

CHAPTER XXVI - HOME CARE AGENCIES

Section 1 – Statutory Authority and Applicability

- 1.1 The statutory authority for the promulgation of these rules is set forth in Sections 25-1.5-103 and 25-27.5-101, et seq., C.R.S.
- 1.2 A home care agency, as defined herein, shall comply with all applicable federal and state statutes and regulations, including but not limited to, the following:
- (A) This Chapter XXVI.
 - (B) 6 CCR 1011-1, Chapter II, General Licensure Standards, unless otherwise specified herein.
 - (C) Section 8-2-113, C.R.S.

Section 2 – Definitions

- 2.1 Authorized representative -**
- 2.2 “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 care~~ 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 ~~conditions of participation as a home health agency~~ **requirements of this Chapter.**
- 2.3 “Bylaws” means a set of rules adopted by a Home Care Agency for governing the agency’s operation.
- 2.4 “Certified Home Care Agency “ means an agency that is certified by either the Federal Centers for Medicare and Medicaid Services (CMS) or the Colorado Department of Health Care Policy and Financing to provide skilled home health or personal care services.
- 2.5 “Clinical note” means a **written** notation of a contact with a consumer that is ~~written~~ **signed** and dated by a member of the ~~health team~~ **home care agency**, and that describes signs and symptoms, treatment, **education** and drugs administered and the consumer's reaction, and any changes in physical or emotional condition.
- 2.6 “Department” means the Colorado Department of Public Health and Environment.
- 2.7 “Encounter/Service note” means a written notation, dated and signed by a member of the home care agency evidencing the care furnished.**
- 2.8 “Home Care Agency ” means any sole proprietorship, partnership, association, corporation, government or governmental subdivision or agency subject to the restrictions in Section 25-1.5-103(1)(a)(II), C.R.S., not-for-profit agency, or any other legal or commercial entity that manages and offers, directly or by contract, skilled home health services or personal care services to a home care consumer in the home care consumer’s temporary or permanent home or place or residence. Home Care Agency is also referred to in these rules as “HCA “or “Agency.”

DRAFT 3 – August 18, 2008

- (A) A residential facility that delivers skilled home health or personal care services which the facility is not licensed to provide, shall either be licensed as a home care agency or require the skilled home health or personal care services to be delivered by a licensed home care agency.
- (B) “Home Care Agency” does not include:
 - (1) Organizations that provide only housekeeping services;
 - (2) Community and rural health networks that furnish home visits for the purpose of public health monitoring and disease tracking;
 - (3) An individual who is not employed by or affiliated with a home care agency and who acts, alone, without employees or contractors;
 - (4) Outpatient rehabilitation agencies and comprehensive outpatient rehabilitation facilities certified pursuant to Title XVIII or XIX of the “Social Security Act”, as amended;
 - (5) Consumer-directed attendant programs administered by the Colorado Department of Health Care Policy and Financing;
 - (6) Licensed dialysis centers that provide in-home dialysis services, supplies, and equipment;
 - (7) Subject to the requirements of section 25-27.5-103(3), C.R.S., a facility otherwise licensed by the Department; or
 - (8) A home care placement agency as defined in section 2.8 of this chapter.
- 2.9 “Home care consumer” means a person who receives skilled home health services or personal care services in his or her temporary or permanent home or place of residence from a home care agency or home care placement agency.
- 2.10 “Home care placement agency” means an organization that, for a fee, provides only referrals of providers to home care consumers seeking services. A home care placement agency does not provide skilled home health services or personal care services to a home care consumer in the home care consumer’s temporary or permanent home or place of residence directly or by contract. Such organizations shall follow the requirements of sections 25-27.5-103(2), 25-27.5-104(1)(c), and 25-27.5-107, C.R.S.
- 2.11 “Parent home health agency” means the agency that develops and maintains administrative controls of branch offices.
- 2.12 “Personal care services” means assistance with activities of daily living, including but not limited to bathing, dressing, eating, transferring, walking or mobility, toileting, and continence care. It also includes housekeeping, personal laundry, medication reminders, and companionship services furnished to a home care consumer in the home care consumer’s temporary or permanent home or place of residence, and those normal daily routines that the home care consumer could perform for himself or herself were he or she physically capable, which are intended to enable that individual to remain safely and comfortably in the home care consumer’s temporary or permanent home or place of residence.

