The Home Health Conditions of Participation —and— Interpretive Guidelines
The Home Health

Conditions of Participation

and

Interpretive Guidelines
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The Omnibus Budget Reconciliation Act of 1987 had a major impact on the delivery of home health care services. The revised *Conditions of Participation* focused on the health and safety of patients and emphasized patient rights and home health aide competency. The survey process began in 1991 and has created many challenges. Coping with these changes is not easy but it is something that agencies must do.

To meet the challenges, agencies must implement a simple, three-point strategy:

1. Staff must know the requirements for service delivery
2. Staff must deliver services according to the regulations
3. Staff must document appropriately

It is the first point in that strategy which creates the biggest obstacle for agencies. Exactly what rules govern the survey process? How can an agency obtain these regulations? Initially published in the *Federal Register* on August 14, 1989, the *Conditions of Participation* have been revised many times. In February 1999, the Health Care Financing Administration (HCFA), now the Centers for Medicare & Medicaid Services (CMS), added a new condition on comprehensive assessment and the OASIS. And in July 2000, HCFA revised some conditions as part of the final rule for the Prospective Payment System (PPS). These changes became effective October 1, 2000, followed by some changes in 2003, 2006, and 2007. But, it is very difficult to obtain a complete set of the *Conditions*, incorporating the revised regulations, so agencies must “cut and paste,” so to speak.

The Interpretive Guidelines interpret the *Conditions* and provide surveyors with direction for the survey process. The Guidelines were originally published in the State Operations Manual in March 1991 and like the *Conditions*, they have been updated several times.

In 2005, CMS converted all of its publications to Internet manuals. During that transition, the Interpretive Guidelines lost its three-column format. This manual retains that feature: the G-tag and regulation next to the corresponding guidelines.
So, that brings us to the reason why Beacon Health decided to publish this manual. We simply wanted to pull together one concise, up-to-date set of the rules and interpretations that agencies can use in the orientation and training of staff and as a reference during care delivery.

**Hints for Using This Manual**

As you use this manual, please note the following important points:

1. This manual now incorporates the regulations for certification, which are the *Conditions of Participation*, and payment. Since the implementation of the PPS, payment regulations have much more impact on the delivery of services. Only the *Conditions for certification* have corresponding Interpretive Guidelines.

2. In the interest of readability, we've taken the liberty of reproducing the *Conditions of Participation* in a slightly larger type size, with important, frequently consulted sections presented in boldface type.

3. The manual incorporates some CMS interpretations affecting care delivery and compliance, which were not reflected in the revisions. The text notes these statements in italics and includes the reference.

   *The Conditions of Participation do not prohibit a physician licensed in one state from signing the plan of care for a patient receiving home health services from an HHA located in another state.*

4. The guidelines include several G tags that do not appear in chronological order (e.g., G301 and G310). CMS probably did this to avoid renumbering all the G tags.

5. The Index of Key Points provides a convenient way to reference important points.

Download the additional materials for this book with the purchase of this product.
## The Conditions of Participation

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Subpart A — General Provisions
§484.1 Basis and scope.
(a) Basis and scope. This part is based on the indicated provisions of the following sections of the Act:
(1) Sections 1861(o) and 1891 establish the conditions that an HHA must meet in order to participate in Medicare.
(2) Section 1861(z) specifies the Institutional planning standards that HHAs must meet.
(3) Section 1895 provides for the establishment of a prospective payment system for home health services covered under Medicare.
(b) This part also sets forth additional requirements that are considered necessary to ensure the health and safety of patients.
§484.2 Definitions.

As used in this part, unless the context indicates otherwise —

"Bylaws or equivalent" means a set of rules adopted by an HHA for governing the agency’s operation.

"Branch office" means a location or site from which a home health agency provides services within a portion of the total geographic area served by the parent agency. The branch office is part of the home health agency and is located sufficiently close to 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.

"Clinical note" means a notation of a contact with a patient that is written and dated by a member of the health team, and that describes signs and symptoms, treatment and drugs administered and the patient’s reaction, and any changes in physical or emotional condition.

"HHA" stands for home health agency.


"Parent home health agency" means the agency that develops and maintains administrative controls of subunits and/or branch offices.

"Primary home health agency" means the agency that is responsible for the services furnished to patients and for implementation of the plan of care.

"Progress note" means a written notation, dated and signed by a member of the health team that summarizes facts about care furnished and the patient’s response during a given period of time.

"Proprietary agency" means a private profit-making agency licensed by the State.

