

61-77. STANDARDS FOR LICENSING HOME HEALTH AGENCIES.

Editor's Note

Unless otherwise noted, the following constitutes the history for 61-77, §§ 101 to 1701.

HISTORY: Adopted by State Register Volume 3, Issue No. 4, eff April 23, 1979. Amended by State Register Volume 6, Issue No. 5, eff May 22, 1982; State Register Volume 13, Issue No. 4, eff April 28, 1989; State Register Volume 23, Issue No. 5, eff May 28, 1999.

PART I DEFINITIONS AND LICENSING REQUIREMENTS.

Section 101. Definitions.

For the purpose of these standards, the following definitions shall apply:

A. 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 home health agency and is located sufficiently close to the agency home office to share administration, supervision and services in a manner that renders it unnecessary for the branch independently to meet the licensure requirements as a home health agency.

B. Consultation. A visit to a licensed home health agency by individuals authorized by the Department to provide information to agencies to enable/encourage agencies to better comply with the regulations.

C. Continuing Care Retirement Community. A community in which there is furnished, pursuant to a continuing care contract, to two or more persons not related to the administrator or owner of the facility within the third degree of consanguinity, board or lodging together with nursing, medical, or other health-related services, regardless of whether the services or lodging are provided at the same location or not. It does not include an institution operating solely as a nursing home or community residential care facility licensed by the Department.

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

E. Health Assessment. An evaluation of the health status of a staff member by a physician, physician's assistant, or registered nurse in accordance with agency policy.

F. Home Health 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.

G. Home Health Aide. 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.

H. 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 6, below, in a place of temporary or permanent residence used as the individual's home as follows: Part-time or intermittent skilled nursing care as ordered by a physician or podiatrist and provided by or under the supervision of a registered nurse and at least one other service listed below:

1. Physical, occupational or speech therapy;
2. Medical social services;
3. Home health aide services;
4. Other therapeutic services, e.g., pulmonary therapy, IV therapy;
5. Medical supplies as indicated in the treatment plan, and the use of medical appliances, to include durable medical equipment;

6. 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/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. Transportation of the individual in connection with any such items or services is not included.

I. 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.

J. Intermittent. Any combination of temporary skilled nursing, home health aide, and/or therapy services, provided on a less-than-daily basis, or if provided daily, is less than eight hours per day.

K. 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.

L. License. A certificate issued by the Department to a home health agency to provide home health services in designated counties within the State.

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

N. 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.

O. Medical Social Worker. A person who has a master's degree from a school of social work accredited by the Council on Social Work Education, has one 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.

P. Medical Social Worker Assistant. A person who has a baccalaureate degree in social work, psychology, sociology, or other field related to social work, has at least one year of social work experience in a health care setting, and is licensed by the South Carolina Board of Social Work Examiners. This individual must provide services under the supervision of a "medical social worker" as defined in 101.O.

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

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

S. Parent Home Health Agency. The agency that develops and maintains administrative control of subunits or branch offices.

T. Part-time. Any combination of temporary skilled nursing, home health aide, and/or therapy services being provided for less than eight hours per day.

U. Patient. A person who receives treatment, services, or care from a home health agency licensed by the Department.

V. Physician. An individual currently licensed to practice medicine in his/her respective state.

W. Physical Therapist. An individual currently registered as such by the South Carolina Board of Physical Therapy Examiners.

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

Y. Podiatrist. An individual currently licensed as such in his/her respective state.

Z. Quality Assessment/Performance 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.

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

BB. Repeat Violation. The recurrence of a violation cited under the same section of the regulation within a two-year period.

CC. Revoke License. To cancel or annul a home health agency license by recalling, withdrawing, or rescinding its authority to operate.

DD. Skilled Nursing. A service that must be provided by a registered nurse, or by a licensed practical nurse under the supervision of a registered nurse. In determining whether a service requires the skills of a nurse, consideration must be given to:

1. The inherent complexity of the service;
2. The condition of the patient;
3. Accepted standards of medical and nursing practice, *i.e.*, SC Code Section 44-33-10, *et seq.*, Nurse Practice Act, SC Board of Nursing.