DRAFT 3 – August 18, 2008

- 2.13 "Progress note" means a written notation, dated and signed by a member of the ~~health team~~ **home care agency**, that summarizes facts about care furnished and the consumer's response during a given period of time.
- 2.14 "Skilled home health services" means health and medical services furnished to a home care consumer in the home care consumer's temporary or permanent home or place of residence that include wound care services; use of medical supplies including drugs and biologicals prescribed by a physician; in-home infusion services; nursing services; home health aide or certified nurse aide services that require the supervision of a licensed or certified health care professional acting within the scope of his or her license or certificate; occupational therapy; physical therapy; respiratory care services; dietetics and nutrition counseling services; medication administration; medical social services; and speech-language pathology services. "Skilled home health services" does not include the delivery of either durable medical equipment or medical supplies.
- 2.15 "State Board" means the State Board of Health.
- 2.16 "Subdivision" means a component of a multi-function health agency, such as the home care department of a hospital or the nursing division of a health department, which independently meets the licensure requirements for HCAs. A subdivision that has ~~subunits or~~ branch offices is considered a parent agency.
- 2.17 "Summary report" means the compilation of the pertinent factors of a home care consumer's clinical notes and progress notes that is submitted to the home care consumer's physician.
- 2.18 "Supervision" means authoritative procedural guidance by a qualified person for the accomplishment of a function or activity. Unless otherwise specified in this ~~part~~ Chapter, the supervisor shall be on the premises to supervise an individual.

Section 3 - Licensure Requirements

- 3.1 The HCA shall disclose the following information to the Department at the time of the HCA's initial request for licensure, for each survey, and at the time of any change in ownership or management:
- (A) The name and address of all persons with an ownership or control interest in the HCA as defined in 6 CCR 1011-1, Chapter II, Section 2.35.
 - (B) The name and address of each person who is an officer, a director, an agent or a managing employee of the HCA..
 - (C) The name and address of the corporation, association, or other company that is responsible for the management of the HCA, and the name and address of the chief executive officer and the chairman of the board of directors of that corporation, association, or other company responsible for the management of the HCA.
- 3.2 The HCA and its staff shall comply with accepted professional standards and principles that apply to professionals furnishing services in an HCA.
- 3.3 The HCA shall provide evidence of and maintain either liability insurance coverage or a surety bond in lieu of liability insurance coverage in the amount of

Section 4 - Home Care Consumer Rights

DRAFT 3 – August 18, 2008

- 4.1 ~~The home care consumer has the right to be informed of his or her rights.~~ **The consumer or the consumer's authorized representative has the right to be informed of the consumer's rights through an effective means of communication.** The HCA shall protect and promote the exercise of these rights.
- 4.2 Notice of rights.
- (A) The HCA shall provide the consumer with a written notice of the consumer's rights in advance of furnishing care to the consumer or during the initial evaluation visit before the initiation of ~~treatment services~~. **The written notice of consumer rights shall be made available in any language that is spoken as the primary language by more than 10 percent of the population in the agency's service.**
 - (B) **The HCA shall establish and implement written policies and procedures regarding the rights of consumers and the implementation of these rights. A complete statement of these rights, including the right to file a complaint with the department, shall be distributed to all staff and contracted personnel upon hire and annually thereafter.**
 - (C) The HCA shall maintain documentation showing that it has complied with the requirements of this section.
- 4.2 Exercise of rights and respect for property and person.
- (A) The consumer **or their authorized representative** has the right to exercise his or her rights as a consumer of the HCA.
 - ~~(B) The consumer's family or guardian may exercise the consumer's rights when the consumer has been judged incompetent.~~
 - (B) The consumer has the right to have his or her **person and** property treated with respect. **The consumer has the right to be free from verbal, physical, and psychological abuse and to be treated with courtesy, consideration, respect, and recognition of his or her dignity, individuality, and right to privacy, including, but not limited to, auditory and visual privacy and confidentiality concerning consumer services and disclosures.**
 - (C) **The consumer has the right to freedom from restraints, unless they are authorized by a physician for a limited period of time to protect the consumer or others from injury in accordance with 6 CCR 1011-1, Chapter II, Part 8.**
 - (D) The consumer has the right to voice grievances regarding ~~treatment services~~ or care that is (or fails to be) furnished, or regarding the lack of respect for **person and** property by anyone who is furnishing services on behalf of the HCA and shall not be subjected to discrimination or reprisal for doing so.
 - (E) With regard to complaints, the HCA shall be responsible for the following:
 - (1) Investigating complaints made by a consumer ~~the consumer's family or guardian,~~ **or others** regarding ~~treatment services~~ or care that is (or fails to be) furnished, or regarding the lack of respect for the consumer's **person or** property by anyone furnishing services on behalf of the HCA.