"Public agency" means an agency operated by a State or local government.

"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 conditions of participation for HHAs. A subdivision that has subunits or branch offices is considered a parent agency.

"Subunit" means a semi-autonomous organization that—

(1) Serves patients in a geographic area different from that of the parent agency; and

(2) Must independently meet the conditions of participation for HHAs because it is too far from the parent agency to share administration, supervision, and services on a daily basis.

"Summary report" means the compilation of the pertinent factors of a patient’s clinical notes and progress notes that is submitted to the patient’s physician.

"Supervision" means authoritative procedural guidance by a qualified person for the accomplishment of a function or activity. Unless otherwise specified in this part, the supervisor must be on the premises to supervise an individual who does not meet the qualifications specified in §484.4.

§484.4 Personnel qualifications.

Staff required to meet the conditions set forth in this part are staff who meet the qualifications specified in this section.

"Administrator, home health agency." A person who:

(a) Is a licensed physician, or

(b) Is a registered nurse, or

(c) 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.

"Audiologist." A person who:

(a) Meets the education and experience requirements for a Certificate of Clinical Competence in audiology granted by the American Speech-Language-Hearing Association; or

(b) Meets the educational requirements for certification and is in the process of accumulating the supervised experience required for certification.

"Home health aide." Effective for services furnished after August 14, 1990, a person who has successfully completed a State-established or other training program that meets the requirements of §484.36(a) and a competency evaluation program or State licensure program that meets the requirements of §484.36(b) or (e), or a competency evaluation program or State licensure program that meets the requirements of §484.36(b) or (e). An individual is not considered to have completed a training and
competency evaluation program, or a competency evaluation program if, since the individual’s most recent completion of this program(s), there has been a continuous period of 24 consecutive months during none of which the individual furnished services described in §409.40 of this chapter for compensation.

“Occupational therapist.” A person who:
(a)(1) Is licensed or otherwise regulated, if applicable, as an occupational therapist by the State in which practicing, unless licensure does not apply;
(2) Graduated after successful completion of an occupational therapist education program accredited by the Accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA), or successor organizations of ACOTE; and
(3) Is eligible to take, or has successfully completed the entry-level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).
(b) On or before December 31, 2009:
(1) Is licensed or otherwise regulated, if applicable, as an occupational therapist by the State in which practicing; or
(2) When licensure or other regulation does not apply:
   (i) Graduated after successful completion of an occupational therapist education program accredited by the Accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA) or successor organizations of ACOTE; and
   (ii) Is eligible to take, or has successfully completed the entry-level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).
(c) On or before January 1, 2008:
(1) Graduated after successful completion of an occupational therapy program accredited jointly by the committee on Allied Health Education and Accreditation of the American Medical Association and the American Occupational Therapy Association; or
(2) Is eligible for the National Registration Examination of the American Occupational Therapy Association or the National Board for Certification in Occupational Therapy.
(d) On or before December 31, 1977:
   (1) Had 2 years of appropriate experience as an occupational therapist; and
   (2) Had achieved a satisfactory grade on an occupational therapist proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.
(e) If educated outside the United States:
(1) Must meet both of the following:
   (i) Graduated after successful completion of an occupational therapist education program accredited as substantially equivalent to occupational therapist assistant entry level education in the United States by one of the following:
      (A) The Accreditation Council for Occupational Therapy Education (ACOTE);
      (B) Successor organizations of ACOTE.
      (C) The World Federation of Occupational Therapists.
   (D) A credentialing body approved by the American Occupational Therapy Association.
(2) Successfully completed the entry-level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).
(3) On or before December 31, 2009, is licensed or otherwise regulated, if applicable, as an occupational therapist by the State in which practicing.

