



SOUTH CAROLINA
DEPARTMENT OF
PUBLIC HEALTH

Regulation 61-77 Standards for Licensing Home Health Agencies

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SECTION 100 – DEFINITIONS AND LICENSURE

101. Definitions.

A. Abuse. Physical Abuse or Psychological Abuse.

1. Physical Abuse. Intentionally inflicting or allowing to be inflicted physical injury on a Patient by an act or failure to act. Physical abuse includes, but is not limited to, slapping, hitting, kicking, biting, choking, pinching, burning, actual or attempted sexual battery, use of medication outside the standards of reasonable medical practice for the purpose of controlling behavior, and unreasonable confinement. Physical Abuse also includes the use of a restrictive or physically intrusive procedure to control behavior for the purpose of punishment except that a therapeutic procedure prescribed by a licensed physician or other qualified professional or that is part of a written plan of care by a licensed physician or other qualified professional is not considered physical abuse. Physical abuse does not include altercations or acts of assault between Patients.

2. Psychological Abuse. Deliberately subjecting a Patient to threats or harassment or other forms of intimidating behavior causing fear, humiliation, degradation, agitation, confusion, or other forms of serious emotional distress.

B. Administrator. The individual designated by the governing body or Licensee who is in charge of and responsible for the administration of the Home Health Agency. May also be referred to as Director.

C. Authorized Healthcare Provider. An individual authorized by law and currently licensed in South Carolina as a Physician, advanced practice registered nurse, or physician assistant to provide specific treatments, care, and services to Patients.

D. Branch Office. 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 Agency and is located sufficiently close to share administration, supervision, and services in a manner that renders it unnecessary for the branch independently to meet the licensure requirements as an Agency.

E. Comprehensive Assessment. An individualized assessment that reflects each Patient's current health status, includes information that may be used to demonstrate the Patient's progress toward achievement of the desired outcomes, identifies the Patient's need for Home Health Services, and reflects the Patient's medical, nursing, rehabilitative, social and Discharge planning needs.

F. Consultation. A visit by individuals authorized by Department representatives who will provide information to Agencies with the goal of facilitating compliance with the regulations.

G. Contracted Party. An individual, business, or other entity who enters into an agreement with a Home Health Agency to provide care, treatment, or services normally provided by the Home Health Agency to a Patient.

H. Department. The South Carolina Department of Health and Environmental Control.

I. Direct Care Staff. Those individuals who provide direct treatment, care, and services to Patients, including:

1. A Registered Nurse, Licensed Practical Nurse, or certified nurse assistant;

2. Any other licensed professional employed by or contracting with a Home Health Agency who provides to Patients direct care or services and includes, but is not limited to, a physical, speech, occupational, or respiratory care therapist;

3. A person who is not licensed but provides physical assistance or care to a Patient served by a Home Health Agency;

4. A person employed by or under contract with a Home Health Agency who works within any building housing Patients; or

5. A person employed by or under contract with a Home Health Agency whose duties include the possibility of Patient contact.

J. Discharge. The point at which treatment, care, and services provided by a Home Health Agency are terminated and the Home Health Agency no longer maintains active responsibility for the care of the Patient.

K. Exploitation. 1) Causing or requiring a Patient to engage in activity or labor which is improper, unlawful, or against the reasonable and rational wishes of the Patient. Exploitation does not include requiring a Patient to participate in an activity or labor which is a part of a written plan of care or which is prescribed or authorized by a licensed physician attending the Patient; 2) An improper, unlawful, or unauthorized use of the funds, assets, property, power of attorney, guardianship, or conservatorship of a Patient by a person for the profit or advantage of that person or another person; or 3) Causing a Patient to purchase goods or services for the profit or advantage of the seller or another person through: undue influence, harassment, duress, force, coercion, or swindling by overreaching, cheating, or defrauding the vulnerable adult through cunning arts or devices that delude the vulnerable adult and cause him to lose money or other property.

L. Health Assessment. An evaluation of the health status of a Staff member by a Physician, other Authorized Healthcare Provider, or Registered Nurse in accordance with Agency policy.

M. Home Health Agency (“Agency”). A public, nonprofit, or proprietary organization, whether owned or operated by one or more persons or legal entities, which furnishes or offers to furnish Home Health Services.

N. Home Health Aide Services. Services provided by an individual supervised by a Registered Nurse or licensed therapist who renders assistance in the home to Patients with personal care problems and who meets minimum qualifications and training as set by the Home Health Agency.

O. Home Health Services. Those items and services furnished to an individual by a Home Health Agency, or by others under arrangement with the Home Health Agency, on a visiting basis and, except for subsection 5, below, in a place of temporary or permanent residence used as the individual's home as follows:

1. Part-time or Intermittent skilled nursing care as ordered by a Physician or other Authorized Healthcare Provider and provided by or under the supervision of a Registered Nurse and at least one other service listed below:

2. Physical, occupational or speech therapy;

3. Medical social services, Home Health Aide Services, and other therapeutic services;

4. Medical supplies and the use of medical appliances;

5. Any of the above items and services provided on an outpatient basis under arrangements made by the Home Health Agency with a hospital, nursing home, or rehabilitation center and the furnishing of which involves the use of equipment of such a nature that the items and/or services cannot readily be made available to the individual in his/her home, or which are furnished at one of the above facilities while the Patient is there to receive such items or services, but not including transportation of the individual in connection with any such items or services.

