

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
280 State Drive
Waterbury, VT 05671-2020

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This material is available upon request in alternative formats.

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I. General Provisions

1.1 Purpose. It is the purpose of these rules to implement the laws of the State of Vermont (“State”) governing the designation, re-designation, and designation revocation of home health agencies, and the minimum program standards for home health agencies.

1.2 Policy. It is the policy of the State to ensure that, subject to available funding from the State, all Vermont residents within the State have access to comprehensive, medically necessary, high quality home health services without regard to the patient’s ability to pay. It is further the policy of the State to ensure that such services are delivered in an efficient and cost-effective manner, under a regulatory framework designed to control costs while not compromising quality or duplicating services.

1.3 Statutory Authority. These rules are adopted pursuant to 33 V.S.A. § 6303(a).

1.4 Statement of Intent. Upon the effective date of these regulations, all home health agencies in Vermont shall be required to adhere to the regulations as adopted. Any designated service provided under an approved separate entity is also subject to these regulations. Services which are not subject to designation include wellness and prevention services, clinics, and private duty services.

1.5 Exception and Severability. If any provision of these regulations, or the application of any provision of these regulations, is determined to be invalid, the determination of invalidity will not affect any other provision of these regulations or the application of any other provision of these regulations.

1.6 Taxes. All home health agencies in Vermont shall be in good standing with the Vermont Department of Taxes, pursuant to 32 V.S.A. §3113. Failure to do so shall result in the denial or revocation of designation as a home health agency.

1.7 Material Misstatements. A material misstatement related to designation, re-designation or the law governing home health agencies in Vermont made to the State Survey Agency by a home health agency during the designation or re-designation process, or at any time during which the home health agency is an agency in Vermont, may result in the denial of designation or re-designation, designation revocation or other enforcement action.

1.8 Fair Hearing. A person or entity aggrieved by a decision of the Division of Licensing and Protection's State Survey Agency may file a request for a fair hearing with the Human Services Board as provided in 3 V.S.A. §3091.

II. Definitions.

2.1 General Definitions. For purposes of these regulations, words and phrases are given their ordinary meanings unless otherwise specifically defined herein.

2.2 Specific Definitions. The words and phrases below, as used in these regulations, have the following meanings, unless otherwise indicated:

(a) *Activities of Daily Living* means routine activities related to self-care, including, but not limited to, dressing and undressing, bathing, personal hygiene, bed mobility, toilet use, transferring, mobility in and around the home and eating.

(b) *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.

(c) *Applicant* means the individual who signs the application for a home health agency designation.

(d) *Applicant for services* means an individual residing in a designated service area requesting services or care from a home health agency.

(e) *Branch Office* means a location or site from which a home health agency provides services within a portion of the total geographic area served by the parent agency. The branch office is part of the home health agency and is located sufficiently close to the parent agency so that it shares administration, supervision, and services with the parent agency on a daily basis. The branch office is not required to independently meet the Conditions of Participation as a home health agency.

(f) *Clinician orders for life-sustaining treatment or COLST* means a clinician's order or orders for treatment, such as intubation, mechanical ventilation, transfer to hospital, antibiotics, artificially administered

nutrition, or other medical intervention. A COLST order is designed for use in outpatient settings and health care facilities and may include a DNR order that meets the requirements of 18 V.S.A. § 9708.

(g) *Commissioner* means the Commissioner of the Department of Disabilities, Aging and Independent Living.

(h) *Complaint* means a concern raised by a patient, a patient's family member or a patient representative, regarding treatment or care that is (or that fails to be) furnished, or regarding the lack of respect for the patient or the patient's property, by the agency or by anyone furnishing services on behalf of the home health agency.

(i) *Conditional designation* means a designation upon which certain requirements for operation have been imposed by the Department of Disabilities, Aging and Independent Living.

(j) *Critical Incident* means an unexpected occurrence, related to the provision of home health services, involving death, patient suicide, poisoning, and/or serious physical or psychological injury that requires medical treatment or hospitalization. Such incidents may include, but are not limited to, equipment failure, medication error, the misuse of medical devices or restraints or suspected abuse, neglect or exploitation.

(k) *Department* means the Department of Disabilities, Aging and Independent Living.

(l) *Designated Services* means:

1. Medically necessary, intermittent, skilled home health services provided by Medicare-certified home health agencies of the type covered under Title XVIII (Medicare) or XIX (Medicaid) of the Social Security Act;
2. Hospice services of the type covered under Title XVIII (Medicare) or XIX (Medicaid) of the Social Security Act; and
3. Personal care, respite care, companion care and homemaker services provided under the Choices for Care program and authorized within the State's mandated funding limits.
4. The term "designated services" shall not include any other service provided by a home health agency.

(m) *Discharge* means the termination of the services provided to a patient by the home health agency.

(n) *Eligible* means the individual meets the clinical and financial criteria for the applicable service or program and the requested care and services are appropriate to be delivered in the home environment.

(o) *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.

(p) *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.

(q) *Home health agency* means a for-profit or nonprofit home health care business, certified by the Centers for Medicare and Medicaid Services to participate in Medicare and Medicaid, which provides part-time or intermittent skilled nursing services and at least one of the following other therapeutic services, made available on a visiting basis, in a place of residence used as a patient’s home: physical, speech, or occupational therapy; medical social services; home health aide services; or other non-nursing therapeutic services, including, but not limited to, the services of nutritionists, dietitians, psychologists, and licensed mental health counselors.

(r) *Home health services* means the activities and functions of a home health agency 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.

(s) *Homemaker Services* means certain activities that help 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 supportive services (shopping and errands) essential to maintain the living quarters.

(t) *Instrumental Activities of Daily Living (“IADLs”)* means activities that are not necessary for basic functioning but are necessary to live independently. These activities may include, but are not limited to, light housework, preparing and cleaning up after meals, shopping and mobility in the community.