“Occupational therapy assistant.” A person who:
(a) Meets all of the following:
   (1) Is licensed or otherwise regulated, if applicable, as an occupational therapy assistant by the State in which practicing, unless licensure does not apply.
   (2) Graduated after successful completion of an occupational therapy assistant education program accredited by the Accreditation Council for Occupational Therapy Education, (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA) or its successor organizations.
(3) Is eligible to take or successfully completed the entry-level certification examination for occupational therapy assistants developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).
(b) On or before December 31, 2009:
   (1) Is licensed or otherwise regulated as an occupational therapy assistant, if applicable, by the State in which practicing; or any qualifications defined by the State in which practicing, unless licensure does not apply; or
   (2) Must meet both of the following:
       (i) Completed certification requirements to practice as an occupational therapy assistant established by a credentialing organization approved by the American Occupational Therapy Association.
       (ii) After January 1, 2010, meets the requirements in paragraph (a) of this section.
   (c) After December 31, 1977, and on or before December 31, 2007:
      (1) Completed certification requirements to practice as an occupational therapy assistant established by a credentialing organization approved by the American Occupational Therapy Association;
      or
      (2) Completed the requirements to practice as an occupational therapy assistant applicable in the State in which practicing.
   (d) On or before December 31, 1977:
      (1) Had 2 years of appropriate experience as an occupational therapy assistant; and
      (2) Had achieved a satisfactory grade on an occupational therapy assistant proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.
   (e) If educated outside the United States, on or after January 1, 2008:
      (1) Graduated after successful completion of an occupational therapy assistant education program that is accredited as substantially equivalent to occupational therapist assistant entry level education in the United States by:
          (i) The Accreditation Council for Occupational Therapy Education (ACOTE).
          (ii) Its successor organizations.
          (iii) The World Federation of Occupational Therapists.
          (iv) By a credentialing body approved by the American Occupational Therapy Association; and
      (2) Successfully completed the entry-level certification examination for occupational therapy assistants developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

“Physical therapist.” A person who is licensed, if applicable, by the State in which practicing, unless licensure does not apply and meets one of the following requirements:
   (a)(1) Graduated after successful completion of one of a physical therapist education program approved by one of the following:
       (i) The Commission on Accreditation in Physical Therapy Education (CAPTE).
       (ii) Successor organizations of CAPTE.
       (iii) An education program outside the United States determined to be substantially equivalent to physical therapist entry-level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or an organization identified in 8 CFR 212.15(e) as it relates to physical therapists.
   (2) Passed an examination for physical therapists approved by the State in which physical therapy services are provided.
   (b) On or before December 31, 2009:
      (1) Graduated after successful completion of a physical therapy curriculum approved by the Commission on Accreditation in Physical Therapy Education (CAPTE); or
      (2) Meets both of the following:
          (i) Graduated after successful completion of an education program determined to be substantially equivalent to physical therapist entry level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or identified in 8 CFR 212.15(e) as it relates to physical therapists.
          (ii) Passed an examination for physical therapists approved by the State in which physical therapy services are provided.
   (c) Before January 1, 2008:
      (1) Graduated from a physical therapy curriculum approved by one of the following:
          (ii) The Committee on Allied Health Education and Accreditation of the American Medical Association.
      (2) On or before December 31, 1977, was licensed or qualified as a physical therapist and meets both of the following:
(1) Has 2 years of appropriate experience as a physical therapist.
(2) Has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.
(e) Before January 1, 1966:
(1) Was admitted to membership by the American Physical Therapy Association;
(2) Was admitted to registration by the American Registry of Physical Therapists; and
(3) Has graduated from a physical therapy curriculum in a 4-year college or university approved by a State department of education.
(f) Before January 1, 1966 was licensed or registered, and before January 1, 1970, had 15 years of full-time experience in the treatment of illness or injury through the practice of physical therapy in which services were rendered under the order and direction of attending and referring doctors of medicine or osteopathy.
(g) If trained outside the United States before January 1, 2008, meets the following requirements:
(1) Was graduated since 1928 from a physical therapy curriculum approved in the country in which the curriculum was located and in which there is a member organization of the World Confederation for Physical Therapy.
(2) Meets the requirements for membership in a member organization of the World Confederation for Physical Therapy.

“Physical therapist assistant.” A person who is licensed, unless licensure does not apply, registered, or certified as a physical therapist assistant, if applicable, by the State in which practicing, and meets one of the following requirements:
(a)(1)(i) Graduated from a physical therapist assistant curriculum approved by the Commission on Accreditation in Physical Therapy Education of the American Physical Therapy Association; or if educated outside the United States or trained in the United States military, graduated from an education program determined to be substantially equivalent to physical therapist assistant entry level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or identified at 8 CFR 212.15(e); and
(2) Passed a national examination for physical therapist assistants.
(b) On or before December 31, 2009, meets one of the following:
(1) Is licensed, or otherwise regulated in the State in which practicing.
(2) In States where licensure or other regulations do not apply, graduated before December 31, 2009, from a 2-year college-level program approved by the American Physical Therapy Association and effective January 1, 2010, meets the requirements of paragraph (a) of this definition.
(c) Before January 1, 2008, where licensure or other regulation does not apply, graduated from a 2-year college-level program approved by the American Physical Therapy Association.
(d) On or before December 31, 1977, was licensed or qualified as a physical therapist assistant and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

“Physician.” A doctor of medicine, osteopathy, or podiatry legally authorized to practice medicine and surgery by the State in which such function or action is performed.