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

FF. Staff. Those individuals who are employees of the home health agency.

GG. Subunit. A semi-autonomous organization which serves patients in a geographic area different from that of the parent home health agency. The subunit, by virtue of the distance between it and the parent agency, is judged incapable of sharing administration, supervision and services on a daily basis with the parent agency and must, therefore, independently meet the conditions of participation for home health agencies.

HH. Suspend license. To require a licensee to cease operations for a period of time.

II. Therapeutic Services. A service that must be provided by an individual licensed in the particular skilled therapeutic service required or that is provided by an individual under the supervision of an individual licensed in the particular skilled therapeutic service. Determining whether a service requires a skilled therapist, consideration must be given to:

1. The inherent complexity of the service;
2. The reasonableness and necessity of the service to the treatment of the patient's illness or injury or to the restoration of maintenance of function affected by the patient's illness or injury;
3. Documented medical complications of the patient which may necessitate services which without those complications, such services would not be needed.

Section 102. License Requirements.

A. License. No person, private or public organization, political subdivision, or governmental agency shall establish, conduct, or maintain a home health agency in this State, provide home health services in this State, or represent itself as providing home health services in this State without first obtaining a license from the Department. Admission of patients prior to the effective date of licensure is a violation of Section 44-69-30 of the South Carolina Code of Laws. Current/previous violations of the SC Code and/or Department regulations may jeopardize the issuance of a license for the agency or the licensing of any other agency, facility (an entity licensed by the Department), or addition to an existing facility which are owned by the licensee. The home health agency may 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 will not be issued to a proposed home health agency, not previously and continuously licensed under Department regulations, until the applicant has demonstrated to the Department that the proposed home health agency is in substantial compliance with the licensing standards. A 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/facility shall be in substantial compliance with the applicable standards prior to the Department issuing a license to the proposed home health agency.

C. Issuance of License.

1. A license is issued by the Department and shall be posted 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. A license is subject to revocation at any time by the Department for 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 must be licensed separately even though they are owned by the same entity.

D. Home Health Agency Name. No proposed home health agency shall be named, nor may any existing home health agency have its name changed to the same or similar name as any other home health agency licensed in the State. 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. The Department shall decide if names are similar and notify the prospective licensee of its determination.

E. Application. Applicants for a license shall submit to the Department a completed 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 application must indicate the counties in which the home health agency will provide services.

F. Licensing Fees. The initial and renewal license fee shall be \$100.00 plus \$50.00 for each county served. Such fees shall be made payable to the Department and are non-refundable. Governmental home health agencies are exempt from payment of license fees.

G. Late Fee. Failure to submit a renewal application or fee prior to 30 days before the license expiration date may result in a late fee(s) of 25% of the licensing fee amount, but not less than \$75.00, in addition to the licensing fee.

H. License Renewal. For a license to be renewed, applicants shall file an application with the Department, pay a license fee, and must not be under consideration for an enforcement action by the Department, or undergoing enforcement actions by the Department. If the license renewal is delayed due to enforcement actions the renewal license will be issued only when the matter has been resolved satisfactorily by the Department, or when the adjudicatory process is completed, whichever is applicable.

I. Change of License.

1. A home health agency shall request issuance of an initial license by application to the Department prior to any change of ownership.

2. Changes in a home health agency name, location from one geographic site to another, or address as notified by the post office (no location change), may be accomplished by application or by letter from the licensee.

J. Licensed Area. No home health agency may serve counties other than those identified on the face of the license, and the entire licensed county(ies) identified must be served. (II)

K. Exceptions to Licensing Standards. The Department reserves the right to make exceptions to these standards where it is determined that the health, safety, and well-being of the patients are not compromised, and provided the standard is not specifically required by state law.

PART 2 ENFORCING REGULATIONS.

Section 201. Inspections/Investigations.