P. Incident. An unusual, unexpected adverse event, including any accidents, that could potentially cause harm, injury, or death to Patients or Staff members.

Q. Inspection. A visit by individuals authorized by the Department to a licensed Home Health Agency or to a proposed Home Health Agency for the purpose of determining compliance with this regulation.

R. Intermittent. Any combination of temporary skilled nursing, Home Health Aide, and/or Therapeutic Services, provided on a less-than-daily basis, or if provided daily, is less than eight (8) hours per day.

S. Investigation. A visit by individuals authorized by the Department to an unlicensed or licensed Home Health Agency for the purpose of determining the validity of allegations of violations received by the Department relating to this regulation.

T. Joint Annual Report. An annual statistical and utilization data report submitted to the South Carolina Revenue and Fiscal Affairs Office.

U. License. A License issued by the Department to a Home Health Agency to provide Home Health Services in designated counties within the state.

V. Licensed Practical Nurse. An individual who is currently licensed as such by the South Carolina Board of Nursing.

W. Licensee. The individual, corporation, or public entity who has received a License to provide Home Health Services and with whom rests the ultimate responsibility for compliance with this regulation.

X. Medical Social Worker. A person who has one (1) year of social work experience in a health care setting and is licensed by the South Carolina Board of Social Work Examiners at the Master (LMSW) or Independent (LISW) level.

Y. Medical Social Worker Assistant. A person who has at least one (1) year of social work experience in a health care setting, is licensed by the South Carolina Board of Social Work Examiners, and provides services under the supervision of a Medical Social Worker as defined in 101.X.

Z. Neglect. The failure or omission of a caregiver to provide the care, goods, or services necessary to maintain the health or safety of a Patient including, but not limited to, food, clothing, medicine, shelter, supervision, and medical services and the failure or omission has caused, or presents a substantial risk of causing, physical or mental injury to the Patient. Noncompliance with regulatory standards alone does not constitute Neglect. Neglect includes the inability of a Patient, in the absence of a caretaker, to provide for his or her own health or safety which produces or could reasonably be expected to produce serious physical or psychological harm or substantial risk of death.

AA. Occupational Therapist. A person currently licensed as such by the South Carolina Board of Occupational Therapy.

BB. Occupational Therapist Assistant. A person who is currently licensed as such by the South Carolina Board of Occupational Therapy.

CC. Parent Home Health Agency (“Parent Agency”). The Agency that develops and maintains administrative control Branch Offices.

DD. Part-time. Any combination of temporary skilled nursing, Home Health Aide, and/or Therapeutic Services being provided for less than eight (8) hours per day.

EE. Patient. A person who receives treatment, services, or care from a Home Health Agency licensed by the Department.

FF. Physician. A doctor of medicine, podiatrist, or doctor of osteopathic medicine licensed by the South Carolina Board of Medical Examiners.

GG. Physical Therapist. An individual currently licensed as such by the South Carolina Board of Physical Therapy.

HH. Physical Therapist Assistant. An individual who is currently licensed as such by the South Carolina Board of Physical Therapy.

II. Quality Improvement. The process used by the Home Health Agency to examine its methods and practices of providing care, identifying the opportunities to improve its performance, and taking actions that result in higher quality of care for the Home Health Agency’s Patients.

JJ. Registered Nurse. An individual who is currently licensed as such by the South Carolina Board of Nursing.

KK. Representative. The Patient’s legal representative, such as a guardian, who makes healthcare decisions on the Patient’s behalf, or a Patient-selected representative who participates in making decisions related to the Patient’s care or well-being, including but not limited to, a family member or an advocate for the Patient.

LL. Revocation of License. An action by the Department to cancel or annul a Home Health Agency license by recalling, withdrawing, or rescinding its authority to operate.

MM. Skilled Nursing. A service provided by a registered nurse that:

1. Is ordered by a Physician or other Authorized Healthcare Provider;
2. Requires the skills of technical or professional personnel such as Registered Nurses, Licensed Practical Nurses, Physical Therapists, Occupational Therapists and speech pathologists or audiologists; and
3. Is furnished directly by, or under, the supervision of such personnel.

NN. Speech Therapist. An individual currently licensed as such by the South Carolina Board of Speech-Language Pathology and Audiology.

OO. Staff. Those individuals, including Direct Care Staff, who are employees of the Home Health Agency.

PP. Start of Care Date. The first visit where the Home Health Agency provides hands-on, direct care services, or treatments to the Patient.

QQ. Suspension of License. An action by the Department requiring a Licensee to cease operations for a period of time and/or requiring a Home Health Agency to cease admitting Patients, until such time as the Department rescinds that restriction.

RR. Therapeutic Services. Services provided by a licensed or supervised therapist within their scope of practice and as prescribed by a Physician or other Authorized Healthcare Provider, which can be safely provided in the home.