“Practical (vocational) nurse.” A person who is licensed as a practical (vocational) nurse by the State in which practicing.

“Public health nurse.” A registered nurse who has completed a baccalaureate degree program approved by the National League for Nursing for public health nursing preparation or post registered nurse study that includes content approved by the National League for Nursing for public health nursing preparation.

“Registered nurse (RN).” A graduate of an approved school of professional nursing, who is licensed as a registered nurse by the State in which practicing.

“Social work assistant.” A person who:
(1) Has a baccalaureate degree in social work, psychology, sociology, or other field related to social work and has had at least 1 year of social work experience in a health care setting, or
(2) Has 2 years of appropriate experience as a social work assistant and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that these determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as a social work assistant after December 31, 1977.
“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-language pathologist.” A person who meets either of the following requirements:


(b) The educational requirements for certification and is in the process of accumulating the supervised experience required for certification.

Subpart B — Administration

§484.10 Condition of participation: Patient rights.

The patient has the right to be informed of his or her rights. The HHA must protect and promote the exercise of these rights.

(a) Standard: Notice of rights. (1) The HHA must provide the patient with a written notice of the patient’s rights in advance of furnishing care to the patient or during the initial evaluation visit before the initiation of treatment.

(2) The HHA must maintain documentation showing that it has complied with the requirements of this section.

(b) Standard: Exercise of rights and respect for property and person. (1) The patient has the right to exercise his or her rights as a patient of the HHA.

(2) The patient’s family or guardian may exercise the patient’s rights when the patient has been judged incompetent.

(3) The patient has the right to have his or her property treated with respect.

(4) The patient has the right to voice grievances regarding treatment or care that is (or fails to be) furnished, or regarding the lack of respect for property by anyone who is furnishing services on behalf of the HHA and must not be subjected to discrimination or reprisal for doing so.

(5) The HHA must investigate complaints made by a patient or the patient’s family or guardian regarding treatment or care that is (or fails to be) furnished, or regarding the lack of respect for the patient’s property by anyone furnishing services on behalf of the HHA, and must document both the existence of the complaint and the resolution of the complaint.

(c) Standard: Right to be informed and to participate in planning care and treatment.

(1) The patient has the right to be informed, in advance about the care to be furnished, and of any changes in the care to be furnished.

(i) The HHA must advise the patient in advance of the disciplines that will furnish care, and the frequency of visits proposed to be furnished.

(ii) The HHA must advise the patient in advance of any change in the plan of care before the change is made.

(2) The patient has the right to participate in the planning of the care.

(i) The HHA must advise the patient in advance of the right to participate in planning the care or treatment and in planning changes in the care or treatment.

(ii) The HHA complies with the requirements of Subpart I of Part 489 of this chapter relating to maintaining written policies and procedures regarding advance directives. The HHA must inform and distribute written information to the patient, in advance, concerning its policies on advance directives, including a description of applicable State law. The HHA may furnish advance directives information to a patient at the time of the first home visit, as long as the information is furnished before care is provided.

(d) Standard: Confidentiality of medical records. The patient has the right to confidentiality of the clinical records maintained by the HHA. The HHA must advise the patient of the agency’s policies and procedures regarding disclosure of clinical records.

(e) Standard: Patient liability for payment. (1) The patient has the right to be advised, before care is initiated, of the extent to which payment for the HHA services may be expected from Medicare or other sources, and the extent to which payment may be required from the patient. Before the care is initiated, the HHA must inform the patient, orally and in writing, of:
(i) The extent to which payment may be expected from Medicare, Medicaid, or any other Federally funded or aided program known to the HHA;

(ii) The charges for services that will not be covered by Medicare; and

(iii) The charges that the individual may have to pay.

(2) The patient has the right to be advised orally and in writing of any changes in the information provided in accordance with paragraph (e)(1) of this section when they occur. The HHA must advise the patient of these changes orally and in writing as soon as possible, but no later than 30 calendar days from the date that the HHA becomes aware of a change.

(f) Standard: Home health hotline. The patient has the right to be advised of the availability of the toll-free HHA hotline in the State. When the agency accepts the patient for treatment or care, the HHA must advise the patient 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 HHAs. The patient also has the right to use this hotline to lodge complaints concerning the implementation of the advance directive requirements.

§484.11 Condition of participation: Release of patient-identifiable OASIS information.

