

**RULES AND REGULATIONS  
FOR  
HOME HEALTH CARE AGENCIES**

**28 Pa. Code, Part IV, Health Facilities**

**Subpart F. Chapter 601**

**and**

**Subpart A. Chapter 51**

**NOTICE OF CHANGE**

On December 18, 1992, the Pennsylvania Health Care Facilities Act was amended. Section 807 of the Act, "Application for License," established a new fee of \$250.00 for application or renewal of a license for a home health agency.

PA Department of Health  
Division of Home Health

HOME HEALTH CARE AGENCIES

601.1 Subpart F. HOME HEALTH CARE AGENCIES

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Authority

The provisions of this Subpart F issued under Chapter 8 of the act of July 19, 1979 (P.L. 130. No. 48) (35 P.S. §§118.801-118.820) unless otherwise noted.

Source

The provisions of this Subpart F adopted October 14, 1986, effective April 23, 1987. 16 Pa.B. 4065 unless otherwise noted.

Chapter 601. HOME HEALTH CARE AGENCIES

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**GENERAL PROVISIONS****§601.1. Legal base.**

(a) This subpart is promulgated by the Department under the powers granted and the duties mandated by Chapter 8 of the Act (35 P.S. §§ 118.801a – 448.820).

(b) The Department has the power and is duty to promulgate, after consultation with the Health Care Policy Board, the regulations necessary to implement the provisions and purpose of Chapter 8 of the Act (35 P.S. §§ 118.801a – 148.820) and to assure that its regulations and the Act are enforced.

(c) The purpose of this subpart is to protect and promote the public health and welfare through the establishment and enforcement of regulations setting minimum standards in the construction, maintenance and operation of Home Health Agencies. The standards are intended by the Department to assure safe, adequate and efficient home health care of the patients of the Home Health Care Agencies. It is also the purpose of this subpart to assure quality health care through appropriate and nonduplicative review and inspection with regard to the protection of the health and rights of privacy of patients and without unreasonably interfering with the operation of the Home Health Agency.

**§601.2. Affected Home Health Care Agencies.**

(a) This subpart applies to Home Health Care Agencies, profit or nonprofit, operated in this Commonwealth, as defined in this subpart.

(b) Existing Home Health Care Agencies which were Home Health Care Agencies prior to April 23, 1987 shall be required to meet the same standards as Home Health Care Agencies created after April 23, 1987 unless an exceptions granted by the Department under §601.5 (relating to exceptions).

(c) A Home Health Agency certified to participate in the Medicare program shall be deemed to comply with and satisfy this subpart upon compliance with §601.11(a)—(c) (relating to licensure process).

**§601.3. Requirements for Home Health Care Agencies.**

(a) A current copy of this subpart shall be maintained at the Home Health Care Agency.

(b) Home Health Care Agencies licensed under this subpart shall comply with applicable environmental, health, sanitation, and professional licensure standards, which are required by Federal, State and local authorities. This includes, but is not limited to, standards promulgated by the State Boards of Medicine, Nursing, Pharmacy, Physical Therapy Examiners—49 Pa. Code Chapters 16-18, 21, 27 and 40—and the Occupational Therapy Practice Act (63 P.S. §§1501-1519). Home Health Care Agencies shall also comply with Chapter 27 (relating to communicable and non-communicable diseases) and Chapter 25 (relating to controlled substances, drugs, devices and cosmetics).

(c) If there is a difference in applicable State or local standards, the standards established under State statutes apply for the purpose of compliance with this subpart.

**§601.4. Inspections.**

The Home Health Care Agency shall be subject to Inspection at any time by authorized representatives of the Department. Inspections may be scheduled in advance or be unannounced.

**§601.5. Exceptions.**

The Department may grant an exception to the standards and this subpart when the policy objective of the standards and this subpart is met in existing Home Health Care Agencies. The exception shall be requested in writing and be made by the Home Health Care Agency. The reason for granting the exceptions and the time period for the exceptions shall be made in writing by the Department, and incorporated as part of the permanent record of the Home Health Care Agency maintained on file in the Department.

**Cross Reference**

This section cited in Pa. Code § 601.2 (relating to affected Home Health Care Agencies).

**§601.6. Definitions.**

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

*Act* – The Health Care Facilities Act (35 P.S. §§448.101—448.904).