(u) *Medically Necessary Services* means health care services, including diagnostic testing, preventive services, and aftercare, that are appropriate, in terms of type, amount, frequency, level, setting, and duration to the patient's diagnosis or condition. Medically necessary care must be consistent with generally accepted practice parameters as recognized by health care providers in the same or similar general specialty as typically treat or manage the diagnosis or condition, and

- (1) help restore or maintain the patient's health; or
- (2) prevent deterioration or palliate the patient's condition; or
- (3) prevent the reasonably likely onset of a health problem or detect an incipient problem.

(v) *Medicare Conditions of Participation (CoP)* means federal regulations with which particular health care facilities must comply in order to participate in the Medicare and Medicaid programs.

(w) *Nonprofit home health agency* means a home health agency exempt from Federal income tax under Section 501 of the Internal Revenue Code.

(x) "*Patient record*" or "*Patient records*" mean documents in the custody of the home health agency, written or electronic, that pertain to the care and services provided to patients by a home health agency, whether authored by the home health agency or not.

(y) *Patient representative* means an individual who is authorized by the patient to communicate with the home health agency on behalf of the patient. A patient representative includes, but is not limited to, an attorney, a representative payee, a guardian, or an agent under a power of attorney or advance directive. Depending on the authority granted by the patient or under state or federal law, a patient representative may support the patient with decision-making, accessing information and conveying concerns for the patient including, but not limited to, grievances, complaints and appeals, and to receive information from the home health agency on behalf of the patient regarding these matters.

(z) *Personal Care* means providing or assisting an individual with the Activities of Daily Living that the individual otherwise would be unable to complete.

(aa) *Plan of care* means a written description of the steps that will be taken to meet personal, psychosocial, social, nursing, rehabilitative and/or medical needs of the patient.

(bb) *Plan of correction* means the home health agency's response to the statement of deficiencies issued by the State Survey Agency that describes the steps the agency will take to achieve regulatory compliance.

(cc) *Poisoning* means the ingestion of any toxic substance that impairs health or destroys life when ingested, inhaled or absorbed in a relatively small amount.

(dd) *Provisional designation* means a temporary designation approval from the Department of Disabilities, Aging and Independent Living for not more than one year for a home health agency seeking initial Medicare certification.

(ee) *Shared Services Agreement* means cooperative arrangements between or among two or more home health agencies, which are approved by the Commissioner or the Commissioner's designee, to pool or share one or more home health services, including, but not limited to, skilled services, for the purpose of addressing the special needs or exceptional circumstances of patients located in one or more of their designated services areas or obtaining cost savings and efficiencies for the benefit of patients.

(ff) *Skilled services* means medically necessary services that require the skills of a qualified technical or professional health personnel such as registered nurses, licensed practical nurses, physical therapists, occupational therapists and speech-language pathologists. Skilled services shall meet the Medicare Conditions of Participation and must be provided directly by, or under the general supervision of, these skilled nursing or skilled rehabilitation personnel to assure the safety of the patient and to achieve the medically desired result.

(gg) *Variance* means a written determination from the State Survey Agency, based upon the written request of a licensee, which, temporarily and in limited, defined circumstances, waives compliance with a specific regulation.

III. Variances

3.1 Variances from these regulations may be granted upon a determination by the State Survey Agency, the Commissioner, or Commissioner's designee. It is incumbent upon the home health agency to demonstrate that:

- (a) strict compliance would impose a substantial hardship on the home health agency or the patient; and
- (b) any hardship alleged to result from imposition of a regulation from which a variance is sought was not created by the home health agency; and
- (c) the home health agency will otherwise meet the goal or satisfy the intent of the regulation that is the subject of the variance request and the relevant statutory provision.; and
- (d) a variance will not result in decreased services to the patients served by the agency nor will it result in a decrease in the protection of the health, safety or welfare of the patients served by the agency; and
- (e) a variance will not conflict with other legal requirements.

3.2 Requests for a variance shall be submitted to the State Survey Agency in writing. The request shall include:

- (a) the citation for the regulation that is the subject of the variance request; and
- (b) the reason(s) why the variance is being requested, and
- (c) a description of the alternative method proposed for meeting the intent of the regulation that is the subject of the variance request.

3.3 A variance shall not be granted from a regulation pertaining to patient rights.

3.4 Variances are subject to review and termination by the State Survey Agency at any time.

IV. The Designation Process

4.1 Any person, partnership, association or corporation, including a home health agency established outside of Vermont, seeking to become a home health agency in Vermont shall apply for and obtain a Certificate of Need (“CON”) from the Green Mountain Care Board (“GMCB”) prior to filing an application for designation with the Department.

4.2 Any person, partnership, association or corporation, including a home health agency established outside of Vermont, seeking to become a home health agency in Vermont shall, in addition to obtaining a CON from the

GMCB, obtain and maintain federal certification as a home health agency by the Centers for Medicare and Medicaid Services ("CMS") prior to filing an application for designation with the Department. If nationally accredited and deemed, the home health agency shall 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.

4.3 Any person, partnership, association or corporation, including a home health agency established outside of Vermont, seeking to become a home health agency in Vermont, shall, after obtaining a CON from the GMCB, file an application for designation with, and obtain approval from, the Department prior to the commencement of such operation.

4.4 Applications to become a home health agency in Vermont shall be submitted upon forms approved by the Department.

4.5 A home health agency's application for designation shall include:

(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 completed disclosure of ownership form (obtained from 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 geographic service area where designation is sought;

(e) Proof of Medicare home health agency 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, specifying the amount, and the name of each physician with financial interest or ownership of any amount in the home health agency, specifying the amount;
- (j) A local community services plan;
- (k) A list of specific services provided by the home health agency, and a list of those services the home health agency arranges for the provision of by contract; and
- (l) A sample home health services admission packet.