SS. Treatment Plan. A written plan that describes the Patient's condition and details the treatment to be provided, expected outcomes, and expected duration of the treatment prescribed by the Physician or other Authorized Healthcare Provider.

102. Licensure.

A. License. No person, private or public organization, political subdivision, or governmental agency shall establish, conduct, or maintain a Home Health Agency or represent itself as providing Home Health Services without first obtaining a License from the Department. No Agency shall admit Patients prior to the effective date of licensure. When it has been determined by the Department that Home Health Services are being provided at a location, and the owner has not been issued a License from the Department, the owner shall cease operations immediately and ensure the safety, health, and well-being of Patients. Current and/or previous violations of the S.C. Code of Laws or Department regulations may jeopardize the issuance of a License for the Agency, the licensing of any other Agency or facility type, or addition to an existing Agency or facility. The Home Health Agency shall provide only the services, treatment, or care it is licensed to provide pursuant to the Home Health Services definition in Section 101.H of this regulation. (I)

B. Compliance. An initial License shall not be issued to a proposed Home Health Agency, until the applicant has demonstrated to the Department that the proposed Home Health Agency is in substantial compliance with the licensing standards. A paper or electronic copy of the licensing standards shall be maintained at the Home Health Agency and accessible to all Home Health Agency Staff. In the event a Licensee, who already has a Home Health Agency or facility licensed by the Department, makes application for another Home Health Agency, the currently licensed Home Health Agency and/or facility shall be in substantial compliance with the applicable standards prior to the Department issuing a License to the proposed Home Health Agency.

C. Licensed Services. The Home Health Agency shall provide services only in the county(ies) identified on the face of the License and shall provide services to the entire county(ies) identified on the License. (I)

D. Issuance of License.

1. The Home Health Agency shall post the License issued by the Department in a conspicuous place in a public area within the Home Health Agency.

2. The issuance of a License does not guarantee adequacy or quality of individual care, treatment, personal safety, fire safety, or the well-being of any Patient of the Home Health Agency.

3. A License is not assignable or transferable and is subject to revocation at any time by the Department for the Licensee's failure to comply with the laws and regulations of this state.

4. A License shall be effective for a specified Home Health Agency, at a specific location(s), for a specified period following the date of issue as determined by the Department. A License shall remain in effect until the Licensee is notified otherwise by the Department.

5. Multiple types of care on the same premises shall be licensed separately even though they are owned by the same entity.

E. Home Health Agency Name. No proposed Home Health Agency shall be named, nor any existing Home Health Agency have its name changed, to the same or similar name as any other Home Health Agency licensed in South Carolina. If the Home Health Agency is part of a "chain operation" it shall then have the geographic area in which it is located as part of its name.

F. Application. Applicants for a License shall submit to the Department a complete and accurate application, on a form prescribed, prepared, and furnished by the Department, prior to initial licensing and periodically thereafter at intervals determined by the Department. The applicant shall ensure the application is signed by the owner(s) if an individual or partnership; by two (2) officers if a corporation; or by the head of the governmental department having jurisdiction if a governmental unit. Corporations or limited partnerships, limited liability companies, or any other organized business entity shall be registered with the South Carolina Secretary of State's Office if required to do so by state law.

G. Required Documentation. The applicant shall ensure the application for initial licensure includes:

1. The full name and address of the proposed Home Health Agency and the owner, and the names of the persons in control of the Home Health Agency. The Department may require additional information, including affirmative evidence of the applicant's ability to comply with this regulation;

2. The applicant's oath assuring that the contents of the application are accurate and true;

3. Proof of ownership of real property in which the Agency is located, or lease agreement allowing the Licensee to occupy the real property in which the Agency is located; and

4. The county(ies) in which the Home Health Agency will provide services.

H. Licensing Fees. Each applicant shall pay a License fee prior to the issuance of a License. The initial and renewal License fee shall be one hundred dollars (\$100.00) plus fifty dollars (\$50.00) for each county served. All fees are non-refundable, shall be made payable to the Department by credit card or secured portal or specific website, and shall be submitted with the application. Governmental Home Health Agencies are exempt from payment of License fees. Annual licensing fees shall also include any outstanding Inspection fees.

I. Licensing Late Fee. Failure to submit a renewal application and fee to the Department by the License expiration date may result in a late fee(s) of twenty-five percent (25%) of the License fee amount, but not less than seventy-five dollars (\$75.00), in addition to the License fee. Failure to submit the License fee and late fees to the Department within thirty (30) calendar days of the License expiration date shall render the Home Health Agency unlicensed.

J. License Renewal. For a License to be renewed, applicants shall file an application with the Department, shall pay the License renewal fee, and shall not have pending enforcement actions by the

Department. If the License renewal is delayed due to enforcement actions, the License renewal shall be issued only when the matter has been resolved satisfactorily by the Department, or when the adjudicatory process is completed, whichever is applicable.