- (2) Documenting ~~both the existence, of the complaint~~ the investigation, and the resolution of the complaint. The agency shall notify the complainant of the results of the investigation and the agency's plan to resolve the issue.
- (3) Providing the consumer with a copy of the agency policy regarding appeal of the agency's decision.
- (4) **Preparing an annual summary of complaints and their resolution that shall be available to the public.**
- (5) **Incorporating the findings of its annual complaint summary into its quality assurance program in order to evaluate and implement systemic changes where needed.**

4.3 Right to be informed and to participate in planning care and ~~treatment~~ **services.**

- (A) The consumer has the right to be informed in advance about the care **and services** to be furnished, and of any changes in the care **and services** to be furnished **so that they can give informed consent.**
 - (1) The HCA shall advise the consumer in advance of the disciplines that will furnish care, and the frequency of visits proposed to be furnished. THE HCA WILL PROVIDE A VISIT CALENDAR TO EACH CONSUMER AT LEAST 7 DAYS IN ADVANCE TO ENSURE THE CONSUMER KNOWS WHO IS TO VISIT AND WHEN. CHANGES TO THE CALENDAR WILL BE COMMUNICATED TO THE CONSUMER WITHIN A REASONABLE TIME FRAME AFTER THE NECESSARY CHANGE IS IDENTIFIED.
 - (2) The HCA shall advise the consumer in advance of any change in the plan of care before the change is made.
- (B) The consumer has the right to participate in the planning of the care AND RECEIVE APPROPRIATE INSTRUCTION AND EDUCATION REGARDING THE PLAN.
 - (1) The HCA shall advise the consumer in advance of the right to participate in planning the care or treatment and in planning changes in the care or treatment.
 - (2) HCA shall inform and distribute written information to the consumer, in advance, concerning its policies on advance directives, including a description of applicable State law. The HCA may furnish advance directives information to a consumer at the time of the first home visit, as long as the information is furnished before care is provided.
 - (3) The HCA shall comply with the consumer's advance directives.
 - (4) EACH PATIENT SHALL HAVE A RIGHT TO REQUEST INFORMATION ABOUT THE PATIENT'S DIAGNOSIS, PROGNOSIS, AND SERVICES, INCLUDING ALTERNATIVES TO CARE AND RISKS INVOLVED, IN TERMS THAT THE PATIENT AND THE PATIENT'S FAMILY CAN READILY UNDERSTAND SO THAT THEY CAN GIVE THEIR INFORMED CONSENT.

- (5) EACH PATIENT SHALL HAVE THE RIGHT TO REASONABLE CONTINUITY OF CARE.
- (6) EACH CONSUMER SHALL HAVE A RIGHT TO BE ADMITTED FOR SERVICE ONLY IF THE AGENCY HAS THE ABILITY TO PROVIDE SAFE, QUALITY CARE AT THE LEVEL OF FREQUENCY AND INTENSITY NEEDED.
- (7) EACH CONSUMER DISCHARGED FOR ANY REASON SHALL HAVE THE RIGHT TO RECEIVE ASSISTANCE FROM THE HCA TO FIND AN APPROPRIATE PLACEMENT WITH ANOTHER AGENCY IF THE CONSUMER CONTINUES TO REQUIRE CARE AND/OR SERVICES UPON DISCHARGE. THE HCA MUST DOCUMENT DUE DILIGENCE IN ENSURING CONTIUIITY OF CARE UPON DISCHARGE AS NECESSARY TO PROTECT THE CONSUMERS SAFETY AND WELFARE.
- (8) THE CONSUMER HAS A RIGHT TO RECEIVE COORDINATED CARE AMONG ALL HCA PROVIDERS DELIVERING SERVICES IN THE HOME.