4.6 When an applicant is a corporation, the application shall be signed by two (2) officers of the corporation and by the corporation's Chief Executive Officer or Executive Director, all of whom shall have the authority to legally bind the corporation.

4.7 The Department shall consider each of the following factors in determining whether a home health agency's application or re-application shall be approved for designation or re-designation, as applicable:

- (a) CON determination;
- (b) Record of compliance with, or violation of, any 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:
 - (1) an annual audit report, which includes an unqualified opinion from an independent auditor and indicates that a home health agency is in compliance with generally accepted accounting standards and that the financial reports are an accurate representation of the agency's financial condition;
 - (2) credit reports;
 - (3) history of tax withholding;
 - (4) history of financial fraud with any third-party payer or vendor;

- (5) history of inappropriate referral arrangements; and
- (6) 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 service plan.

4.8 A home health agency designated to provide home health services in Vermont shall have the obligation and the responsibility to provide or arrange for the provision of all designated services to all eligible patients within its designated geographic area who request services, subject to state funding limits.

4.9 A home health agency shall not assign or transfer any authority or designation issued to it by the State Survey Agency.

4.10 A home health agency's designation or re-designation shall remain in effect for four (4) years unless suspended or revoked by an enforcement action.

4.11 The Department may issue a provisional designation for a period not to exceed one (1) year for a home health agency seeking initial Medicare certification.

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

V. Re-designation

5.1 A home health agency shall submit to the Department a completed renewal application at least 60 calendar days prior to the expiration of the current designation.

5.2 The Department shall review the 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 four (4) years;
- (b) Grant the home health agency a conditional or provisional designation; or
- (c) Deny the application.

- 5.3 The Department may grant a conditional designation at any time.
- 5.4 A conditional designation shall specify the timeframe and terms of the conditional designation.

VI. Governing Bodies and Advisory Boards

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 Chief Financial Officer or Chief Executive Officer, 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 Except as set forth in section 6.3, the board of each not-for profit designated home health agency shall be representative of the demographic makeup of the area(s) served by the home health agency or by the health care 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 home health agency or from the healthcare facility governed by the board and family members of individuals who have received or currently are receiving such services.

(b) The president of the board shall survey its members annually and certify to the Commissioner that the composition of the governing body or advisory 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 of a not-for-profit home health agency shall have overall responsibility and control of the planning and operation of the home health agency, including, but not limited to, development of the local community services plan.

6.3 A for-profit home health agency, or multistate home health agency, shall have a consumer advisory board that is representative of the demographic makeup of the area or areas served by the home health agency in Vermont.

(a) A majority of the members of the consumer 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 consumer_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 consumer advisory_board shall also be confirmed by the home health agency's annual independent audit.

(d) The consumer_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.

VII. Requirements of Operations

7.1 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 regulation shall apply.

7.2 A home health agency shall demonstrate compliance with the federal Home and Community-Based Services regulations.

7.3 A home health agency shall conduct business and ensure delivery of services in compliance with the Americans with Disabilities Act.

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

7.5 Local Community Services Plans:

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

(1) The home health care needs of the population within the geographic service area for which the home health agency is designated or wishes to become designated;

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

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

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

- (5) 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;
- (6) How public input was obtained and reflected in the plan; and
- (7) How the final plan shall be made available to the public.

(b) A home health agency shall revise its local community services plan at least every four (4) years.

7.6 A home health agency shall not employ or have a contract with any worker who has a substantiated record of abuse, neglect or exploitation of a child as determined by the Department for Children and Families or a substantiated record of abuse, neglect, or exploitation of a vulnerable adult as determined by the Department. A home health agency shall conduct background checks, in accordance with the Department's background check policy, on all employees, independent contractors and volunteers that provide direct care to its patients.

7.7 A home health agency shall ensure that staff, services and necessary supplies are available to meet the needs of its patients and that there are established contingency plans in the event of unexpected shortages of scheduled staff or supplies, or disruption in scheduled services.

7.8 A home health agency shall develop, maintain, enforce and, upon request, provide to the Department policies and procedures concerning, but not limited to:

- (a) Admission, transfer, reduction in services and discharge of patients;
- (b) Medical supervision and plans of care;
- (c) Emergency care;
- (d) Patient records and other patient information, including, but not limited to, confidentiality, use, retention, protection, storage, disposition and disclosure;
- (e) Personnel, including, but not limited to, qualifications, credential verification, staff orientation, training and evaluation, and, as applicable, policies pertaining to students and volunteers;
- (f) Quality improvement and program improvement plans;

- (g) Handling complaints and grievances;
- (h) Use of electronic records addressing data integrity, confidentiality, security, authentication, non-repudiation, encryption, as warranted, and ability to be audited, as appropriate to the system and type(s) of information;
- (i) Supervision of licensed and unlicensed personnel; and
- (j) Advance directives.

7.9 A home health agency shall develop and maintain an emergency management plan describing how it will continue to provide services or arrange for the provision of services (including, but not limited to, crisis response) for its patients in times of emergency, crisis or disaster. The plan shall identify how the home health agency will address individual patient needs in the event of an unexpected, temporary disruption of services resulting from the emergency, crisis or disaster. A home health agency shall make its emergency management plan available to the Department upon request.

7.10 A home health agency shall develop and maintain a technological infrastructure that enables the home health agency to collect information, submit data, conduct needs assessments of patients in its designated area, and perform other required functions in a cost-effective manner.

7.11 A home health agency shall have written contracts for clinical or direct care services provided on behalf of the home health agency by other home health agencies, independent contractors or sub-contractors. The contracts shall include:

- (a) Names and signatures of parties to the agreement;
- (b) Contract term;
- (c) Specifications of work to be performed;
- (d) Each party's responsibilities, functions and objectives during the contract term;
- (e) Payment provisions;
- (f) Business Associate Agreement, when applicable;
- (g) Statement that the home health agency shall retain administrative responsibility for services rendered, including, but not limited to, subcontracted services;

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

(i) Requirement that the other party to a contract (i.e., home health agency, independent contractor or subcontractor) shall provide the home health agency written documentation regarding the amount and type(s) of services provided.