The HHA and agency acting on behalf of the HHA in accordance with a written contract must ensure the confidentiality of all patient-identifiable information contained in the clinical record, including OASIS data, and may not release patient-identifiable OASIS information to the public.

§484.12 Condition of participation: Compliance with Federal, State, and local laws, disclosure and ownership information, and accepted professional standards and principles.

(a) Standard: Compliance with Federal, State, and local laws and regulations. The HHA and its staff must operate and furnish services in compliance with all applicable Federal, State, and local laws and regulations. If State or applicable local law provides for the licensure of HHAs, an agency not subject to licensure is approved by the licensing authority as meeting the standards established for licensure.

(b) Standard: Disclosure of ownership and management information. The HHA must comply with the requirements of Part 420, Subpart C of this chapter. The HHA also must disclose the following information to the State survey agency at the time of the HHA’s initial request for certification, for each survey, and at the time of any change in ownership or management:

(1) The name and address of all persons with an ownership or control interest in the HHA as defined in §§420.201, 420.202, and 420.206 of this chapter.

(2) The name and address of each person who is an officer, a director, an agent or a managing employee of the HHA as defined in §§420.201, 420.202, and 420.206 of this chapter.

(3) The name and address of the corporation, association, or other company that is responsible for the management of the HHA, 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 HHA.

(c) Standard: Compliance with accepted professional standards and principles. The HHA and its staff must comply with accepted professional standards and principles that apply to professionals furnishing services in an HHA.

§484.14 Condition of participation: Organization, services, and administration.

Organization, services furnished, administrative control, and lines of authority for the delegation of responsibility down to the patient care level are 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 are maintained for each subunit.

(a) Standard: Services furnished. Part-time or intermittent skilled nursing services and at least one 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 place of residence used as a patient’s home. An HHA must provide at least one of the qualifying services directly through agency employees, but may provide the second qualifying service and additional services under arrangements with another agency or organization.

(b) Standard: Governing body. A governing body (or designated persons so functioning) assumes full legal authority and responsibility for the operation of the agency. The governing body appoints a qualified administrator, arranges for professional advice as required under §484.16, adopts and periodically reviews written bylaws or an acceptable equivalent, and oversees the management and fiscal affairs of the agency.

(c) Standard: Administrator. The administrator, who may also be the supervising physician or registered nurse required under paragraph (d) of this section, organizes and directs the agency’s ongoing functions; maintains ongoing liaison among the governing body, the group of professional personnel, and the staff; employs qualified personnel and ensures adequate staff education and evaluations; ensures the accuracy of public information materials and activities; and implements an effective budgeting and accounting system. A qualified person is authorized in writing to act in the absence of the administrator.

(d) Standard: Supervising physician or registered nurse. The skilled nursing and other therapeutic services furnished are 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, is available at all times during operating hours and participates in all activities relevant to the professional services furnished, including the development of qualifications and the assignment of personnel.

(e) Standard: Personnel policies. Personnel practices and patient care are supported by appropriate, written, personnel policies. Personnel records include qualifications and licensure that are kept current.

(f) Standard: Personnel under hourly or per visit contracts. If personnel under hourly or per visit contracts are used by the HHA, there is a written contract between those personnel and the agency that specifies the following:

1. Patients are accepted for care only by the primary HHA.
2. The services to be furnished.
3. The necessity to conform to all applicable agency policies including personnel qualifications.
4. The responsibility for participating in developing plans of care.
5. The manner in which services will be controlled, coordinated, and evaluated by the primary HHA.
6. The procedures for submitting clinical and progress notes, scheduling of visits, periodic patient evaluation.
7. The procedures for payment for services furnished under the contract.

(g) Standard: Coordination of patient 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 patient care does occur. A written summary report for each patient is sent to the attending physician at least every 60 days.

(h) Standard: Services under arrangements. Services furnished under arrangements are subject to a written contract conforming with the requirements specified in paragraph (f) of this section and with the requirements of section 1861(w) of the Act (42 U.S.C.1495x(w)).

(i) Standard: Institutional planning. The HHA, under the direction of the governing body, prepares an overall plan and a budget that includes an annual operating budget and capital expenditure plan.

1. Annual operating budget. There is an annual operating budget that includes all anticipated income and expenses related to items that would, under generally accepted accounting principles, be considered income and expense items. However, it is not required that there be prepared, in connection with any budget, an item by item identification of the
components of each type of anticipated income or
expense.