*Administrator* – A person who performs the functions as outlined in §601.21(d) (relating to organization, services and administration) and is one of the following:

- i. A licensed physician.
- ii. A registered nurse
- iii. Has training and experience in health service administration and at least 1 year of supervisory or administrative experience in home health care or related health programs.

*Agency* – An administrative unit that is responsible financially and legally.

*Bylaws* – A set of rules adopted by a Home Health Care Agency for governing the agency's operation.

*Branch Office* – A location or site from which a Home Health Care Agency provides services within a portion of the total geographic area served by the parent agency. The term includes an office that is part of the Home Health Care Agency and is sufficiently accessible to share administration, supervision and services in a manner that renders it unnecessary for the branch independently to meet the requirements of this subpart as a Home Health Care Agency.

*Clinical Note* – A dated written notation by a member of the health team of a single contact with a patient, containing a description of signs and symptoms, treatment or drug given, the patient's reaction and changes in physical or emotional condition.

*Department* – The Department of health of the Commonwealth.

*Health team* – Persons associated with the agency and assigned to a particular patient to provide services.

*Home health aide* – A nonprofessional person who has completed a minimum of 60 hours of classroom instruction prior to or during the first 3 months of employment. The term includes aids who are carefully trained in methods of assisting patients to achieve maximum self-reliance, principles of nutrition and meal preparation, the aging process and emotional problems of illness, changes in patient's condition that should be reported, work of the agency and the health team, ethics, confidentiality and record keeping.

*Home Health Care Agency* – An organization or part thereof staffed and equipped to provide skilled nursing and at least 1 therapeutic service—physical therapy, occupational therapy, speech pathology, medical social services or home health aides—to disabled, aged, injured or sick persons on a part-time or intermittent basis in their place of residence. The term includes an agency that also provides other health-related services to protect and maintain persons in their own homes.

*Licensed practical nurse* – A practical nurse who holds a current and valid license to practice in this Commonwealth under the Practical Nurse Law (63 P.S. §§651—667).

*Occupational therapist* – A person who is currently licensed as an occupational therapist in this Commonwealth under the Occupational Therapy Act (63 P.S. §§1501—1519).

*Occupational therapist assistant* – A person who is currently licensed as an occupational therapist assistant in this Commonwealth, under the Occupational Therapy Act (63 P.S. §§1501—1519).

*Parent Home Health Care Agency* – The agency that develops and maintains administrative control of subunits or branch offices. The term includes a subdivision which has subunits or branches.

*Part-time intermittent services* – Services which are provided for less than 8 hours a day or less than 40 hours a week.

*Pharmacist* – A person who is currently licensed as a pharmacist in this Commonwealth under the Pharmacy Act (63 P.S. §§390-1—390-13).

*Physical Therapist* – A person who is currently licensed as a physical therapist in this Commonwealth under the Physical Therapy Practice Act (63 P.S. §§1301—1312).

*Physical Therapist Assistant* – A person who is currently licensed as a physical therapist assistant in this Commonwealth under the Physical Therapy Practice Act (63 P.S. §§1301—1312).

*Physician* – A Doctor of Medicine or Doctor of Osteopathy who holds a current valid license to practice in this Commonwealth.

*Primary Home Health Care Agency* – The agency that is responsible for the service rendered to patients and for implementation of the plan of treatment.

*Progress note* – A dated, written notation by a member of the health team summarizing facts about care and the patient's response during a given period of time.

*Registered Nurse* – A person licensed to practice professional nursing under the Professional Nursing Law (63 P.S. §§211—225).

*Secretary* – The Secretary of the Department.

*Skilled nursing services* – High intensity comprehensive, planned service provided with maximum efficiency by a registered professional nurse in instances where judgment is required, or by a licensed practical nurse under the supervision of a registered nurse.

*Social work assistant* – A person who has a baccalaureate degree in social work, psychology, sociology or other field related to social work, or 2 years of social work experience in a health care setting.

*Social worker* – A person who has a master's degree from a school of social work accredited by the Council on Social Work Education, and has 1 year of social work experience in a health care setting.

*Speech pathologist/audiologist* – A person who meets 1 of the following:

- (i) The education and experience requirements for a Certificate of Clinical Competence in the appropriate area—speech pathology or audiology—granted by the American Speech and Hearing Association.
- (ii) The educational requirements for certification and is in the process of accumulating the supervised experience required for certification.