VIII. Required Functions and Administration

8.1 A home health agency shall:

(a) Provide high quality, comprehensive services that are responsive to the population it serves; and

(b) Monitor the services delivered by its contracted service providers.

8.2 A home health agency shall provide or arrange for the provision of all designated services to all eligible patients within its designated service area and to all eligible patients accepted onto service based on referrals from other designated agencies, subject to state funding limits.

8.3 When a home health agency determines that it is unable to provide services to a patient or applicant for services, the agency shall provide information regarding alternative providers that may be able to serve the individual. The home health agency shall facilitate a referral to the alternative provider(s) unless the individual objects to the referral or the necessary funding for the service(s) is unavailable. In the event the home health agency determines that it cannot provide or arrange for the provision of designated services, the home health agency shall provide notice to the individual as required below in Section 16.5.

8.4 A home health agency shall develop a fee schedule which shall be provided upon request to all patients or their patient representative and to the public.

8.5 A home health agency shall provide each of its participants in the Global Commitment to Health Section 1115 Demonstration Waiver Choices for Care program written notice 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 State and Regional Long-Term Care Ombudsman.

8.6 A home health agency shall ensure that the State Long-Term Care Ombudsman or Office of the Health Care Advocate, or representatives of either or both offices, have:

(a) Access to review the patient records of an individual receiving home health services if:

(1) The patient or the patient representative consents; or

(2) The patient is unable to consent to the review and has no patient representative.

(b) Access to review the patient records of an individual receiving home health services as is necessary to investigate a complaint by, or on behalf of, a patient if:

(1) The patient representative refuses to give the permission;

(2) The State Long-Term Care Ombudsman, the Office of the Health Care Advocate, or the representative of either, has reasonable cause to believe that the patient representative is not acting in the best interests of the patient; and

(3) The Regional Long-Term Care Ombudsman has obtained the approval of the State Long-Term Care Ombudsman, if applicable.

8.7 A home health agency shall report critical incidents involving its patients to the Division of Licensing and Protection (DLP) Survey and Certification Unit by the next business day after it learns of the incident. Verbal reports shall be followed by written reports that summarize the incident.

(a) A home health agency, as a mandatory reporter, shall report or cause a report to be made to the DLP's Adult Protective Services Unit when it knows of or has received information of abuse, neglect or exploitation of a vulnerable adult, or when it has reason to suspect that a vulnerable adult has been abused, neglected, or exploited. The report shall be made within 48 hours.

(b) If a member of a home health agency staff qualifies as a mandatory reporter pursuant to 33 V.S.A. § 4913, the staff member shall report to the Department for Children and Families within 24 hours of when it reasonably suspects a child is being abused, neglected, or exploited, in accordance with 33 V.S.A. Chapter 49.

8.8 A home health agency shall cooperate and collaborate with Vermont Emergency Management Services (“EMS”) personnel in its designated service area, as needed.

8.9 A home health agency shall:

- (a) Monitor and submit reports as requested by the Department regarding the provision of services, including, but not limited to, costs, outcomes, service accessibility and service delivery;
- (b) Submit reports as requested by the Department regarding quality assurance, quality improvement, and outcome activities; and
- (c) Protect confidentiality of its patient information when data are transferred by ensuring that the method of transferring the information is in compliance with state and federal laws and regulations.

8.10 A home health agency shall establish mechanisms for the collection of data to be reported on an annual basis to the Department. Data to be collected and reported shall include, but not be limited to, the following information:

- (a) Complaints;
- (b) Number of individuals on waiting lists for services;
- (c) Number of individuals ineligible for services;
- (d) Number of patients under the age of 65 currently receiving services and the number that have received services since the last reporting cycle;
- (e) Number of patients 65 years of age and older currently receiving services and the number that have received services since the last reporting cycle;
- (f) Total number of visits and visiting hours provided to patients;
- (g) Charitable and subsidized programs and services available through the home health agency for uninsured or low-income persons; and
- (h) 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.

8.11 The home health agency shall provide the Department, at the Department’s request, with the results of patient surveys, data from federal and state surveys, scoring by national accrediting organizations, audited

annual financial statements and annual cost reports. The home health agency shall provide the results to the Department within ten (10) business days of its receipt of the Department's request.

IX. Fiscal Management

9.1 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 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) Insurance coverage for fire, professional liability, general liability, and directors/officers' liability.

9.2 A home health agency shall provide the Department with sufficient financial detail about home health agency services for purposes of collaborating with the Department to analyze data, costs and efficiencies of home health agency services paid for by the State.

9.3 A home health agency shall disclose to the Department the information required in its application, as reflected in Section 4.5 above, 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.

X. Petitions to Commissioner

10.1 A home health agency may petition the Commissioner to cease providing [a] designated service(s), with 90 calendar days' notice, when an agency can demonstrate that financial losses from the home health service threaten the continued operation of the home health agency, disregarding private donations and municipal and town funds.

10.2 A home health agency experiencing financial distress may petition the Commissioner for temporary financial relief. The Commissioner, in his or her discretion, and if funds are available, may grant such temporary financial relief after a review of the home health agency's financial status. 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 assistance is provided.

XI. Skilled Services

11.1 A home health agency shall furnish skilled services according to the Medicare Conditions of Participation (CoPs) and in accordance with the patient's plan of care. The Medicare HHA CoPs do not apply to those individuals who receive only chore services or other non-medical services.

XII. Unlicensed Caregiver Services

12.1 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/or homemaker services.