A. Inspections shall be conducted prior to initial licensing of a home health agency and subsequent inspections shall be conducted as determined by the Department.

B. All agencies are subject to inspection/investigation at any time without prior notice by properly identified staff of the Department and other legally authorized individuals.

C. Individuals authorized by the Department shall have access to all properties and areas, objects, and records, 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. (II)

D. When there is noncompliance with the licensing standards, the agency shall submit an acceptable written plan of correction to the Department that shall be signed by the administrator and returned by the date specified on the report of inspection/investigation. The written plan of correction shall describe:

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

E. The most recent report of an inspection conducted by the Department, including the agency response, shall be made available upon request. (II)

Section 202. Consultations.

Consultations shall be provided by the Department as requested by the agency or as deemed appropriate by the Department.

PART 3 ENFORCEMENT ACTIONS.

Section 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 license, or impose a monetary penalty.

Section 302. Violation Classifications.

Violations of standards in this regulation are classified as follows:

A. Class I violations are those that the Department determines to 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 said 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 said time shall be considered a subsequent violation.

C. Class III violations are those that are not classified as Class I or II in these regulations or those that are against the best practices as interpreted by the Department. 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 said time shall be considered a subsequent violation.

D. Class I and II violations are indicated by notation after each applicable section, *i.e.*, "(I)" or "(II)." Sections not annotated in that manner denote Class III violations. A classification at the beginning of a section/subsection applies to all subsections following, unless otherwise indicated.

E. In arriving at a decision to take enforcement actions, the Department will consider the following factors: specific conditions and their impact or potential impact on health, safety or well-being of patients; efforts by the agency to correct cited violations; overall conditions; history of compliance; any other pertinent conditions that may be applicable to current statutes and regulations including participating in, or offering, or implying an offer to participate in the practice generally known as rebates, kickbacks or fee-splitting arrangements.

F. When a decision is made to impose monetary penalties, the following schedule will be used as a guide to determine the dollar amount:

Frequency of violation of standard within a 24-month period:

FREQUENCY	MONETARY PENALTY RANGES		
	CLASS I	CLASS II	CLASS III
1st	\$ 200–1000	\$ 100–500	\$ 0
2nd	500–2000	200–1000	100–500
3rd	1000–5000	500–2000	200–1000
4th	5000	1000–5000	500–2000
5th	5000	5000	1000–5000
6th	5000	5000	5000

G. Any enforcement action taken by the Department may be appealed in a manner pursuant to the Administrative Procedures Act, S.C. Code Ann. Section 1–23–310 *et seq.*

PART 4 MANAGEMENT.

Section 401. Administrator/Director.

The home health agency shall designate a qualified individual to serve as Administrator/Director. The Administrator/Director shall have the authority and responsibility for the functions and activities of the agency and must be available within a reasonable time and distance. A qualified staff member shall be designated, in writing, to act in the absence of the Administrator/Director.

Section 402. Director of Professional Services.

A. The home health agency shall designate a physician or a registered nurse to supervise the professional activities in providing home health services in accordance with the orders of the physician or podiatrist responsible for the care of the patient and under the plan of treatment established by such a physician or podiatrist.

B. The Administrator/Director and the Director of Professional Services may be the same individual.

PART 5 POLICIES AND PROCEDURES.

Section 501. General (II).

A. Policies and procedures for operation of the home health agency shall be developed and implemented by the licensee. Additionally, policies and procedures shall be revised as required in order to accurately reflect actual agency practice. Agencies shall establish a time-frame for review of all policies and procedures.

B. The policies and procedures shall describe the means by which the agency will assure that the standards described in this regulation are met and apply to the agency mission, and a demonstration by observable or written evidence that the agency has met these standards.

PART 6 ADMISSIONS.

Section 601. General.

