the person appointed by the court to act on the patient's behalf.

17.14 A patient has the right to appeal a notice of reduction or discontinuation of home health agency services or a denial of admission to the home health agency and to receive information about the appeal process.

17.15 A patient has the right to be informed about how to reach the home health agency at all times.

17.16 A patient has the right to review reports of state and federal surveys and a right to receive copies of the reports upon request to the Division of Licensing and Protection.

17.17 A patient has the right to receive care and treatment free of mistreatment or abuse.

17.18 A patient has the right to file complaints with the Division of Licensing and Protection. If dissatisfied with the resolution of the complaint, the patient may ask for the decision to be reconsidered by the Commissioner.

17.19 Any of the rights enumerated in this section may be exercised by an individual who has the legal authority to act on behalf of the patient when the patient lacks the capacity to exercise those rights.

XVIII. Quality Assurance and Improvement

18.1 A home health agency shall establish an effective, ongoing, data-driven quality assessment and performance improvement program that reflects the full range of home health agency services, including those services furnished under contract or arrangement. The program shall:

(a) Include an ongoing measurable data collection system that tracks and focuses on indicators to improve patient outcomes and reduce errors;

(b) Measure, analyze, and track quality indicators, including adverse patient events, existing or potential problems, and other performance indicators that assess quality, effectiveness and efficiency of agency services and operations;

(c) Identify changes that will lead to improvement;

(d) Implement improvement actions;

(e) Evaluate results of corrective actions; and

(f) Assure systemic integration of successful improvement actions.

18.2 The frequency and detail of data collection shall be specified by the governing body, or board and include detail and data as needed and specified by the Department.

18.3 A home health agency shall participate in the Department's Quality Review processes and monitoring activities, and shall respond in a timely and effective manner to recommendations made in the Department reviews and/or other monitoring reports.

18.4 A home health agency shall establish program priorities for performance improvement activities that:

(a) Focus on high risk, high-volume, or problem prone areas;

(b) Consider the incidence, prevalence, and severity of problems in those areas;

(c) Focus on practices that affect patient safety; and

(d) Identify trends in tracked errors and adverse patient events.

18.5 A home health agency shall obtain and monitor patient and family satisfaction, keep written records of all of its monitoring efforts, and document the use of this information through quality improvement activities. The results of the surveys shall be made available to the Department.

18.6 A home health agency shall establish a quality assurance and improvement committee that shall consist of health professionals and direct care staff representing the scope of the agency's services. The agency quality assurance and improvement committee shall meet with sufficient frequency to identify and address quality issues. The agency may use its professional advisory council as its quality assurance and improvement committee if it includes all required members and responsibilities.

XIX. Survey and Review

19.1 The Department shall survey a home health agency prior to designation and at any other time it considers a survey is necessary to determine if an agency is in compliance with these regulations.

19.2 Regardless of the term of designation, the Department shall monitor a home health agency for continued compliance with applicable laws and rules on at least an annual basis, except that surveys, at the Department's discretion, need not be conducted during a year when a Medicare certification survey is performed. Surveys may be conducted more frequently in any of the following circumstances:

- (a) Change of ownership;
- (b) Receipt of complaints; or
- (c) Other circumstances that could have an impact on the home health agency's ability to meet the needs of the patients in the designated service area.

19.3 The Department shall have access to the home health agency at all times, with or without notice. An application for designation, whether initial or renewal, shall constitute permission for entry into, and survey of, a home health agency by representatives of the Department during the pendency of the application and, if designated, during the period of designation.

19.4 The Department shall investigate whenever it has reason to believe a violation of the law or regulations has occurred. Investigations shall be conducted by the Department and may be conducted at any place or include any person the Department believes possesses information relevant to its regulatory responsibility and authority.

19.5 After each survey or complaint investigation, the Department shall hold an exit conference with the administrator of the home health agency. The exit conference shall include an oral summary of the Department's findings and, if regulatory violations were found, a notice that the home health agency must develop and submit an acceptable plan of correction.

19.6 The Department shall prepare a written report that summarizes the results of the survey. The report shall be sent to the home health agency upon completion. The report shall include the following:

- (a) A description of each condition that constitutes violation;
- (b) Each rule or statutory provision alleged to have been violated;
- (c) The date by which the home health agency must return a plan of correction for the alleged violations;

- (d) The date by which each violation must be corrected;
- (e) Sanctions the Department may impose for failure to correct the violation or failure to provide proof of correction by the date specified;
- (f) The right to apply for a variance;
- (g) The right to an informal review; and
- (h) The right to appeal the determination of violation to the Commissioner within fifteen (15) days of the mailing of the notice of violation.