4.4 The consumer SHALL HAVE the right to confidentiality of ALL records, COMMUNICATIONS, AND PERSONAL INFORMATION. The HCA shall advise the consumer of the agency's policies and procedures regarding disclosure of clinical INFORMATION AND records.

RECORD RETENTION VERBIAGE? (6 YRS MEDICAID/ 5 YRS AFTER LAST COST REPORT)

4.5 The consumer has the right to be advised, before care is initiated, of the extent to which payment for the HCA services may be expected from insurance or other sources, and the extent to which payment may be required from the consumer. Before the care is initiated, the HCA shall inform the consumer, orally and in writing, of the following:

- (A) The extent to which payment may be expected from PRIVATE INSURANCE, Medicare, Medicaid, or any other GOVERNMENT OR GRANT funded or aided program known to the HCA;
- (B) The charges for services that will not be covered by INSURANCE, GRANTS OR DONATED FUNDS; and
- (C) The charges that the consumer may have to pay.
- (D) The consumer has the right to be advised orally and in writing of any changes in the information provided in accordance with this section when they occur. The HCA shall advise the consumer of these changes orally and in writing as soon as possible, but no later than 30 calendar days from the date that the HCA becomes aware of a change. CHANGES THAT INCREASE THE CONSUMERS RESPONSIBILITY FOR PAYMENT SHALL BE PROVIDED TO THE CONSUMER ORALLY AND IN WRITING PRIOR TO IMPLEMENTATION.

4.6 The consumer has the right to be advised of the availability of the toll-free HCA hotline in the State. When the agency accepts the consumer for treatment or care, the HCA shall advise the consumer in writing of the telephone number of the home health hotline established by the State, the hours of its operation, and that the purpose of the hotline is to receive complaints or questions about local HCAs. The consumer also has the right to

use this hotline to lodge complaints REGARDING CARE RECEIVED OR NOT RECEIVED INCLUDING the implementation of the advance directives requirements.

- 4.7 THE HCA SHALL MAKE AVAILABLE TO THE CONSUMER UPON REQUEST A WRITTEN NOTICE IN ADVANCE OF FURNISHING CARE TO THE PATIENT OR DURING THE INITIAL EVALUATION VISIT BEFORE THE INITIATION OF TREATMENT, A LISTING OF ALL INDIVIDUALS OR OTHER LEGAL ENTITIES WHO HAVE OWNERSHIP OR CONTROLLING INTEREST IN THE AGENCY.

Section 5 - Organization, Services and Administration

- 5.1 Organization, services furnished, administrative control, and lines of authority for the delegation of responsibility down to the consumer care level shall be clearly set forth in writing and are readily identifiable. Administrative and supervisory functions are not delegated to another agency or organization and all services not furnished directly, including services provided through subunits are monitored and controlled by the parent agency. If an agency has subunits, appropriate administrative records shall be maintained for each subunit.

5.2 Services Furnished

Part-time or intermittent skilled nursing services, other therapeutic service (physical, speech, or occupational therapy; medical social services; or home health aide services) are made available on a visiting basis, in a consumer's place of residence. An HCA shall provide at least one service directly through agency employees, but may provide additional services under arrangements with another agency or organization.

5.3 Administration

- (A) A governing body (or designated persons so functioning) shall assume full legal authority and responsibility for the operation of the agency. The governing body shall appoint a qualified administrator, arrange for professional advice as required by section 6 of this chapter, periodically review written bylaws and oversee the management and fiscal affairs of the agency.
- (B) The administrator, who may also be the supervising physician or registered nurse required under section 5.5 of this chapter, shall organize and direct the agency's ongoing functions; maintain ongoing liaison among the governing body, the group of professional personnel, and the staff; employ qualified personnel and ensure adequate staff education and evaluations; ensure the accuracy of public information materials and activities; and implement an effective budgeting and accounting system. A qualified person shall be authorized in writing to act in the absence of the administrator.
- (C) The skilled nursing and other therapeutic services furnished shall be under the supervision and direction of a physician or a registered nurse (who preferably has at least 1 year of nursing experience and is a public health nurse). This person, or similarly qualified alternate, shall be available at all times during operating hours and participate in all activities relevant to the professional services furnished, including the development of qualifications and the assignment of personnel.
- (D) The HCA shall have written policies regarding nurse delegation.