12.2 A home health agency shall assure the competency of the unlicensed caregivers it employs, train those caregivers to perform specific tasks for specific patients, and ensure that the caregivers are appropriately supervised by a qualified supervisor, as provided for in the agency's policies and job descriptions.

XIII. Shared Service Agreements and Referrals

13.1 A home health agency may enter into shared services agreements with other home health agencies to provide or arrange for the provision of home health services that it would otherwise not offer, or to provide services more efficiently or effectively.

13.2 Prior to the implementation of a shared service agreement, a home health agency shall submit the proposed agreement in writing to the Commissioner for approval.

13.3 The Commissioner shall have 60 calendar days from receipt of a shared services agreement within which to provide written approval or disapproval of the plan to the home health agencies proposing the agreement.

13.4 A home health agency shall initiate communication with each patient by the close of the next business day after the receipt of a physician order, or as specified by the physician order.

XIV. Change in Status: Ownership, Location or Discontinuation of Operation or Designated Services

14.1 When a change of ownership or location is planned, the home health agency is required to file a new application for designation at least 90 calendar days prior to the proposed date of the change.

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

14.3 A home health agency that intends to discontinue all or part of its operation or designated services, including, but not limited to, ceasing participation in the Global Commitment to Health Section 1115 Demonstration Waiver Choices for Care program, or intends to transfer ownership or change the location or address of the agency in such a way as to necessitate the discharge of patients, shall provide written notice as outlined below. The home health agency is responsible for ensuring that all patients are discharged in a safe and orderly manner.

(a) General Notice Requirements

(1) At least 90 calendar days prior to the proposed date of any such change, a home health agency shall provide written notice to the Department, the Office of the Health Care Advocate and the State Long-Term Care Ombudsman.

(2) At least 60 calendar days prior to the proposed date of any such change a home health agency shall place a legal notice in local 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.

(3) At least 45 calendar days prior to the proposed date of any such change, a home health agency shall provide a detailed written plan to the Department, the Office of the Health Care Advocate and the State Long-Term Care Ombudsman describing how the home health agency intends to provide for the safe and orderly transfer to other service providers or discontinuation of services for its patients. The plan shall include:

(i) Assurances that adequate staff and patient care will be provided during the transfers;

(ii) Arrangements to ensure the orderly transfer of patients to another service provider(s); and

(iii) A protocol for disposition of patient files and home health agency records.

(4) Upon request, the home health agency shall provide to the Department any additional information related to the transfer to other service providers or the discontinuation of designated services or its operations plan, as well as follow-up reports regarding specific placement action.

(b) Patient Notice Requirements.

(1) At least 60 calendar days prior to the proposed date of any change that would necessitate discontinuation of a designated service or transfer to another service provider, a home health agency shall provide written notice to all patients or their patient representatives receiving the designated service(s).

(2) The notice shall be provided on forms approved by the Department for non-Medicare services. The notice shall include:

(i) The reason for the discontinuation of the designated service(s) or transfer to another service provider;

(ii) The date the designated service(s) will be discontinued or the transfer to another service provider will occur; and

(iii) Information about how to contact the Office of the Health Care Advocate and State Long-term Care Ombudsman.

(3) At least 30 calendar days prior to closure of the home health agency or discontinuation of a designated service, a home health agency shall provide to each patient receiving the designated service an individualized plan to ensure continuity of care.

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

(d) When a home health agency intends to make a change (e.g., admission or retention policy, ownership, or location of the agency) in such a way that does not necessitate the discharge of patients or transfer to another service provider, the home health agency shall provide written notice to the Department and the patient(s) at least thirty (30) days prior to such a change.

XV. Notice to Patients and Public Regarding Suspension/Revocation/Non-Renewal of Designation Status

15.1 If a designation is suspended, revoked, or not renewed, a home health agency shall notify all its patients in writing about the action within 5 days of receipt of the notification of a suspension, revocation or non-renewal. The notice shall include the date of the suspension, revocation or non-renewal 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 and the effective date of closure, if applicable.

15.2 If a designation is suspended, revoked, or not renewed, a home health agency shall advise the public of such action. The public notice shall be in the form of a paid legal notice in the local area newspaper(s), published within 15 calendar days following receipt by the home health agency of written notification of the suspension, revocation or non-renewal of the designation.

XVI. Admissions, Denials, Reduction of Services, Discharge of Patients and Notice

16.1 A home health agency shall develop and implement policies and procedures that set forth the steps that the home health agency will follow regarding:

- (a) denial of an admission for designated home health services (as used in this Section, a “denial”);
- (b) reduction of services for patients; and
- (c) discharge of patients.

16.2 Discharge planning for patients shall be initiated at the time of admission of a patient to home health services 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.

16.3 When a home health agency denies an application for admission, or reduces the services being provided to a patient or discharges a patient from services pursuant to 16.4(a), 16.4(b) or 16.4(c), the home health agency shall provide a verbal notice followed by a written notice, to the patient and patient representative as applicable. Notices shall be accessible and written in language that is understandable to a layperson. The home health agency shall provide verbal notice to the patient and patient representative, if applicable, either in person or by telephone. The home health agency shall provide written notice by hand-delivery or by mailing the notice to their last known mailing

addresses. For patients placed on a waiting list for homemaker services, a verbal notice alone shall suffice.