*Subdivision* – A component of 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 requirements of this subpart for Home Health Care Agencies.

*Subunit* – A semi-autonomous organization, which serves patients in a geographic area different from that of the parent agency.

*Summary report* – A compilation of the pertinent factors from the clinical notes and progress notes regarding a patient, which is submitted as to the patient's physician.

### **§601.7. Ownership**

(a) The owner of a Home Health Care Agency may be an individual, partnership, association, corporation or a combination thereof. The following apply to Home Health Care Agencies according to the mode of ownership:

(1) *Individual Ownership* – A complete list of names and addresses of the owners of the Home Health Care Agency shall be submitted with the application. When death occurs to a person who was a sole owner of a Home Health Care Agency, the executor or administrator of the estate may apply for, and the Department may, after review, transfer a license for the Home Health Care Agency.

- (2) *Partnerships* – A complete list of names and addresses of the owners of the Home Health Care Agency, general partners and partners responsible for the management of the Home Health Care Agency shall be submitted with the application. When a license is issued to a partnership and 1 or more of the partners die, the executor or administrator of the deceased's estate, together with the surviving partners may apply for a new license. After review the Department may transfer the license.
- (3) *Association or Corporation* – A complete list of names and addresses of the officers, directors, principal stockholders, either beneficial or of record, of the corporate owner and of the parent corporation, if applicable, and of the persons in charge who are responsible for the management of the Home Health Care Agency, shall be submitted with the application. Ownership interest of 5.0% or more – direct or indirect – shall be disclosed.
- (b) The Department shall be notified in writing within 30 days whenever a change in the partners, officers, directors, principal stockholders or persons in charge of a Home Health Care Agency owned by a partnership or corporation has taken place.

## LICENSURE

### §601.11. Licensure process.

- (a) The application form for a license to operate a Home Health Care Agency shall be obtained from the Pennsylvania Department of Health, Division of Primary Care and Home Health Services, Post Office Box 90, Harrisburg, Pennsylvania 17108.
- (b) Application or renewal forms shall be accompanied by a fee of \$50.
- (c) The Home Health Care Agency shall report yearly to the Department, on forms issued by the Department, statistical information the Department may request.
- (d) Home Health Care Agencies certified as providers by the Department to the Federal government for purposes of the Medicare program, shall be deemed to comply with this subpart upon compliance with subsections (a)—(c).

### Cross Reference

This section cited in 28 Pa. Code §601.2 (relating to affected Home Health Care Agencies).

### §601.12. Issuance of License.

- (a) The Department will issue a regular license to operate a Home Health Care Agency after a survey conducted by the Department indicates that the applicant is in substantial compliance with this subpart. The survey may include an onsite inspection.

(b) A regular license issued by the Department shall expire 1 year from the date of issue.

(c) A provisional license may be issued when there are numerous deficiencies or a serious specific deficiency, which has a substantial impact on governance and management or services, which indicates that the Home Health Care Agency is not in compliance with applicable statutes, ordinances or this title, and the Department finds that:

- (1) The applicant is taking appropriate steps to correct the deficiencies in accordance with a timetable submitted by the applicant and agreed upon by the Department.
- (2) There is no pattern of deficiencies over a period of 2 or more years.
- (3) There is no danger to the health or safety of the patients of the Home Health Care Agency.

(d) The Department may issue a provisional license for a specific period of not more than 6 months. A provisional license may be renewed three times.

(e) The current license shall be posted in a conspicuous place in the Home Health Care Agency.

### **§601.13. Responsibilities of Home Health Care Agency owners.**

(a) The owner shall be responsible for meeting the minimum standards for operation of a Home Health Care Agency as set forth by the Department and by other State and local agencies responsible for the health, welfare and safety of the patients.

(b) When services for the administration or management of the Home Health Care Agency or for the provision of patient care are purchased, the owner shall be responsible for insuring compliance with this title and regulations for other appropriate agencies.

(c) The owner, administrator or designee shall immediately report, by telephone to the Department and by a written follow-up report as soon as possible, a catastrophic incident, such as fire or flood, or an incident which may cause interruption or cessation of the delivery of services, or another interruption of Home Health Care Agency services which would affect the health and safety of the patients.