DRAFT 3 – August 18, 2008

- 5.4 Personnel practices and consumer care are supported by appropriate, written personnel policies. Personnel records include qualifications and licensure that are kept current.
- 5.5 If personnel under hourly or per visit contracts are used by the HCA, there shall be a written contract between those personnel and the agency that specifies the following:
- (A) Home care consumers are accepted for care only by the primary HCA.
 - (B) The services to be furnished.
 - (C) The necessity to conform to all applicable agency policies, including personnel qualifications.
 - (D) The responsibility for participating in developing plans of care.
 - (E) The manner in which services will be controlled, coordinated, and evaluated by the primary HCA.
 - (F) The procedures for submitting clinical and progress notes, scheduling of visits, periodic consumer evaluation.
 - (G) The procedures for payment for services furnished under the contract.
- 5.6 The HCA shall be responsible for the coordination of consumer services. All personnel furnishing services maintain liaison to ensure that their efforts are coordinated effectively and support the objectives outlined in the plan of care. The clinical record or minutes of case conferences establish that effective interchange, reporting, and coordination of consumer care does occur. A written summary report for each consumer shall be sent to the attending physician at least every 60 days.
- 5.7 The HCA, under the direction of the governing body, shall prepare an overall plan and a budget that includes an annual operating budget and capital expenditure plan. The overall plan and budget shall be prepared by a committee consisting of representatives of the governing body, the administrative staff, and the medical staff (if any) of the HCA. The overall plan and budget shall be reviewed and updated at least annually by the committee referred to herein under the direction of the HCA governing body.
- 5.8 Any HCA that performs procedures in the consumer's residence that are considered waived clinical laboratory procedures under the Clinical Laboratory Improvement Act of 1988, shall possess a certificate of waiver from the Health Care Financing Administration (CMS?) or its designated agency.
- 5.9 AN HCA shall have written policies regarding maintenance of consumer's durable medical equipment, and shall make full disclosure of these policies to all clients with durable medical equipment in the home. The policies shall provide such disclosure to the consumer at the time of intake.

Section 6 - Professional Personnel

- 6.1 A group of professional personnel, which includes at least one physician and one registered nurse (preferably a public health nurse), and with appropriate representation from other professional disciplines, shall establish and annually review the agency's policies governing the scope of services offered, admission and discharge policies, medical supervision and plans of care, emergency care, clinical records, personnel

DRAFT 3 – August 18, 2008

qualifications, and program evaluation. At least one member of the group shall be neither an owner nor an employee of the agency.

- 6.2 The group of professional personnel shall meet frequently to advise the agency on professional issues, to participate in the evaluation of the agency's program, and to assist the agency in maintaining liaison with other health care providers in the community and in the agency's community information program. The meetings shall be documented by dated minutes.