K. Amended License.

The Home Health Agency shall request issuance of an amended License by application to the Department prior to any of the following circumstances:

1. Changes of a Home Health Agency location from one geographic site to another;
2. Change of the Home Health Agency's name or address;
3. Change in the county(ies) in which the Home Health Agency provides services. The Home Health Agency shall pay an amended License fee of fifty dollars (\$50.00) for each additional county be served; or
4. Establishment of new Branch Offices of the Home Health Agency.

L. Change of Licensee. The Home Health Agency shall request issuance of a new License by application to the Department prior to any of the following circumstances:

1. A change in the controlling interest even if, in the case of a corporation or partnership, the legal entity retains its identity and name; or
2. A change of the legal entity, for example, sole proprietorship to or from a corporation, partnership to or from a corporation, even if the controlling interest does not change.

M. Variance. The Home Health Agency may request a variance to this regulation in a format as determined by the Department. Variances shall be considered on a case-by-case basis by the Department. The Department may revoke issued variances as it determines appropriate.

SECTION 200 – ENFORCEMENT OF REGULATIONS

201. General.

The Department shall utilize Inspections, Investigations, Consultations, and other pertinent documentation regarding a proposed or licensed Home Health Agency to enforce this regulation.

202. Inspections and Investigations.

A. The Home Health Agency shall be inspected prior to initial licensing and subsequently as determined by the Department.

B. All Home Health Agencies are subject to Inspection and/or Investigation at any time without prior notice by individuals authorized by the South Carolina Code of Laws. When Staff are absent from the Parent Home Health Agency, the Home Health Agency shall post information at the entrance of the Home Health Agency to those seeking legitimate access to the Home Health Agency, as to the expected return of the Staff. The Home Health Agency shall ensure the posted information includes contact information and the expected time of return of the Staff members and Patients. The Home Health Agency shall ensure the contact information includes the name of a designated contact and his or her telephone number. The Home

Health Agency shall ensure the telephone number for the designated contact is not the Home Health Agency telephone number. (I)

C. Individuals authorized by South Carolina law shall be granted access to all properties and areas, objects, documents, and records at the time of Inspections and Investigations and in a timely manner and have the authority to require the Agency to make photocopies of those documents required in the course of Inspections or Investigations. Photocopies shall be used only for purposes of enforcement of regulations and confidentiality shall be maintained except to verify individuals in enforcement action proceedings. Records shall be made available to individuals authorized by the Department in a timely manner. (I)

D. When there is noncompliance with the licensing standards, the Agency shall submit an acceptable written plan of correction in a format determined by the Department. The Agency shall return the plan of correction by the date specified on the report of Inspection and/or Investigation. The Agency shall describe the following in the written plan of correction:

1. The actions taken to correct each cited deficiency;
2. The actions taken to prevent recurrences (actual and similar); and
3. The actual or expected completion dates of those actions. (II)

E. The Home Health Agency shall ensure reports of Inspections or Investigations conducted by the Department, including the Agency response, are provided to the public upon written request with the redaction of the names of those individuals in the report. (II)

F. Inspection Fees. In accordance with S.C. Code Section 44-7-270, the Department may charge a fee for Inspections. The fee for initial and routine Inspections shall be two hundred fifty dollars (\$250.00) plus twenty-five dollars (\$25.00) per county served. The fee for follow-up Inspections shall be one hundred twenty-five dollars (\$125.00) plus twenty-five dollars (\$25.00) per county served.

203. Consultations.

Consultations may be provided by the Department as requested by the Agency or as deemed appropriate by the Department.

SECTION 300 – ENFORCEMENT ACTIONS

301. General.

When the Department determines that a Home Health Agency is in violation of any statutory provision, rule, or regulation relating to the operation or maintenance of such Agency, the Department, upon proper notice to the Licensee, may deny, suspend, or revoke the Licenses, or assess a monetary penalty.

302. Violation Classifications.

Violations of standards in this regulation are classified as follows:

A. Class I violations are those that present an imminent danger to the health, safety, or well-being of the Patients of the Home Health Agency or a substantial probability that death or serious physical harm could result therefrom. A physical condition or one or more practices, means, methods, or operations in use in an Agency may constitute such a violation. The condition or practice constituting a Class I violation shall

be abated or eliminated immediately unless a fixed period of time, as stipulated by the Department, is required for correction. Each day such violation exists after expiration of this time shall be considered a subsequent violation.

B. Class II violations are those, other than Class I violations, that the Department determines to have a direct or immediate relationship to the health, safety, or well-being of the Agency's Patients. The citation of a Class II violation shall specify the time within which the violation is required to be corrected. Each day such violation exists after expiration of this time shall be considered a subsequent violation.

C. Class III violations are those that are not classified as Class I or II in this regulation or those that are against best practices. The citation of a Class III violation shall specify the time within which the violation is required to be corrected. Each day such violation exists after expiration of this time shall be considered a subsequent violation.

D. The notations (I) or (II), placed within sections of this regulation, indicate those standards are Class I or II violations if they are not met, respectively. Failure to meet standards not so annotated are Class III violations.