16.4 A home health agency may reduce the designated services being provided to a patient or discharge a patient from services only as provided for in this subsection:

- (a) A home health agency may reduce the designated services being provided to a patient or discharge a patient from services with verbal and written notice as soon as practicable when one (1) or more of the following occurs:
 - (i) The patient has requested that the home health services be reduced or that the patient be discharged from services;
 - (ii) The patient has moved out of the home health agency's designated service area;
 - (iii) The patient has chosen another provider and arrangements have been made for the alternate provider to assume responsibility for the home health care needs of the patient; or
 - (iv) The patient is admitted to a hospice, hospital, nursing home, residential care home, or rehabilitation facility;
- (b) A home health agency may reduce the designated services being provided to a patient or discharge a patient from services with written notice at least 2 business days before the reduction in or discharge from services when one (1) or more of the following occurs:
 - (i) Goals and treatment objectives have been met and skilled services are no longer medically necessary as determined by the physician and reflected in the physician's orders;
 - (ii) The home health agency has been notified by the third-party payer, the patient or the case manager that the patient no longer meets the eligibility requirements for the services, or the services are no longer authorized or covered by the patient's health insurance plan; or
 - (iii) The home health agency has been unable to obtain written orders for skilled services from the patient's physician.
- (c) A home health agency may reduce the designated services being provided to a patient or discharge a patient from services with written

notice at least 14 calendar days before the reduction in or discharge from services when one (1) or more of the following occurs:

- (i) The patient has failed to pay for services for which he or she is responsible;
 - (ii) After attempting to resolve the situation, the home health agency determines and documents that the patient's needs cannot be adequately met in the home by the home health agency; or
 - (iii) The patient, primary caregiver or other person in the home has exhibited behavior, including, but not limited to, physical abuse, sexual harassment, verbal threats or abuse, or threatening behavior that poses a safety risk to agency staff.
- (d) A home health agency may reduce services or discharge a patient immediately and without advance notice if the patient, primary caregiver or other person in the home has exhibited behavior which presents an imminent risk of harm to agency staff.
- (e) In emergency situations, when the home health agency cannot reasonably provide advance notice, the agency must provide verbal and written notice as soon as practicable.

16.5 The written notice of a denial of admission to home health services, a reduction in existing home health services, or a discharge from services, shall include the following information:

- (1) The specific reason(s) for the denial, reduction of or discharge from services;
- (2) The effective date of the decision to reduce services or discharge a patient from services;
- (3) Specific information about *how* to appeal, in accordance with Section XXIII. of these regulations;
- (4) Contact information for the Office of the Health Care Advocate and the State Long-Term Care Ombudsman;
- (5) A statement that, while an appeal is pending, the patient may request to continue existing services only, or a statement that no services are available for appeals of the denial of admission to home health services; and

(6) A statement that a request for continuing services, if any, following a reduction in or discharge from services under circumstances listed in Section 16.4(c)(ii) or (iii), shall be made to the Division of Licensing and Protection's State Survey Agency and must be made before the effective date of the intended action.

16.6 A home health agency shall provide for the following when discharging a patient to protect the safety of staff pursuant to Section 16.4(c)(iii).

(a) When discharging a patient from services pursuant to Section 16.4(c)(iii) above, the home health agency shall:

(1) notify the physician, if working under a physician's order, and the case manager, if applicable, of the reason for discharge (i.e., safety concerns);

(2) advise the patient and the patient representative, if applicable, that a discharge from services for safety reasons is being considered;

(3) demonstrate and document in the patient's medical record that a reasonable effort has been made to resolve the problem(s) presented by the patient's behavior or the situation that caused safety concerns; and

(4) document in the patient's record the problem(s) and efforts made to resolve the problem(s).

(b) When, based on the specific circumstances, there is an immediate need to reduce services or to discharge a patient from services due to an imminent risk of harm and the home health agency cannot reasonably provide advance notice, the home health agency need not comply with the requirements set forth in 16.5 and 16.7. Rather, the home health agency must adequately document the basis for its determination that an immediate need to discharge or reduce services existed. The determination as to an immediate need to discharge or reduce services shall be based on an assessment by the home health agency that risk of harm to the home health agency staff providing the services is imminent. The home health agency shall notify the physician, if working under a physician's order, and the case manager, if applicable, of the reason for discharge (i.e., safety concerns);

(c) The home health agency shall provide verbal and written notice to the patient and the patient representative, if applicable, as soon as practicable immediately following the determination to discharge from or

reduce services based on an imminent risk of harm. The notification shall explain:

- (1) the description of the imminent risk of harm;
- (2) the basis for the discharge from or reduction of services;
- (3) the reason why advance notice was not given;
- (4) the effective date of the reduction of services or discharge from services;
- (5) what steps, if any, the patient may take to remediate the situation such that services may be restored;
- (6) specific information about how to appeal, in accordance with Section XXIII of these regulations, including, but not limited to, a statement that the patient may request that services currently in place continue while the appeal is pending, if applicable, and that continuing services are not available unless and until the imminent risk of harm has been remediated.

16.7 When a home health agency determines that a patient will require continuing care after services are discontinued, the agency shall arrange, with the patient's consent, or actively assist the patient with arranging for such services. The home health agency shall document its efforts to arrange for, or assist the patient with arranging for, continued care in the patient's clinical record, 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.

16.8 A home health agency shall follow the CMS regulations governing notices and appeal rights when the home health agency reduces Medicare covered services for a patient or discharges a patient receiving only Medicare-covered services.

16.9 When a home health agency discharges a patient from services for any of the circumstances specified in this section, the circumstances shall be documented in the patient record.

16.10 In addition to the requirements of this section, in the event that a home health agency discontinues offering a service (other than a designated service) or ceases operation, notice shall be provided in accordance with Section 14.3 above.

XVII. Patient Assessment and Plan of Care

17.1 All Medicare Certified Services shall follow the Medicare CoPs for the patient assessment and development of the plan of care.

17.2 The patient assessment and plan of care regarding programs not covered by Medicare will follow the applicable program standards. In the absence of standards, the home health agency will respond to referrals in two business days.

17.3 A patient's plan of care shall be person-centered, understandable to a layperson, and formatted in a form accessible to the patient and the patient representative, if applicable.

17.4 A home health agency shall assure that services are furnished to the patient in accordance with the patient's plan of care.

17.5 A home health agency shall respond in a timely manner to patient requests regarding his or her plan of care, including, but not limited to, requests for care conferences or changes in service. Home health agencies shall respond as soon as practicable.