Section 7 - Acceptance of Consumers, Plan of Care and Medical Supervision

- 7.1 Home care consumers shall be accepted for services on the basis of a reasonable expectation that the consumer's medical, nursing, and social needs can be met adequately by the agency in the consumer's place of residence. Care shall follow a written plan of care established and periodically reviewed by a doctor of medicine, osteopathy, or podiatric medicine.
- 7.2 The plan of care shall be developed in consultation with the agency staff covers all pertinent diagnoses, including mental status, types of services and equipment required, frequency of visits, prognosis, rehabilitation potential, functional limitations, activities permitted, nutritional requirements, medications and treatments, any safety measures to protect against injury, instructions for timely discharge or referral, and any other appropriate items.
- 7.3 If a physician refers a consumer under a plan of care that cannot be completed until after an evaluation visit, the physician shall be consulted to approve additions or modifications to the original plan. Orders for therapy services shall include the specific procedures and modalities to be used and the amount, frequency, and duration. The therapist and other agency personnel shall participate in developing the plan of care.
- 7.4 The total plan of care shall be reviewed by the attending physician and HCA personnel as often as the severity of the consumer's condition requires, but at least once every 60 days or more frequently when there is a beneficiary elected transfer; a significant change in condition resulting in a change in the case-mix assignment; or a discharge and return to the same HCA during the 60-day episode. Agency professional staff promptly alert the physician to any changes that suggest a need to alter the plan of care.
- 7.5 Drugs and treatments shall be administered by agency staff only as ordered by the physician with the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per agency policy developed in consultation with a physician, and after an assessment for contraindications. Verbal orders shall be put in writing and signed and dated with the date of receipt by the registered nurse or qualified therapist responsible for furnishing or supervising the ordered services. Verbal orders are only accepted by personnel authorized to do so by applicable state and federal laws and regulations as well as by the HCA's internal policies.
- 7.6 An HCA shall not discontinue or refuse services to a consumer unless documented efforts have been made to resolve the situation that triggers such discontinuation or refusal to provide services.

Section 8 - Skilled Nursing Services

- 8.1 The HCA shall furnish skilled nursing services by or under the supervision of a registered nurse and in accordance with the plan of care.

DRAFT 3 – August 18, 2008

- 8.2 The registered nurse shall be responsible for the following:
- (A) The initial evaluation visit,
 - (B) Regularly reevaluating the consumer's nursing needs,
 - (C) Initiating the plan of care and necessary revisions,
 - (D) Furnishing those services requiring substantial and specialized nursing skill,
 - (E) Initiating appropriate preventive and rehabilitative nursing procedures,
 - (F) Preparing clinical and progress notes, coordinating services, and informing the physician and other personnel of changes in the consumer's condition and needs,
 - (G) Counseling the consumer and family in meeting nursing and related needs, and
 - (H) Participating in in-service programs, and supervising and teaches other nursing personnel.

- 8.3 The licensed practical nurse shall be responsible for the following:
- (A) Furnishing services in accordance with agency policies,
 - (B) Preparing clinical and progress notes,
 - (C) Assisting the physician and registered nurse in performing specialized procedures,
 - (D) Preparing equipment and materials for treatments observing aseptic technique as required, and
 - (E) Assisting the consumer in learning appropriate self-care techniques.

Section 9 - Medical Social Services

- 9.1 If the agency furnishes medical social services, those services shall be given by a qualified social worker or by a qualified social work assistant under the supervision of a qualified social worker, and in accordance with the plan of care.
- 9.2 The social worker shall be responsible for the following:
- (A) Assisting the physician and other team members in understanding the significant social and emotional factors related to the health problems,
 - (B) Participating in the development of the plan of care,
 - (C) Preparing clinical and progress notes,
 - (D) Working with the family,
 - (E) Using appropriate community resources,
 - (F) Participating in discharge planning and in-service programs, and

- (G) Acting as a consultant to other agency personnel.

Section 10 - Home Health/ Nurse Aide Services

- 10.1 Agencies shall select home health/nurse aides on the basis of such factors as a sympathetic attitude toward the care of the sick, ability to read, write, and carry out directions, and maturity and ability to deal effectively with the demands of the job. They shall be closely supervised to ensure their competence in providing care.
- 10.2 Agencies shall ensure that all home health/nurse aides employed by them are certified by the Colorado Department of Regulatory Agencies within four months of obtaining employment, and that such certification remains current.
- 10.3 For all consumers who are expected to need home health/nurse aide services for at least a year, the supervising nurse shall, during supervisory visits, accomplish the following:
 - (A) Obtain the consumer's input, or that of the consumer's designated representative, regarding the home health/nurse aide assignment form, including all home health/nurse aide tasks to be performed during each scheduled time period.
 - (1) Details such as, but not limited to, housekeeping duties and standby assistance, shall be negotiated and included on the home health aide assignment form so that all obligations and expectations are clear.
 - (2) The home health/nurse aide assignment form shall contain information regarding special functional limitations and needs, safety considerations, special diets, special equipment, and any other information that is pertinent to the care that will be given by the aide.
 - (3) The HCA shall ensure that the consumer or the consumer's designated representative signs the form and is provided a copy at the beginning of services and at least once per year thereafter.
 - (B) Provide each consumer and/or the consumer's designated representative, a new copy of the Patient's Rights form and explain those rights whenever the home health/nurse aide assignment form is renegotiated and rewritten.