E. When assessing a monetary penalty, the Department may invoke S.C. Code Section 44-7-320(C) to determine the dollar amount or may utilize the following schedule:

FREQUENCY	CLASS I	CLASS II	CLASS III
1 st	\$500-1,500	\$300-800	\$100-300
2 nd	1,000-3,000	500-1,500	300-800
3 rd	2,000-5,000	1,000-3,000	500-1,500
4 th	5,000	2,000-5,000	1,000-3,000
5 th	5,000	5,000	2,000-5,000
6 th	5,000	5,000	5,000

SECTION 400 – POLICIES AND PROCEDURES

A. The Home Health Agency shall maintain and adhere to written policies and procedures addressing the manner in which the requirements of this regulation shall be met. The Home Health Agency shall be in full compliance with the policies and procedures.

B. The Home Health Agency shall establish a time period for review, not to exceed two (2) years, of all policies and procedures, and such reviews shall be documented and signed by the Administrator. The Home Health Agency shall ensure all policies and procedures are accessible to Agency Staff, printed or electronically, at all times.

SECTION 500 – STAFFING

501. General.

A. Before being employed or contracted as a Staff member, all Direct Care Staff shall undergo a criminal background check pursuant to S.C. Code Section 44-7-2910. Staff members and volunteers of the Home Health Agency shall not have a prior conviction or pled no contest (*nolo contendere*) to unlawful conduct toward a child, as defined by S.C. Code Section 63-45-70; Abuse, Neglect, or Exploitation of a vulnerable adult, as defined by S.C. Code Sections 43-35-10, et seq.; or any similar criminal offense. (I)

B. The Agency shall define in writing the responsibilities, qualifications, and competencies of Staff for all positions. The Agency shall ensure that the type and number of Staff are:

1. Properly licensed or credentialed in their respective professional fields as required for assigned job duties;
2. Trained as necessary to perform the duties for which they are responsible in an effective manner;
3. Capable of rendering care and services to Patients; and
4. Capable of following applicable regulations.

C. The facility shall maintain current information regarding all Staff members, to include:

1. Name, address, and telephone number;
2. Date of hire and date of initial Patient contact;
3. Past employment, experience, and education;
4. Professional licensure or credentials; and
5. Job description signed by the Staff member.

502. Administrator.

A. The Home Health Agency shall have a full-time Administrator who is responsible for the overall management and operation of the Agency and meets one of the following:

1. A Physician or other Authorized Healthcare Provider;
2. A Registered Nurse; or
3. Has training and experience in health service administration and at least one (1) year of supervisory administrative experience in home health care or a related healthcare program.

B. A Staff member shall be designated, in writing, to act in the absence of the Administrator, such as, a listing of the lines of authority by position title, including the names of the persons filling these positions.

503. Clinical Manager.

The Home Health Agency shall designate a Physician or other Authorized Healthcare Provider, or a Registered Nurse to supervise the professional clinical activities in providing Home Health Services in accordance with the orders and Treatment Plan of the Physician or other Authorized Healthcare Provider responsible for the care of the Patient.

504. Health Status. (I)

A. The Home Health Agency shall ensure all Staff members who have contact with Patients have a documented Health Assessment within twelve (12) months prior to initial Patient contact. The Health Assessment shall include tuberculin skin testing as described in Section 1702.

B. If a Staff member is working at multiple Home Health Agencies or facilities operated by the same Licensee, copies of the documented Health Assessment shall be accessible at each location.

SECTION 600 – REPORTING

601. Incidents.

A. The Home Health Agency shall document every Incident, and include an Incident review, investigation, and evaluation as well as corrective action taken, if any. The Home Health Agency shall retain all documented Incidents reported pursuant to this Section for six (6) years after the Patient involved is last Discharged. The Home Health Agency shall ensure the records are readily available and stored for the first year following Patient Discharge.

B. The Home Health Agency shall report the following types of Incidents to the Patient’s Representative or emergency contact for each affected individual at the earliest practicable hour, not exceeding twenty-four (24) hours of the Incident. The Home Health Agency shall notify the Department immediately, not to exceed twenty-four (24) hours, via the Department’s electronic reporting system or as otherwise determined by the Department. Incidents requiring reporting include, but are not limited to:

1. Confirmed or suspected crimes against a Patient by Agency Staff;
2. Confirmed or suspected Abuse, Neglect, or Exploitation of a Patient by Agency Staff;
3. Medication errors with adverse impact by Agency Staff;
4. Hospital admission or death resulting from an Incident while in the care of Agency Staff; and
5. Bone or joint fracture while in the care of Agency Staff.

C. The Home Health Agency shall submit a separate written investigation report within five (5) calendar days of every Incident required to be reported to the Department pursuant to Section 601.A via the Department’s electronic reporting system or as otherwise determined by the Department. The Home Health Agency shall ensure reports submitted to the Department contain: the Home Health Agency name, License number, type of Incident, the date the Incident occurred, a Patient medical record identification number, Patient age and sex, number of Staff directly injured or affected, witness(es)’ name(s), identified cause of the Incident, internal investigation results if cause unknown, a brief description of the Incident including location where occurred, and treatment of injuries.