### **§601.14. Reasons for revocation or nonrenewal of license.**

(a) *Departmental refusals.* The Department may refuse to renew a license, may suspend, revoke or limit a license of a Home Health Care Agency or may suspend admission for any of the following reasons:

- (1) A serious violation of this subpart, the Act or of other statutes and regulations, which seriously threatens the health, safety and welfare of patients.
- (2) Failure of an owner to submit a reasonable timetable for correction of deficiencies.
- (3) The existence of a pattern of cyclical deficiencies, which extends over a period of 2 or more years.

- (4) Failure, by the holder of a provisional license, to correct deficiencies in accordance with a timetable submitted by the applicant and agreed upon by the Department.
- (5) Fraud or deceit in obtaining or attempting to obtain a license.
- (6) Lending, borrowing or using the license of another, or knowingly aiding or abetting the improper granting of a license.
- (7) Incompetence, negligence or misconduct in operating the Home Health Care Agency or in providing services to individuals.
- (8) Mistreating or abusing individuals cared for by the Home Health Care Agency.
- (9) Serious violation of the statutes relating to Medical Assistance or Medicare reimbursement.

(b) *Notice.* Whenever the Department proposes to revoke a license, refuse to issue a license, issue a provisional license or suspend admissions, it will give written notice to the Home Health Care Agency by certified mail.

(c) *Form of Notice* – Notice under subsection (b) will conform to 1 Pa. Code §35.14 (relating to orders to show cause). The order will specify the reasons for the proposed action of the Department and will notify the Home Health Care Agency of its right to a hearing before the State Health Facility Hearing Board. The order will specify the time within which the request of the Home Health Care Agency shall be filed with the board.

(d) *Correction of deficiency.* Whenever a Home Health Care Agency notifies the Department that it has completed a plan of correction and corrected its deficiencies, the Department will conduct a survey to ascertain completion of the plan of correction. Upon finding full or substantial compliance, the Department will issue a regular license.

(e) *Appeal.* A final order or determination by the Department relating to licensure may be appealed to the State Health Facility Hearing Board under section 805 of the Act (35 P.S. §448.805). Administrative proceedings will be conducted under the State Health Facility Hearing Board rules of practice and procedure at 37 Pa. Code Chapter 197 (relating to practice and procedure).

(f) *Practice and Procedure.* Subsection (c) supplements 1 Pa. Code § 35.14.

## GOVERNANCE AND MANAGEMENT

### **§601.21. Organization, service and administration.**

(a) *Writing requirements.* Organization, services provided, administrative control and lines of authority for the delegation of responsibility to the patient care level shall be clearly set forth in writing and shall be readily identifiable. Administrative and supervisory functions may not be delegated to another agency or organization and services not provided directly shall be monitored and controlled by the primary agency,

including services provided through subunits of the parent agency. If an agency has subunits, appropriate administrative records shall be maintained for each subunit. The subunit, by virtue of the lack of accessibility between it and the parent agency, is judged incapable of sharing administration, supervision and services on a daily basis with the parent agency and shall independently meet this subpart.

(b) *Services provided.* Part-time or intermittent skilled nursing services and at least one other therapeutic service—physical therapy, occupational therapy, speech pathology, medical social services or home health aides—shall be made available on a visiting basis, in a place of residence used as a patient’s home. A Home Health Care Agency shall provide at least one of the qualifying services directly through agency employees, but may provide, by written contract, the second qualifying service and additional services under arrangements with another agency or organization.

(c) *Governing body.* 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—see § 601.22 (relating to agency evaluation and review)—adopt and periodically review written bylaws, and oversee the management and fiscal affairs of the agency.

(d) *Administrator.* The administrator, who may also be the supervising physician or registered nurse—see subsection (e)—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.

(e) *Supervising physician or registered nurse.* The skilled nursing and other therapeutic services provided shall be under the supervision and direction of a physician or a registered nurse with at least 1 year of nursing experience. This person, or a similarly qualified alternate, shall be available at all times during the operating hours and participate in activities relevant to the professional services provided, including the development of qualifications and assignments of personnel.

(f) *Personnel policies.* Personnel practices shall be supported by appropriate, written personnel policies. Personnel records shall include job descriptions, qualifications, licensure, performance evaluations, health examinations and documentation of orientation provided. Records shall be kept current.

(g) *Civil rights.* Home Health Care Agencies shall comply with the Pennsylvania Human Relations Act (43 P.S. §§951—963) and 16 Pa. Code Part II Subpart A (relating to the Human Relations Commission).