Admissions shall be deemed appropriate based on the following considerations:

- A. The individual is under the care of a physician or podiatrist; (I)
- B. The individual and/or his/her family agree to/accept home care;
- C. There is an expectation that the individual's medical, nursing, and social needs can be met adequately in his/her place of residence in lieu of admission to a hospital or extended care facility;
- D. The physical facilities in the individual's home are suitable for his/her proper care;

E. The individual has a need for part-time or intermittent services as defined in Section 101 of this regulation.

**PART 7
PATIENT CARE/TREATMENT/SERVICES.**

Section 701. General.

A. Services, treatment, and care relative to the needs of the patient as identified in the treatment plan, to include medical emergency situations, shall be provided in a safe, effective manner, coordinated among those responsible in the continuum of care, modified as warranted based on any changing needs of the patient. Such changes shall be reflected in the treatment plan. The physician or podiatrist shall be notified when planned clinical outcomes are not achieved or when there is a significant change in the patient's clinical condition. In instances of emergency due to disaster, the agency shall have a disaster plan to address the needs of the patients, which includes the continued services/care provided by the agency to the patients, unless the nature of the disaster precludes the agency from continuing such services/care. (I)

B. Nursing and other therapeutic services relative to the needs of the patient, including medications administered, shall be provided in a safe, effective manner and in accordance with federal, state, and local laws and regulations, and with established professional practices; care and services provided shall be supervised by appropriate qualified professionals. (I)

C. The 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 insure 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)

D. In the event of closure of an agency for any reason, the agency shall insure continuity of care by promptly notifying the patient's attending physician or podiatrist and arranging for referral to other home health agencies at the direction of the physician or podiatrist. The Department's Health Licensing Section shall be notified of the closure by the agency a minimum of five working days prior to closure. (II)

**PART 8
PATIENT RIGHTS.**

Section 801. General (II).

- A. Patient rights shall be guaranteed, and, at a minimum, the agency must inform the patient of:
1. The care to be provided and the opportunity to participate in care planning;
 2. Grievance/complaint procedures;
 3. Confidentiality of patient records;
 4. Respect for the patient's property;
 5. Specific coverage and non-coverage of services and of his/her liability for payment;
 6. The telephone number, purpose, and hours of operation of the home health hotline;
 7. Advance directive options;
 8. Freedom from abuse and exploitation;
 9. Respect and dignity in receiving care.
- B. A copy of the agency patient rights shall be provided to the patient.

**PART 9
PATIENT RECORDS.**

Section 901. Content (II).

A. The content of the patient record will be determined by the home health agency, but must contain documentation needed to properly identify the patient and verify appropriate care rendered.

B. A comprehensive, patient-specific assessment shall be conducted at the time of admission for each patient, including, but not limited to: review of the drug regimen, pertinent medical data, psycho-social status, and functional limitations. The assessment shall be used in making individual treatment decisions and shall meet the patient's medical, nursing, rehabilitative, social, and discharge planning needs; reassessment shall be accomplished based upon change in the patient's condition.

C. A treatment plan shall be developed based on the interdisciplinary needs of the patient as determined by the assessment. The plan shall identify desired measurable clinical outcomes and the methods by which the outcomes are achieved through implementation of the plan. The treatment plan shall be approved by a physician or podiatrist and reviewed periodically at a frequency as determined by the agency but no later than every 62 days.

D. Patient records shall reflect services, treatment, and care provided directly to the patient by the agency or by another agency under contract, including patient progress, and descriptions of the planned clinical outcomes achieved.

E. Health care providers to whom patients are transferred or referred shall be provided transfer summaries and other appropriate information concerning the patient no later than two working days from the notification of the transfer in order to insure continuity of quality care.

Section 902. Record Maintenance.

A. Records of patients are the property of the home health agency and must not be removed from the agency's patient record storage area, except for home visits, without court order.

B. The licensee must provide accommodations, space, supplies, and equipment adequate for the function, protection, and storage of patient records.

C. The patient record is confidential and may be made available only to authorized individuals. Active patient records, with the exception of records utilized by providers during home visits, must be available at the home health agency at all times and must be accessible by the staff member in charge, and by other authorized individuals such as representatives of the Department. (II)

D. Records generated by organizations/individuals contracted by the home health agency for services, treatment, or care shall be maintained by the home health agency that has admitted the patient.