Section 11 - Physical Therapy or Speech Pathology Service

- 11.1 An agency that wishes to furnish outpatient physical therapy or speech pathology services shall meet all the pertinent conditions of this section.
- 11.2 For each consumer in need of outpatient physical therapy or speech pathology services, there shall be a written plan of care that shall be periodically reviewed by a physician, or by a physical therapist or speech pathologist respectively. The agency shall have a physician available to furnish necessary medical care in case of emergency.
- 11.3 Before or at the time treatment is initiated, the agency shall obtain the following:
 - (A) The consumer's significant past history.
 - (B) Current medical findings, if any.
 - (C) Diagnosis(es), if established.

DRAFT 3 – August 18, 2008

- (D) Physician's orders, if any.
- (E) Rehabilitation goals, if determined.
- (F) Contraindications, if any.
- (G) The extent to which the consumer is aware of the diagnosis(es) and prognosis.
- (H) If appropriate, the summary of treatment furnished and results achieved during previous periods of rehabilitation services or institutionalization.

11.4 Plan of Care

- (A) For each consumer there shall be a written plan of care established by the physician or by the physical therapist or speech-language pathologist who furnishes the services.
- (B) The plan of care for physical therapy or speech pathology services shall indicate anticipated goals and specify the following for those services:
 - (1) Type;
 - (2) Amount;
 - (3) Frequency; and
 - (4) Duration.
- (C) The plan of care and results of treatment shall be reviewed by the physician or by the individual who established the plan at least as often as the consumer's condition requires, and the indicated action is taken.
- (D) Changes in the plan of care shall be noted in the clinical record. If the consumer has an attending physician, the therapist or speech-language pathologist who furnishes the services promptly notifies him or her of any change in the consumer's condition or in the plan of care.

11.5 The agency shall provide for one or more doctors of medicine or osteopathy to be available on call to furnish necessary medical care in case of emergency. The established procedures to be followed by personnel in an emergency shall cover immediate care of the consumer, persons to be notified, and reports to be prepared.

11.6 Physical Therapy Services

- (A) If the agency offers physical therapy services, it shall provide an adequate program of physical therapy and have an adequate number of qualified personnel and the equipment necessary to carry out its program and to fulfill its objectives. The agency is considered to have an adequate outpatient physical therapy program if it can:
 - (1) Provide services using therapeutic exercise and the modalities of heat, cold, water, and electricity;
 - (2) Conduct consumer evaluations; and

DRAFT 3 – August 18, 2008

- (3) Administer tests and measurements of strength, balance, endurance, range of motion, and activities of daily living.
- (B) A qualified physical therapist shall be present or readily available to offer supervision when a physical therapist assistant furnishes services.
 - (1) If a qualified physical therapist is not available during all hours of operation, services shall be scheduled so as to ensure that the therapist is present when special skills are needed, for example, for evaluation and reevaluation.
 - (2) When a physical therapist assistant furnishes services, those services shall be supervised by a qualified physical therapist who makes an onsite supervisory visit at least once every 30 days.
- (C) The agency shall have the equipment and resources required to provide the range of services necessary in the treatment of the types of disabilities it accepts for service.
- (D) Physical therapy services shall be provided by, or under the supervision of, a qualified physical therapist. The number of qualified physical therapists and qualified physical therapist assistants shall be adequate for the volume and diversity of physical therapy services offered. A qualified physical therapist shall be readily available during the operating hours of the agency.
- (E) If personnel are available to assist qualified physical therapists by performing services incident to physical therapy that do not require professional knowledge and skill, these personnel shall be instructed in appropriate consumer care services by qualified physical therapists who retain responsibility for the treatment prescribed by the attending physician.