(h) *Coordination of patient services.* Personnel providing services shall maintain liaison to assure their efforts effectively complement one another and support the objectives outlined in the plan of treatment. The clinical record or minutes of case conferences shall establish that effective interchange, reporting and coordinated patient evaluation does occur. A written summary report for each patient shall be sent to the attending physician at least every 60 days.

(i) *Institutional planning.* The Home Health Care Agency, under the direction of the governing body, and in conjunction with representatives of the administrative and health professional staff, shall prepare an overall plan and budget.

#### **Cross References**

This section cited in 28 Pa. Code § 601.6 (relating to definitions).

### **§601.22. Agency evaluation and review.**

(a) *Annual policy review.* Professional personnel, which includes at least one physician and one registered nurse with appropriate representation from other professional disciplines, shall establish and annually review the agency's policies governing scope of services offered, admission and discharge policies, medical supervision and plans of treatment, emergency scope of services offered, medical care, clinical records, personnel qualifications and program evaluation.

(b) *Advisory and evaluation function.* The group of professional personnel shall meet at least annually 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 its community information program. Its meetings shall be documented by dated minutes.

(c) *Annual program evaluation.* The Home Health Care Agency 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, home health care agency 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 shall be maintained separately as administrative record.

As part of the evaluation process, the policies and administrative practices of the agency shall be reviewed to determine the extent to which they promote patient care that is appropriate, adequate, effective and efficient. Mechanisms shall be established in writing of the collection of pertinent data to assist in evaluation. The data to be considered may include, but are not limited to: Number of patients receiving each service offered, number of patient visits, reasons for discharge, breakdown by diagnosis, sources of referral, number of patients not accepted with reasons and total staff days for each service offered.

(d) *Clinical record review.* 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 assure that established policies are followed in providing services—direct services as well as services under arrangement. There shall be a continuing review of clinical records for each 60-day period that a patient receives home health care services to determine adequacy of the plan of treatment and appropriateness of continuation of care.

#### **Cross Reference**

This section cited in 28 Pa. Code § 601.21 (relating to organization, services and administrations).

## **SERVICES**

### **§ 601.31. Acceptance of patients, plan of treatment and medical supervision.**

(a) *Patient acceptance.* Patients shall be accepted for treatment on the basis of a reasonable expectation that the patient's medical, nursing and social needs can be met adequately by the agency in the patient's place of residence. Patient care shall follow a written plan of treatment established and periodically reviewed by the attending physician, and patient care shall continue under the supervision of the attending physician.

(b) *Plan of treatment.* The plan of treatment shall be developed in consultation with the agency staff and shall cover 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, safety measures to protect against injury, instructions for timely discharge or referral and other appropriate items. If an attending physician refers a patient under a plan of treatment, which cannot be completed until after an evaluation visit, the attending 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 of the procedures and modalities. The therapist and other agency personnel shall participate in developing the plan of treatment.

(c) *Periodic review of plan of treatment.* The total plan of treatment shall be reviewed by the attending physician and home health care agency personnel as often as the severity of the patient's condition requires, but at least once every 60 days. Agency professional staff shall promptly alert the physician to changes that suggest a need to alter the plan of treatment.

(d) *Conformance with physician's orders.* Prescriptions and nonprescription (over-the-counter) drugs, devices, medications and treatments, shall be administered by agency staff in accordance with the written orders of the physician. Prescription drugs and devices shall be prescribed by a licensed physician. Only licensed pharmacists shall dispense drugs and devices. Licensed physicians may dispense drugs and devices to the patients who are in their care. The licensed nurse or other individual, who is authorized by appropriate statutes and the State Boards in the Bureau of Professional and Occupational Affairs, shall immediately record and sign oral orders and obtain the physician's countersignature within 7 days. Agency staff shall check medicines a patient may be taking to identify possibly ineffective drug therapy or adverse reactions, significant side effects, drug allergies, and contraindicated medication, and shall promptly report problems to the physician.

#### Source

The provisions of this § 601.31 corrected February 13, 1987, effective April 23, 1987, 17 Pa. B. 718. Immediately preceding text appears as serial pages (113300) to (113301).

#### Cross References

This section cites in 28 Pa. Code § 601.36 (relating to clinical records).

### **§601.32. Skilled nursing service.**

(a) *Supervision.* The Home Health Care Agency shall provide skilled nursing services by or under the supervision of a registered nurse and in accordance with the plan of treatment.