17.6 A home health agency shall consider a patient's preferences for services and caregivers and shall collaborate with the patient's other service providers, service agencies or service systems, if appropriate and requested by the patient.

XVIII. Patient Rights

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

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

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

18.4 A patient has a right to receive care and treatment free of maltreatment, including, but not limited to, abuse, neglect and exploitation.

18.5 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 type of providers that will provide care and the frequency of visits.

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

18.7 A patient has the right to be informed of his or her right to formulate advance directives.

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

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

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

18.11 A patient has the right to be informed by the home health agency of the telephone number for the toll-free home health hotline. The home health agency shall inform the patient that the purpose of the hotline is to receive complaints or questions about local home health agencies.

18.12 A patient has the right to receive from the home health agency an admission packet that includes relevant information, including, but not limited to, the contact information for the Office of the Health Care Advocate or, if the patient receives services under the Global Commitment to Health 1115 Medicaid Waiver as a Choices for Care program participant, the State Long-Term Care Ombudsman.

18.13 A patient has the right to be fully informed of home health agency policies and charges for services, including, but not limited to, eligibility for third-party reimbursements. Before the care is initiated, the home health agency shall inform the patient of:

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

- (b) The charges that may be the responsibility of the patient.

18.14 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.

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

18.16 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 reviewed by the Commissioner.

18.17 A patient has the right to review reports of state and federal surveys of the home health agency and a right to receive copies of the survey reports upon request to the Division of Licensing and Protection.

18.18 Any of the rights enumerated in this section may be exercised by an individual who has the legal authority (e.g., patient representative) to act on behalf of the patient, when the patient lacks the capacity to exercise those rights.

XIX. Quality Assurance and Improvement

19.1 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, but not limited to, those services furnished under contract or other formal or informal 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, but not limited to, 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 quality improvement(s) and corrective action(s);
- (e) Evaluate results of quality improvement(s) and correction action(s); and
- (f) Assure systemic integration of successful quality improvement actions and corrective action(s).

19.2 The frequency and detail of data collection shall be specified by the governing body or board of the home health agency and shall include detail and data as needed and specified by the Department.

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

19.4 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.

19.5 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. These written records shall be made available to the Department upon request.

19.6 A home health agency's quality assurance and improvement activities shall include, but not be limited to, involvement by direct care staff in the identification and planning of quality improvement activities.

XX. Survey and Review

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

20.2 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.

20.3 The Department shall have access to the home health agency at all times, with or without notice, to conduct investigations. 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.

20.4 The Department shall investigate whenever it has reason to believe a violation of the law or regulations by the home health agency 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.

20.5 After each survey or complaint investigation, the Department shall hold an exit conference with the Chief Executive Officer or Executive Director 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. The Department shall post the survey statements on the Department's website.

20.6 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 a 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 violation(s);
- (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 15 calendar days of the date of the notice of violation.

20.7 If a home health agency receives a notice of violation(s) from the Department, it shall submit a written plan of correction to the Department within ten (10) business days of the date 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 the person responsible for overseeing the plan of correction.

(b) A home health agency shall post statements of deficiencies in a location readily visible to patients and to the public on those premises where the home health agency's business operations are conducted.

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

20.8 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.

20.9 Patients, patient 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 for the copies of the reports consistent with state record copying costs.

XXI. Enforcement

21.1 The Department may take immediate enforcement action when necessary to eliminate a condition at a home health agency or a condition that exists through the provision of its services 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 violation.

21.2 The Department may require a home health agency to take corrective action to eliminate a violation of a rule or statute and provide the Department with proof of correction of the violation(s) within a period of time specified by the Department.

(a) If the Department does require corrective action, 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) 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 in accordance with these regulations and governing federal and state law.

21.3 The Department may assess administrative penalties against a home health agency for failure to correct a violation or failure to comply with a plan of corrective action. The Department shall determine the primary purpose of the rule or provision at issue and may assess administrative penalties in accordance with the daily financial penalties set forth below:

(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 initial notice of violation.

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

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

(b) 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 health, safety, or welfare of patients to whom home health services are provided.

(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.

21.5 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.

21.6 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 Office of the Health Care Advocate and, if applicable, the State Long-Term Care Ombudsman.

21.7 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 Office of the Health Care Advocate and, if applicable, the State Long-Term Care Ombudsman.

21.8 The Department may enforce a final order for appointment of a receiver 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.

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

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

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

21.12 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 for the orderly transfer of its patients at least 60 calendar days prior to closure;
- (2) When an emergency exists in a home health agency which threatens the health, safety 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, 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 the home health agency's designated service area;
- (2) Additional costs that would have reasonably been incurred by the home health agency 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 within the salary requirements listed in (c) above.

(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 or when it is determined that the home health agency will no longer be designated.

XXII. Complaints Received by Home Health Agencies Regarding Staff, Management or Other Service Providers

22.1 A home health agency shall investigate complaints regarding its staff or management, or anyone furnishing services or supplies on behalf of the home health agency. The complaints may be submitted to the home health agency by patients, a patient's family, a patient representative, the State Long-Term Care Ombudsman or the Office of the Health Care Advocate. The home health agency shall furnish patients with the toll-free telephone number for the Home Health Hotline to report complaints.

22.2 The home health agency shall respond to all complaints, whether received orally or in writing, within two (2) business days of receiving the complaint(s).

22.3 A home health agency shall keep a log of all complaints. The log shall include the date of the complaint(s), the name of the complainant(s), the subject of the complaint(s), the name of the person assigned to investigate the complaint, and the date and resolution of the complaint(s).

22.4 A home health agency shall report to the Division of Licensing and Protection any quality of care or service-related complaint not resolved to the satisfaction of the patient within 8 business days of the home health agency receiving the complaint.