602. Administrator Changes.

A. The Agency shall notify the Department, in a means as determined by the Department, within seventy-two (72) hours of any change in Administrator status.

B. The Licensee shall notify the Department in a means as determined by the Department within ten (10) calendar days of any change in the Administrator, including the name of the newly-appointed individual, their qualifications pursuant to Section 502, and effective date of the appointment.

603. Agency Closure.

In the event of closure of an Agency for any reason, the Home Health Agency shall ensure continuity of care by promptly notifying the Patient's Physician or other Authorized Healthcare Provider and arranging for referral to other Home Health Agencies at the direction of the Physician or other Authorized Healthcare Provider. The Home Health Agency shall notify the Department in writing of the closure by the Agency no later than five (5) business days prior to closure. (II)

604. Joint Annual Report.

All Home Health Agencies shall submit a Joint Annual Report as specified by the Department.

SECTION 700 – PATIENT RECORDS

701. Content (II).

A. The Home Health Agency shall maintain an organized record for each Patient. The Home Health Agency shall ensure all entries in the Patient record are permanently written, typed, or electronic media, authenticated by the author, and dated.

B. The Home Health Agency shall ensure Patient records reflect services, treatment, and care provided directly to the Patient by the Home Health Agency or by the Contracted Party, including Patient progress, and descriptions of the planned clinical outcomes achieved.

C. The Home Health Agency shall ensure the specific Patient record entries and documentation include, at a minimum:

1. Face sheet;
 - a. Basic identification information;
 - b. Diagnosis;
 - c. Primary care Physician's name and phone number;
 - d. Representative's name, or name of other individual to be contacted in case of emergency, and phone number;
 - e. Patient's address and phone number;
 - f. Admission date; and
 - g. Start of Care Date;
2. Comprehensive Assessment;
3. Original Treatment Plan and subsequent reviews and changes;
4. Clinical notes including all interventions, medication administration, treatments, and services, and responses to those interventions;

5. Physician or other Authorized Healthcare Provider orders; and
6. Signed and dated original Informed Consent.

702. Record Maintenance.

A. The Licensee shall provide accommodations, space, supplies, and equipment for the protection, storage, and maintenance of Patient records in an organized manner. The Home Health Agency shall determine the medium in which information is stored.

B. Patient records are the property of the Licensee. The Home Health Agency shall maintain all Patient records at the Home Health Agency, including Contracted Party Patient records, and make available to Staff and other authorized individuals at all times, with the exception of Patient records being utilized with active Patients or by court order. (II)

C. The Home Health Agency shall ensure Patient record confidentiality and shall only make Patient records available to individuals authorized by law. (II)

703. Authentication.

Home Health Agencies shall have policies and procedures to prohibit the use or authentication of Patient records by unauthorized users.

704. Record Retention.

A. The Home Health Agency shall ensure Patient records are completed upon Discharge within a timeframe as determined by the Home Health Agency, but no later than thirty (30) calendar days from the Patient's Discharge.

B. The Home Health Agency shall retain all Patient records for at least ten (10) years from the Patient's Discharge. The Home Health Agency shall retain all other documentation required by this regulation at least twelve (12) months or since the last Inspection, whichever is the longer period. If the Patient is a minor, the Home Health Agency shall retain the Patient's records at least until after the expiration the period of election following achievement of majority as prescribed by applicable law.

C. The Licensee shall arrange for preservation of records prior to closing a Home Health Agency, and shall notify the Department, in writing, describing these arrangements within ten (10) calendar days of closure.

D. In the event of change of ownership, the Home Health Agency shall ensure all active Patient records or copies of active Patient records are transferred to the new owner(s).

SECTION 800 – ADMISSIONS, DISCHARGES, AND TRANSFERS

801. Admission.

The Home Health Agency shall admit Patients for treatment on the basis of a reasonable expectation that the Patient's medical, nursing, and social needs can be met by the Agency in the Patient's place of residence.

802. Discharge.

The Home Health Agency shall ensure each Patient, or Representative if applicable, is informed of and participates in Discharge planning. The Home Health Agency shall develop and maintain a written plan of Discharge with the Patient or Representative that includes Patient or Representative signature and date, a Discharge summary, and Discharge instructions.

803. Transfer.

The Home Health Agency shall provide requested Patient record information to healthcare providers no later than two (2) business days following notification of the transfer to ensure continuity of care.

SECTION 900 – PATIENT CARE, TREATMENT, AND SERVICES

901. General.

The Home Health Agency shall ensure nursing and other Therapeutic Services relative to the needs of the Patient, including medications administered, are provided in a safe and effective manner; in accordance with federal, state, and local laws and regulations; and established professional practices. The Home Health Agency shall ensure the care and services provided are supervised by appropriate qualified professionals.
(I)

902. Comprehensive Assessment.

The Home Health Agency shall complete a Patient-specific Comprehensive Assessment consistent with the Patient's immediate needs within a time period determined by the Home Health Agency, but no later than five (5) business days after admission. The Home Health Agency shall ensure the Comprehensive Assessment addresses the Patient's medical, nursing, rehabilitative, social, and Discharge planning needs and is used in making individual treatment decisions. The Home Health Agency shall review and/or revise the Comprehensive Assessment as changes in the Patient's condition occur or due to a major decline or improvement in the Patient's health status.