E. The agency shall determine the medium in which information is stored.

F. Agencies employing electronic signatures or computer-generated signature codes shall insure authentication and security.

G. Upon discharge of a patient, the patient record shall be completed and filed in an inactive/closed file within a time-frame as determined by the home health agency but no later than 30 days after discharge. Closed patient records must be stored by the licensee and retained for 10 years following the discharge of the patient. Such records shall be made available to the Department upon request.

H. Prior to the closing of a home health agency for any reason, the licensee must arrange for preservation of records to insure compliance with these regulations. The licensee must notify the Department, in writing, describing these arrangements within 10 days of closure.

I. Patient records may be destroyed after 10 years provided that records of minors are retained until after the expiration of the period of election following achievement of majority as prescribed by statute.

J. In the event of change of ownership, all active patient records or copies of active patient records shall be transferred to the new owner(s).

PART 10 PERSONNEL.

Section 1001. General (I).

A. Appropriate staff in numbers and training, including an Administrator/Director and Director of Professional Services, shall be provided appropriate to suit the needs and condition of the patients. Training/qualifications for the tasks each performs shall be in compliance with all federal, state, and

local laws, and professional standards, including licensing or certification as required/recommended. Direct care staff/volunteers shall not have prior conviction(s) of child or patient or elder abuse, neglect or mistreatment.

B. Staff practices shall promote conditions that prevent the spread of infectious, contagious, or communicable diseases and provide for the proper disposal of toxic and hazardous substances. These preventive measures/practices shall be in compliance, as applicable, with the Occupational Safety and Health Act of 1970, Regulation 61–105, Infectious Waste Management Regulation, June 28, 1991, the South Carolina Guidelines For Prevention and Control of Antibiotic Resistant Organisms in Health Care Settings, March, 1998, and other applicable federal, state, and local laws and regulations, applicable guidelines of the Centers for Disease Control and Prevention, and other professionally recognized organizations.

Section 1002. Health Status (II).

A. All staff/volunteers who have contact with patients shall have a health assessment within one year prior to patient contact.

B. All staff/volunteers shall undergo a two-step tuberculin skin test within three months prior to patient contact, unless a previously positive reaction can be documented. Persons who have a documented negative tuberculin skin test (at least single-step) within the previous 12 months shall only be required to have one tuberculin skin test. The intradermal (Mantoux) method, using five tuberculin units of stabilized purified protein derivative (PPD) is to be used. Staff/volunteers with tuberculin test reactions of 10mm or more of induration and known HIV-positive staff/volunteers with tuberculin test reactions of 5mm or more of induration shall be referred for appropriate evaluation.

1. Staff/volunteers with negative tuberculin skin tests shall have an annual tuberculin skin test and, depending upon the test results, shall be followed as described in this regulation.

2. Initial or routine chest radiographs on staff/volunteers with negative tuberculin tests who are asymptomatic are not required.

3. Upon initial health assessment, staff/volunteers who have a history of tuberculosis disease shall be required to have certification by a physician that they are not contagious.

4. All staff/volunteers who have direct contact with patients, and who are known or suspected to have tuberculosis, shall be required to be evaluated by a physician and will not be allowed to return to work until they have been declared noncontagious.

5. Preventive treatment of new positive reactors without disease is strongly recommended for staff/volunteers with patient contact, unless specifically contraindicated. Routine annual chest radiographs of positive reactors are not required or recommended.

a. Staff/volunteers who complete treatment, either for disease or infection, may be exempt from further routine chest radiographic screening unless they have symptoms of tuberculosis.

b. Positive reactors who are unable or unwilling to take preventive treatment need not receive an annual chest radiograph. These individuals must be assessed annually for symptoms of tuberculosis and advised of their lifelong risk of developing and transmitting tuberculosis to individuals in the institution and in the community. They shall be informed of symptoms which suggest the onset of tuberculosis, and the procedure to follow should such symptoms develop.