22.5 When a quality of care or service-related complaint is not resolved to the satisfaction of the patient within five (5) business days, a home health agency shall notify the complainant in writing of the right to request assistance from

the Office of the Health Care Advocate or, if applicable, the State Long-Term Ombudsman and provide the contact information for those offices. If both the home health agency and the patient are actively seeking resolution but the issue(s) is(are) not resolved within 30 calendar days of receiving the complaint, the home health agency shall notify the patient in writing that he or she may complain to the Department at that time.

XXIII. Patient Appeals

23.1 A patient or the patient representative, if applicable, who is notified by CMS of a reduction in or a discharge from Medicare services must follow the appeals process outlined in the written notification from CMS.

23.2 A patient or the patient representative, if applicable, who is notified by Medicaid or another third-party payer of a reduction in or a discharge from services must follow the appeals process outlined by the payer.

23.3 A patient or the patient representative, if applicable, who is notified by a home health agency of a denial of an application for admission, reduction of or discharge from services, and plans to appeal that decision must follow the appeals process outlined in this section of the regulations.

23.4 To appeal the decision of the home health agency to deny admission to services, or reduce or discharge a patient from services, the patient or the patient representative, if applicable, must, within 30 calendar days of the date of the written notice of decision from the home health agency, contact the Division of Licensing and Protection's State Survey Agency to appeal the home health agency's decision to the Director of the State Survey Agency.

23.5 The Division of Licensing and Protection's State Survey Agency shall issue its decision within 30 calendar days of its receipt of the request for appeal. The State Survey Agency may extend the time for resolving an appeal by up to 14 calendar days upon request of the patient or patient representative, or upon showing there is a need for additional information and how the delay is in the best interest of the patient.

23.6 Copies of all materials submitted to the Division of Licensing and Protection's State Survey Agency by the home health agency shall be available to the patient or the patient representative, if applicable, upon request.

23.7 The written decision rendered by the Director of the State Survey Agency at the Division of Licensing and Protection shall be sent to the patient or patient representative, if applicable, and the home health agency, and shall include the reason(s) for the decision and a statement that if the decision is not favorable to the patient, the decision may be appealed to the Human Services

Board, with information about how to request a fair hearing, and the timeline for requesting an appeal to the Human Services Board. The notice shall include contact information for the Human Service Board and inform the patient or the patient representative, if applicable, that a request for a fair hearing may be made either orally or in writing and shall be directed to the Human Services Board.

23.8 Upon the request of a patient or patient representative, a home health agency shall provide or arrange for continuing services for the patient during the pendency of the patient's appeal to the Human Services Board concerning a reduction of or discharge from services if the payment source provides for continuing services. The home health agency shall document its efforts regarding patients' continuing services in the patient's clinical record. Services shall not be provided or continued when an immediate need exists to end services due to an imminent risk of harm to the home health agency staff providing the services and the imminent risk of harm has been documented in the patient record and other relevant home health agency records, unless and until the imminent risk of harm has been remediated.

23.9 There is no right to an appeal if the sole issue is a state or federal law requiring an automatic change adversely affecting some or all patients. A patient retains the right to appeal the application of the law to the facts of an individual's case.

XXIV. Home Health Agency Appeals

24.1 A home health agency aggrieved by a notice of violation may file a request for an informal review with the State Survey Agency. The request must be made to the State Survey Agency within 10 business days of receipt of the notice of violation.

24.2 A home health agency applying for re-designation or any person, partnership, association or corporation applying 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.

24.3 A home health agency may request a Commissioner's hearing regarding any action by the Department set forth in Section 24.2 above.

- (a) The request for a Commissioner's hearing shall be in writing and shall be made within 15 calendar days of the date of the decision or action notice of the Department.
- (b) The request for hearing shall be accompanied by a clear statement of the basis for the request.
- (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.
- (d) Proceedings under this section are not subject to the requirements of 3 V.S.A. chapter 25.

24.4 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 fair hearing shall be initiated by calling the Human Services Board or by filing a written request for a fair hearing with the Human Services Board within 30 calendar 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.

XXV. Patient Records

25.1 A home health agency shall maintain a patient record for every patient receiving home health services from the agency. The patient record shall include pertinent and comprehensive information regarding the patient's history and current findings as to the patient's condition(s) and status, in accordance with accepted professional standards and in accordance with the requirements of the program under which the patient is served by the home health agency. A home health agency shall ensure that whenever a patient's advance directive, including a DNR or COLST, is provided to the agency, a copy is included in the patient record.

25.2 A home health agency shall maintain the confidentiality of all patient records, including, but not limited to, personal and medical information contained in the patient records, and shall safeguard patient record information against loss or unauthorized use.

25.3 A home health agency shall develop written policies and procedures governing the use and destruction of patient records and the release of information from patient records to a patient or other authorized individual or entity in accordance with state and federal law.

(a) The home health agency shall obtain the patient's or the patient representative's written consent prior to release of information from the patient record, excepting access to the patient record by authorized employees of the home health agency, or in the case of a patient transfer to another provider or as permitted by law.

(b) The home health agency's policy pertaining to the release of information from patient records shall establish a reasonable cost, consistent with state record copying costs, for the provision of copies of patient records.

25.4 A home health agency shall retain patient records for ten (10) years after the month the cost report to which the records apply is filed with the fiscal intermediary, unless state or federal law stipulates a longer period of time. A home health agency shall arrange for the retention of the records, in accordance with applicable federal and state laws and regulations, even if the home health agency discontinues operations.

25.5 If a patient is transferred to a health care facility, the home health agency shall send a copy of the patient record or patient health abstract with the patient.

25.6 A home health agency shall ensure that a patient's advance directive, including a DNR or COLST, is accessible to authorized individuals and that home health agency staff are familiar with the patient's wishes and with the requirement that the patient's wishes and preferences be honored.