(b) *Duties of the registered nurse.* The registered nurse shall make the initial evaluation visit, regularly reevaluate the patient's nursing needs, initiate the plan of treatment and necessary revisions, provide services requiring substantial specialized nursing skill, initiate appropriate preventive and rehabilitative nursing procedures, prepare clinical and progress notes, coordinate service, inform the physician and other personnel of changes in the patient's condition and needs, counsel the patient and family in meeting nursing and related needs, participate in in-service programs and supervise and teach other nursing personnel.

(c) *Duties of the licensed practical nurse.* The licensed practical nurse shall provide services in accordance with agency policies, prepare clinical and progress notes, assist the physician or registered nurse in performing specialized procedures, prepare equipment and materials for treatments, observing aseptic technique as required and assist the patient in learning appropriate self-care techniques.

**§601.33. Therapy services.**

(a) *Qualified therapist.* Therapy services offered by the Home Health Care Agency directly or under agreement shall be given by a qualified therapist or by a qualified therapist assistant under the supervision of a qualified therapist in accordance with the plan of treatment. The qualified therapist shall assist the physician in evaluating level of function, help develop the plan of treatment—revising as necessary—prepared clinical and progress notes, advise and consult with the family and other agency personnel and participate in in-service programs.

(b) *Supervision of occupational therapy assistant.* Services provided by a qualified occupational therapy assistant may be furnished under the supervision of a qualified occupational therapist.

(c) *Supervision of speech therapy services.* Speech therapy services shall be provided only by or under supervision of a qualified speech pathologist or audiologist.

**§601.34. Medical social services.**

Medical social services, when provided, 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 treatment. The social worker shall assist the physician and other team members in understanding the significant social and emotional factors related to the health problems, participate in the development of the plan of treatment, prepare clinical and progress notes, work with the family, utilize appropriate community resources, participate in discharge planning, and in-service programs and act as a consultant to other agency personnel.

**§601.35. Home health aide services.**

(a) *Selection of aides.* Home health aides shall be selected on the basis of such factors as a sympathetic attitude towards the care of the sick, ability to carry out directions, maturity and ability to deal effectively with the demands of the job. Aides shall be carefully trained in methods of assisting patients to achieve maximum self-reliance, principles of nutrition and meal preparation, the aging process and emotional problems of illness, procedures for maintaining a clean, healthful and pleasant environment, changes in patient's condition that should be reported, work of the agency and the health team, ethics, confidentiality and record keeping. They shall be closely supervised to assure their competence in providing care.

(b) *Assignment and duties of the home health aide.* The home health aide shall be assigned to a particular patient by a registered nurse. Written instructions for patient shall be prepared by a registered nurse or therapist as appropriate. Duties shall include the performance of simple procedures as an extension of therapy services, personal care, ambulation and exercise, household services essential to health care at home, assistance with medications that are ordinarily self-administered, reporting changes in the patient's conditions and needs and completing appropriate records.

(c) *Supervision.* The registered nurse, or appropriate professional staff member, if other services are provided, shall make a supervisory visit to the patient's residence at least every 2 weeks, either when the aide is present to observe and assist, or when the aide is absent, to assess relationships and determine whether goals are being met.

### **§601.36. Clinical records.**

(a) *Maintenance and content of records.* A clinical record containing pertinent past and current findings in accordance with accepted professional standards shall be maintained for every patient receiving home health care services. In addition to the plan of treatment—see §601.31(b)(relating to acceptance of patients, plan of treatment and medical supervision)—the record shall contain appropriate identifying information; name of physician; drug and dietary treatment; activity orders; signed and dated clinical and progress notes by the individual who delivered the service—clinical notes are written the day service is rendered and incorporated into the clinical record no less often than weekly; copies of summary reports sent to the physician; and a discharge summary.

(b) *Retention of records.* Clinical records shall be retained for 7 years after discharge of the patient. Policies shall provide for retention even if the home health agency discontinues operations. If the patient is transferred to another home health care agency, a copy of the record or abstract shall accompany the patient.

(c) *Protection of records.* Information contained in the patient's record shall be privileged and confidential. Clinical record information shall be safeguarded against loss or unauthorized use. Written procedures shall govern use and removal of records and conditions for release of information. The patient's written consent shall be required for release of information outside the home health care agency, except as otherwise provided by law or third-party contractual arrangements.