19.7 Upon receipt of a notice of violation from the Department, a home health agency shall submit a written plan of correction to the Department within ten (10) days of the date of the receipt of the notice of violation.

(a) A home health agency's plan of correction shall describe how the agency intends to correct each violation, the expected date of completion, how the plan will be monitored and shall identify who is responsible.

(b) A home health agency shall make statements of deficiencies readily available to patients and to the public.

(c) The Department may accept the plan of correction as written or may require modification.

19.8 If as a result of an investigation or survey the Department determines that a home care business is operating without designation and meets the definition of a home health agency, written notice of the violation shall be prepared and provided to the business.

19.9 Patients, their legal representatives and the public shall have the right to review current and past state and federal survey and inspection reports of the home health agency, and, upon request, to receive from the home health agency a copy of any such report. Copies of reports shall be available for review during normal business hours at one location in the home health agency. The home health agency may charge an amount not to exceed the community standard for more than one copy per patient.

XX. Enforcement

20.1 The Department may take immediate enforcement action when necessary to eliminate a condition that can reasonably be expected to cause death or serious harm to patients' or staff's health or safety. If the Department takes immediate enforcement action, it shall explain its actions and the reasons for those actions in the notice of the violation.

20.2 The Department may require a home health agency to take corrective action to eliminate a violation of a rule or statute within a specified period of time. If the Department does require corrective action:

(a) The Department may, within the limits of resources available to it, provide technical assistance to the home health agency to enable it to comply with the statutory and regulatory requirements;

(b) A home health agency shall provide the Department with proof of correction of the violation within the time specified; and

(c) If a home health agency has not corrected the violation by the time specified, the Department may take such further action as it deems appropriate.

20.3 The Department may assess administrative penalties against an agency for failure to correct a violation or failure to comply with a plan of corrective action as follows:

(a) Up to \$500.00 for each day a violation remains uncorrected if the rule or provision violated was adopted primarily for administrative purposes;

(b) Up to \$800.00 for each day a violation remains uncorrected if the rule or provision violated was adopted primarily to protect the welfare or the rights of patients;

(c) Up to \$1000.00 for each day a violation remains uncorrected if the rule or provision violated was adopted primarily to protect the health or safety of patients;

(d) For purposes of imposing administrative penalties under this subsection, a violation shall be deemed to have first occurred as of the date of the notice of violation.

20.4 The Department may suspend, revoke, modify or refuse to renew a designation upon any of the following grounds:

(a) Violation by a home health agency of any of the provisions of the law or regulations;

(b) Conduct inimical to the public health, morals, welfare and safety of the people of the State of Vermont in the maintenance and operation of the premises for which a designation is issued or in the provision of home health services;

(c) Financial incapacity of a home health agency to provide or arrange for adequate care and services; or

(d) Failure by a home health agency to comply with a final decision or action of the Department.

20.5 The Department may suspend admissions to a home health agency for a violation that may directly impair the health, safety or rights of patients, or for operating without designation.

20.6 The Department, the attorney general, or a patient may bring an action for injunctive relief against a home health agency in accordance with the Rules of Civil Procedure to enjoin any act or omission which constitutes a violation of the law or regulation. Notice of such action shall be given to the Health Care Ombudsman or, if applicable, the State Long-Term Care Ombudsman.

20.7 The Department, the attorney general, or a patient may bring an action in accordance with the Rules of Civil Procedure for appointment of a receiver for a home health agency, if there are grounds to support suspension, revocation, modification or refusal to renew the agency's designation. Notice of such action shall be given to the Health Care Ombudsman or, if applicable, the State Long-Term Care Ombudsman.

20.8 The Department may enforce a final order by filing a civil action in the superior court in the county in which the home health agency is located or in Washington Superior Court.

20.9 The remedies provided for violations of the law or regulations are cumulative.

20.10 A person or home health agency that knowingly violates the designation or confidentiality requirements of these rules shall be subject to criminal penalties pursuant to 33 V.S.A. §7116.

20.11 The Department may suspend or revoke a home health agency's designation for any violation of applicable laws and rules, for committing, permitting, aiding or abetting any illegal practices in the operation of the home health agency or for conduct or practices detrimental to the welfare of patients to whom home health services are provided.

20.12 Upon suspension or revocation of a designation, the home health agency shall immediately surrender the certificate of designation to the Department.

20.13 The Department, working in collaboration with a home health agency, may appoint a temporary manager to operate a home health agency as a substitute manager. The temporary manager shall have the authority to hire, terminate or reassign staff, obligate funds, alter agency policies and procedures and manage the provision of home health services to correct operational deficiencies.