903. Treatment Plan.

The Home Health Agency shall develop and implement a Treatment Plan based on the interdisciplinary needs of the Patient as determined by the Comprehensive Assessment. The Home Health Agency shall ensure the Treatment Plan identifies desired measurable clinical outcomes and the methods by which the outcomes are achieved through implementation of the plan and includes medical emergency situations. The Home Health Agency shall notify the Physician or other Authorized Healthcare Provider when planned clinical outcomes are not achieved or when there is a significant change in the Patient's clinical condition. The Home Health Agency shall ensure the Treatment Plan is approved and reviewed by a Physician or other Authorized Healthcare Provider at a frequency as determined by the Agency but no less frequently than every sixty (60) calendar days.

SECTION 1000 – PATIENT RIGHTS

1001. General (II).

A. The Home Health Agency shall ensure Patient rights are guaranteed, and inform each Patient of:

1. The care to be provided and the opportunity to participate in care planning;
2. Grievance and complaint procedures including the Department's contact information and provisions prohibiting retaliation;
3. Confidentiality of Patient records;
4. Respect for the Patient's property;
5. Specific coverage and non-coverage of services and of his or her liability for payment;
6. Advance directive options;
7. Freedom from Abuse, Neglect, and Exploitation; and
8. Respect and dignity in receiving care.

1002. Informed Consent.

The Home Health Agency shall obtain written informed consent from the Patient, or Representative, for Home Health Services upon admission and provide a copy to the Patient. The informed consent between the Patient and the Home Health Agency shall include at least the following:

- A. An explanation of the specific care, services, and/or equipment provided by the Home Health Agency;
- B. An explanation of the conditions under which the Patient may be Discharged; and
- C. Documentation of the explanation of the Patient's rights pursuant to Section 1001 and the grievance procedure.

1003. Patient Protections.

The Home Health Agency shall comply with all relevant federal, state, and local laws and regulations related to Patient protections, as appropriate, including Title VI, Section 601 of the Civil Rights Act of 1964 and the Americans with Disabilities Act, and ensure that there is no discrimination with regard to source of payment in the recruitment, location of Patient, and acceptance or provision of goods and services to Patients or potential Patients, provided that payment offered is not less than the cost of providing services.
(II)

SECTION 1100 – [RESERVED]

SECTION 1200 – MEDICATION AND TREATMENT ORDERS

The Home Health Agency shall ensure orders for medications and treatments are signed by a Physician or other Authorized Healthcare Provider and incorporated in the Patient's record. The Home Health Agency shall ensure verbal orders are received by a licensed nurse or licensed therapist and include the time of receipt of the order, description of the order, identification of the Physician or other Authorized Healthcare Provider and the individual receiving the order. The Home Health Agency shall ensure the verbal orders are authenticated and dated by a Physician or other Authorized Healthcare Provider pursuant to the Home

Health Agency's policies and procedures, but no later than thirty (30) calendar days after the order is given.
(II)

SECTION 1300 – AGREEMENTS WITH CONTRACTED PARTIES

A. When a Home Health Agency utilizes a Contracted Party to provide services, treatment, or care, the Home Health Agency shall maintain a written agreement with the Contracted Party which describes how the services provided are in accordance with the Patient Treatment Plan and which ensures that personnel providing these services are qualified and properly supervised.

B. The Home Health Agency shall ensure the Contracted Party complies with this regulation.

SECTION 1400 – EMERGENCY PROCEDURES AND DISASTER PREPAREDNESS. (II)

1401. Disaster Preparedness.

A. The Home Health Agency shall develop and maintain a written emergency preparedness plan that shall be reviewed and updated at least annually. The Home Health Agency shall ensure the emergency preparedness plan addresses the needs of the Patients, and includes continuity of treatment, care, and services provided by the Agency to the Patients.

B. The Home Health Agency shall provide data, evacuation status, and other requested information during an emergent event as determined by the Department, and at a frequency as determined by the Department.

1402. Continuity of Care, Treatment, and Services.

The Home Health Agency shall have a written plan to be implemented to ensure the continuation of essential Patient services for such reasons as power outage, water shortage, or in the event of the absence from work of any portion of the work force resulting from inclement weather or other causes.

SECTION 1500 – [RESERVED]

SECTION 1600 – [RESERVED]

SECTION 1700 – INFECTION CONTROL

1701. Staff Practices. (I)

A. The Home Health Agency shall maintain and implement Staff practices that prevent the spread of infectious, contagious, and communicable diseases, including but not limited to, standard precautions, transmission-based precautions, contact precautions, airborne precautions, and isolation techniques. The Home Health Agency shall ensure proper disposal of toxic and hazardous substances. The Home Health Agency shall ensure the preventive measures and practices are in compliance with applicable guidelines of the Bloodborne Pathogens Standard of the Occupational Safety and Health Act of 1970, the Centers for Disease Control and Prevention, R.61-105, Infectious Waste Management, and other applicable federal, state, and local laws and regulations.