6. Post exposure skin tests shall be provided for tuberculin negative staff/volunteers 12 weeks after termination of contact for any suspected exposure to a documented case of tuberculosis.

7. A staff member shall be designated at each agency to coordinate tuberculosis control activities.

PART 11 REPORTING.

Section 1101. Communicable Diseases.

All cases of diseases which are required to be reported in accordance with DHEC Regulation 61–20, Communicable Diseases, 1992, shall be reported to the appropriate county health department within 24 hours. (I)

Section 1102. Administrator/Director Change.

The Department shall be notified in writing by the licensee within 10 days of any change in the Administrator/Director. The notice shall include at least the name of the newly-appointed individual and effective date of the appointment.

Section 1103. Branch Office Additions.

The Department must be notified within five days of the establishment of any new branches of the agency, including the location address.

Section 1104. Joint Annual Report.

All home health agencies required by the Planning and Certificate of Need Section of the Department to submit a "Joint Annual Report" shall complete and return this report within the time period specified by that Section.

PART 12 DRUG AND TREATMENT ORDERS.

Section 1201. General.

Orders for drugs and treatment shall be signed by a physician or podiatrist and incorporated in the patient's record maintained by the home health agency. Verbal/telephonic orders received must be signed and dated by a licensed nurse or licensed therapist. The agency shall establish lists of categories of diagnostic or therapeutic verbal orders associated with any potential hazard to the patient that must be authenticated by the physician or podiatrist within a limited agency-determined time-frame, but in no case shall any orders be authenticated later than 30 days from the date of the order.
(II)

PART 13 AGREEMENTS WITH OTHER AGENCIES/INDIVIDUALS.

Section 1301. General.

A. When services, treatment, or care are provided by another agency/individual, there shall be a written agreement with the agency/individual which describes how the services provided are in accordance with the patient treatment plan and which insures that personnel providing these services are qualified and properly supervised.

B. The agency/individual with whom a home health agency has a written agreement shall comply with this regulation in regard to records, and patient care, treatment, services, and rights.

PART 14 QUALITY IMPROVEMENT PROGRAM.

Section 1401. General (II).

A. There shall be 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 quality improvement program, as a minimum, shall:

1. Establish desired outcomes and the criteria by which policy and procedure effectiveness is regularly, systematically, and objectively measured;
2. Identify, evaluate, and determine the causes of any deviation from the desired outcomes;
3. Identify the action taken to correct current deviations and prevent future deviation, and the persons responsible for implementation of these actions;
4. Address 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 plan of care;

- c. Effectiveness of the communication among agency staff.
5. Analyze the appropriateness and clinical necessity of admission, continued stays, and supportive care and services;
6. Establish a systematic method of obtaining feedback from patients and other interested persons, e.g., family members and peer organizations, as expressed by the level of satisfaction with services, treatment, and care received.

PART 15
CONTINUING CARE RETIREMENT COMMUNITY.

Section 1501. General.

A. In order to provide home health services, a Continuing Care Retirement Community (CCRC) shall obtain a home health license from the Department pursuant to this regulation. In addition the CCRC shall:

1. Be multilevel and incorporate a skilled nursing facility;
2. Maintain a current CCRC license issued by the Department of Consumer Affairs;
3. Furnish or offer to furnish home health services only to residents who reside in living units provided by the CCRC pursuant to a continuing care contract;
4. Insure that the residents of the CCRC may choose to obtain home health services from other licensed home health agencies.

B. Staff from other areas of the CCRC may deliver home health services to residents of the CCRC; however, at no time may staff levels in the CCRC nursing home fall below licensing standards or impair the services provided.

C. If the CCRC charges for home health services in its base contract, it is prohibited from billing additional fees for those services.

PART 16
SEVERABILITY.

Section 1601. General.

In the event that any portion of these regulations 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 these regulations, and they shall remain in effect, as if such invalid portions were not originally a part of these regulations.

PART 17
GENERAL.

Section 1701. 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.