(a) A temporary manager may be appointed in the following circumstances:

(1) When the home health agency intends to close, but has not arranged at least sixty (60) days prior to closure for the orderly transfer of its patients;

- (2) When an emergency exists in a home health agency which threatens the health, security or welfare of its patients; or
 - (3) When a home health agency is in substantial or habitual violation of the standards of health, safety or patient care established under State or federal regulations to the detriment of the welfare of the patients.
- (b) A temporary manager shall be qualified based on experience and education to oversee the correction of operational deficiencies and shall not:
- (1) Have been found guilty of misconduct by any licensing board or professional society in any state;
 - (2) Have, nor shall a member of his or her immediate family have, ~~ne~~ a financial ownership interest in the home health agency, and;
 - (3) Currently serve or, within the past 2 years, have served as a member of the staff of the home health agency.
- (c) A temporary manager's salary shall be paid directly by the home health agency and shall be at least equivalent to the sum of the following:
- (1) The prevailing salary paid by providers for positions of this type in what the Department considers to be the home health agency's geographic area;
 - (2) Additional costs that would have reasonably been incurred by the provider if such person had been in an employment relationship; and
 - (3) Any other costs incurred by such a person in furnishing services under such an arrangement or as otherwise set by the Department.
- (d) A temporary manager's salary may exceed the amount specified in subsection (c) above if the Department is otherwise unable to attract a qualified temporary manager.
- (e) If a home health agency fails to relinquish authority to the temporary manager as described in this section, the Department shall terminate the designation.
- (f) A home health agency's failure to pay the salary of the temporary manager is considered a failure to relinquish authority to temporary management.
- (g) Temporary management shall end when a home health agency meets the conditions specified in this section and receives approval from the Commissioner.

XXI. Appeals

21.1 A patient may appeal a notice of reduction or discontinuation of home health agency services or a denial of admission to the home health agency by requesting a Commissioner's review.

(a) The request for a Commissioner's review by a patient may be made orally or in writing, and shall be made within fifteen (15) days of receiving written notice. The home health agency shall include in the written notice information on how to contact the Health Care Ombudsman or, if applicable, the Long-Term Care Ombudsman. The written notice also shall inform the patient that the request for a Commissioner's review shall be made by calling or writing to:

Commissioner's Office
Department of Disabilities, Aging & Independent Living
103 South Main Street
Waterbury, VT 05671
802-241-2401

(b) The Commissioner shall send written notice of the decision, which shall include the reasons for the decision, to the patient. If applicable, the notice shall include information on how to appeal the Commissioner's decision with the Human Services Board.

(c) A patient, or legal representative, may appeal a Commissioner's decision by filing a request for a fair hearing with the Human Services Board.

(1) The request for a fair hearing must be made within thirty (30) days of receiving the written notice of determination or the written notice of the decision of the Commissioner.

(2) A request for a fair hearing shall be made to:

Human Services Board
120 State Street
Montpelier, VT 05620-4301
802-828-2536

(d) A home health agency shall provide or arrange for services to patients, as long as the payment source provides for continuing benefits, during the pendency of the appeal. Services shall not be provided to patients who are denied admission. Services shall not be continued when the appeal is based solely on a reduction or discontinuation of a benefit required by federal or state law affecting some or all patients, or in an emergency pursuant to 7.3 (a) (4).

21.2 A home health agency or applicant for designation may appeal the Department's decision to take any of the following actions with regard to designation:

- (a) The issuance of a conditional designation;
- (b) The amendment or modification of the terms of a designation;
- (c) The refusal to grant or renew a designation;
- (d) The refusal to grant a conditional designation; or
- (e) A notice of violation.

21.3 A home health agency aggrieved by a notice of violation may file a request for an informal review. The request must be made to the Division of Licensing and Protection within 10 days of receipt of the notice.

21.4 A home health agency may file a request for a Commissioner's hearing regarding any action by the Department set forth in 21.2 above.

(a) The request for hearing with the Commissioner must be in writing and must be filed within 15 days of receipt of the decision or action of the Department.

(b) The request for hearing must be accompanied by a clear statement of the basis for the request for review.

(c) Issues not raised in the request for hearing shall not be raised later in the proceeding or in any subsequent proceeding arising from the same action of the Department, including appeals filed pursuant to 33 V.S.A. §7117.

(d) Proceedings under this section are not subject to the requirements of Title 33 V.S.A. Chapter 25.

21.5 A home health agency aggrieved by a final decision by the Commissioner may file a request for a fair hearing before the Human Services Board.

(a) A request for a hearing shall be initiated by filing a written request for a fair hearing with the Human Services Board within 30 days of the date of the Commissioner's decision.

(b) No appeal may be taken on any issue that was not raised previously in the request for hearing.