B. The Home Health Agency shall ensure the practice of hand hygiene to prevent the hand transfer of pathogens, and the use of barrier precautions such as gloves in accordance with established guidelines.

1702. Tuberculosis Risk Assessment and Screening (I).

A. Tuberculosis (TB) Testing. The Home Health Agency shall utilize either Tuberculin Skin Test or Blood Assay for Mycobacterium tuberculosis (BAMT) for detecting Mycobacterium tuberculosis infection.

B. The Home Health Agency shall conduct an annual tuberculosis risk assessment in accordance with the Centers for Disease Control and Prevention guidelines.

C. Baseline Status.

1. The Home Health Agency shall determine the baseline status of all Staff according to current Centers for Disease Control and Prevention and Department tuberculosis guidelines.

2. Tuberculosis Screening. All Staff within three (3) months prior to Patient contact shall have a baseline two-step Tuberculin Skin Test or a single Blood Assay for Mycobacterium tuberculosis. If a new Staff member has had a documented negative Tuberculin Skin Test or a Blood Assay for Mycobacterium tuberculosis result within the previous twelve (12) months, a single Tuberculin Skin Test or the single Blood Assay for Mycobacterium tuberculosis may be administered and read to serve as the baseline prior to Patient contact.

D. Positive TB Screening Tests.

1. For all Staff with a history of positive TB screening, the Home Health Agency shall secure and maintain documentation of treatment, or if no documentation is available consult with and document consultation with the Department's TB Control.

2. For all Staff with a newly positive reaction (Positive Reactors) for Mycobacterium tuberculosis infection, the Home Health Agency shall secure and maintain documentation of a chest X-ray performed to rule out active disease.

a. If TB is present, the Home Health Agency shall report any known or suspected cases of TB disease to the Department's Bureau of Communicable Disease Prevention and Control in a form and manner as prescribed by the Department within twenty-four (24) hours and exclude the Staff member from work until he or she is evaluated by the Department's TB Control Program.

b. Latent TB Infection (LTBI). For new positive reactors without TB disease, as determined by a normal chest X-ray, the Home Health Agency shall educate him or her on preventative treatment and document in the individual Staff file his or her decision to receive or decline preventative treatment.

4. The Home Health Agency shall maintain documentation that the Positive Reactor who declines preventative treatment is:

a. Assessed annually for signs and symptoms of TB;

b. Advised of the lifelong risk of developing and transmitting TB to Patients, other Staff members, and the community; and

c. Informed of symptoms that suggest the onset of TB and the procedure to follow should such symptoms develop.

E. Post Exposure. After known exposure to a person with potentially infectious tuberculosis disease without the use of adequate personal protection, the Home Health Agency shall ensure the tuberculosis status of all Staff is determined in a manner prescribed in the current Centers for Disease Control and Prevention and Department tuberculosis guidelines.

F. Annual Tuberculosis Training. The Home Health Agency shall ensure all Staff receive annual training regarding tuberculosis to include risk factors and signs and symptoms of tuberculosis disease. The Home Health Agency shall ensure the annual tuberculosis training is documented in a Staff record and maintained at the Agency.

G. Serial Screening. The Home Health Agency shall follow the current Centers for Disease Control and Prevention and Department tuberculosis guidelines related to serial screening.

SECTION 1800 – QUALITY IMPROVEMENT PROGRAM

A. The Home Health Agency shall have a written, implemented quality improvement program, to include risk management and infection control, which provides effective self-assessment and implementation of measures designed to improve the services rendered by the Agency.

B. The Home Health Agency shall ensure the quality improvement program includes:

1. Establishing desired outcomes and the criteria by which policy and procedure effectiveness is regularly, systematically, and objectively measured;

2. Identifying, evaluating, and determining the causes of any deviation from the desired outcomes;

3. Identifying the action taken to correct current deviations and prevent future deviation, and the persons responsible for implementation of these actions;

4. Addressing quality indicator data to evaluate:

a. Quality of Patient care and Staff performance;

b. Appropriateness of the combination of services/mix of professionals reflected on the Treatment Plan; and

c. Effectiveness of the communication among Agency Staff.

5. Analyzing the appropriateness and clinical necessity of admission, treatment, care and services; and

6. Establishing a systematic method of obtaining feedback from Patients and Representatives.

SECTION 1900 – [RESERVED]

SECTION 2000 – [RESERVED]

SECTION 2100 – [RESERVED]

SECTION 2200 – [RESERVED]

SECTION 2300 – [RESERVED]

SECTION 2400 – [RESERVED]

SECTION 2500 – [RESERVED]

SECTION 2600 – [RESERVED]

SECTION 2700 – SEVERABILITY

In the event that any portion of this regulation is construed by a court of competent jurisdiction to be invalid or otherwise unenforceable, such determination shall in no manner affect the remaining portions of this regulation, and they shall remain in effect, as if such invalid portions were not originally a part of this regulation.

SECTION 2800 – GENERAL

Conditions which have not been addressed in these standards shall be managed in accordance with the best practices as determined and interpreted by the Department.