11.7 Speech Pathology Services

- (A) If the agency provides speech pathology services, it shall provide an adequate program of speech pathology and have an adequate number of qualified personnel and equipment necessary to carry out its program and to fulfill its objectives. The agency is considered to have an adequate outpatient speech pathology program when:
 - (1) It can provide the diagnostic and treatment services to effectively treat speech disorders.
 - (2) It has the equipment and resources required to provide the range of services necessary in the treatment of the types of speech disorders it accepts for service.
- (B) Speech pathology services shall be given or supervised by a qualified speech pathologist and the number of qualified speech pathologists shall be adequate for the volume and diversity of speech pathology services offered. At least one qualified speech pathologist shall be present at all times when speech pathology services are furnished.

11.8 If an agency provides outpatient physical therapy or speech pathology services under an arrangement with others, the services shall be furnished in accordance with the terms of

a written contract that specifies the agency shall retain professional and administrative responsibility for, and control and supervision of, the services.

Section 12 - Evaluation of the Agency's Program

- 12.1 The HCA shall have written policies requiring an overall evaluation of the agency's total program at least once a year by the group of professional personnel (or a committee of this group), HCA staff, and consumers, or by professional people outside the agency working in conjunction with consumers. The evaluation shall consist of an overall policy and administrative review and a clinical record review. The evaluation shall assess the extent to which the agency's program is appropriate, adequate, effective, and efficient. Results of the evaluation shall be reported to and acted upon by those responsible for the operation of the agency and are maintained separately as administrative records.
- 12.2 As a part of the evaluation process, the policies and administrative practices of the agency shall be reviewed to determine the extent to which they promote consumer care that is appropriate, adequate, effective, and efficient. Mechanisms shall be established in writing for the collection of pertinent data to assist in evaluation.
- 12.3 At least quarterly, appropriate health professionals, representing at least the scope of the program, shall review a sample of both active and closed clinical records to determine whether established policies are followed in furnishing services directly or under arrangement. There shall be a continuing review of clinical records for each 60-day period that a consumer receives home health services to determine adequacy of the plan of care and appropriateness of continuation of care.

Section 13 - Comprehensive Assessment of Consumers

- 13.1 Each consumer shall receive, and an HCA shall provide, a consumer-specific, comprehensive assessment that accurately reflects the consumer's current health status and includes information that may be used to demonstrate the consumer's progress toward achievement of desired outcomes. The comprehensive assessment shall identify the consumer's continuing need for home care and meet the consumer's medical, nursing, rehabilitative, social, and discharge planning needs.
- 13.2 Initial assessment visit
- (A) A registered nurse shall conduct an initial assessment visit to determine the immediate care and support needs of the consumer. The initial assessment visit shall be held either within 48 hours of referral, or within 48 hours of the consumer's return home, or on the physician-ordered start of care date.
- (B) When rehabilitation therapy service (speech language pathology, physical therapy, or occupational therapy) is the only service ordered by the physician, and if the need for that service establishes program eligibility, the initial assessment visit may be made by the appropriate rehabilitation skilled professional.
- 13.3 Comprehensive assessment
- (A) The comprehensive assessment shall be completed in a timely manner, consistent with the consumer's immediate needs, but no later than five calendar days after the start of care.

DRAFT 3 – August 18, 2008

- (B) Except as provided in section 13.3(C) of this chapter, a registered nurse shall complete the comprehensive assessment.
- (C) When physical therapy, speech-language pathology, or occupational therapy is the only service ordered by the physician, a physical therapist, speech-language pathologist or occupational therapist may complete the comprehensive assessment.
- (D) The comprehensive assessment shall include a review of all medications the consumer is currently using in order to identify any potential adverse effects and drug reactions, including ineffective drug therapy, significant side effects, significant drug interactions, duplicate drug therapy, and noncompliance with drug therapy.
- (E) The comprehensive assessment shall be updated and revised as frequently as the consumer's condition warrants due to a major decline or improvement in the consumer's health status, but not less frequently than:
 - (1) The last five days of every 60 days beginning with the start-of-care date, unless there is a:
 - (a) Beneficiary elected transfer;
 - (b) Significant change in condition resulting in a new case-mix assignment; or
 - (c) Discharge and return to the same HCA during the 60-day episode.
 - (2) Within 48 hours of the consumer's return to the home from a hospital admission of 24 hours or more for any reason other than diagnostic tests;
 - (3) At discharge.