(2) Capital expenditure plan.  (i) There is a capital
expenditure plan for at least a 3-year period, including
the operating budget year. The plan includes and
identifies in detail the anticipated sources of financing
for, and the objectives of, each anticipated expenditure
of more than $600,000 for items that would under
generally accepted accounting principles, be
considered capital items. In determining if a single
capital expenditure exceeds $600,000, the cost of
studies, surveys, designs, plans, working drawings,
specifications, and other activities essential to the
acquisition, improvement, modernization, expansion,
or replacement of land, plant, building, and
equipment are included.

Expenditures directly or indirectly related to
capital expenditures, such as grading, paving, broker
commissions, taxes assessed during the construction
period, and costs involved in demolishing or razing
structures on land are also included. Transactions that
are separated in time, but are components of an
overall plan or patient care objective, are viewed in
their entirety without regard to their timing. Other
costs related to capital expenditures include title fees,
permit and license fees, broker commissions, architect,
legal, accounting, and appraisal fees; interest, finance,
or carrying charges on bonds, notes and other costs
incurred for borrowing funds.

(ii) If the anticipated source of financing is, in any
part, the anticipated payment from title V (Maternal
and Child Health and Crippled Children's Services) or
title XVIII (Medicare) or title XIX (Medicaid) of the
Social Security Act, the plan specifies the following:

(A) Whether the proposed capital expenditure is
required to conform or is likely to be required to
conform to current standards, criteria, or plans
developed in accordance with the Public Health
Service Act or the Mental Retardation Facilities and
Community Mental Health Centers Construction Act
of 1963.

(B) Whether a capital expenditure proposal
has been submitted to the designated planning
agency for approval in accordance with section
1122 of the Act (42 U.S.C. 1320a-1) and imple-
menting regulations.

(C) Whether the designated planning agency has
approved or disapproved the proposed
capital expenditure if it was presented to
that agency.

(3) Preparation of plan and budget. The overall
plan and budget is prepared under the direction of
the governing body of the HHA by a committee
consisting of representatives of the governing body,
the administrative staff and the medical staff (if any)
of the HHA.

(4) Annual review of plan and budget. The
overall plan and budget is reviewed and updated at
least annually by the committee re-referred to in
paragraph (ii)(3) of this section under the direction of
the governing body of the HHA.

(j) Standard: Laboratory services.  (1) If the
HHA engages in laboratory testing outside of
the context of assisting an individual in self-
administering a test with an appliance that has been
cleared for that purpose by the FDA, such testing
must be in compliance with all applicable
requirements of Part 493 of this chapter.

(2) If the HHA chooses to refer specimens for
laboratory testing to another laboratory, the referral
laboratory must be certified in the appropriate
specialties and subspecialties of services in accordance
with the applicable requirements of
Part 493 of this chapter.

§484.16 Condition of participation: Group of
professional personnel.

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, establishes and annually reviews the
agency’s policies governing scope of services offered,
admission and discharge policies, medical supervision
and plans of care, emergency care, clinical records,
personnel qualifications, and program evaluation. At
least one member of the group is neither an owner
nor an employee of
the agency.

(a) Standard: Advisory and evaluation
function. The group of professional personnel
meets 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 are documented
dated minutes.
§484.18 Condition of participation:
Acceptance of patients, plan of care, and medical supervision.

Patients are 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. Care follows a written plan of care established and periodically reviewed by a doctor of medicine, osteopathy, or podiatric medicine.

(a) Standard: Plan of care. The plan of care 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. If a physician refers a patient under a plan of care that cannot be completed until after an evaluation visit, the physician is consulted to approve additions or modifications to the original plan. Orders for therapy services include the specific procedures and modalities to be used and the amount, frequency, and duration. The therapist and other agency personnel participate in developing the plan of care.

(b) Standard: Periodic review of plan of care. The total plan of care is reviewed by the attending physician and HHA personnel as often as the severity of the patient'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 HHA 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.

(c) Standard: Conformance with physician's orders. Drugs and treatments are 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 are put into writing and signed and dated with the date of receipt by the registered nurse or qualified therapist (as defined in §484.4 of this chapter) 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 HHA's internal policies.

§484.20 Condition of participation:
Reporting OASIS information.

HHAs must electronically report all OASIS data collected in accordance with §484.55.

(a) Standard: Encoding and transmitting OASIS data. An HHA must encode and electronically transmit each completed OASIS assessment to the State agency or the CMS OASIS contractor, regarding each beneficiary with respect to which such information is required to be transmitted (as determined by the Secretary), within 30 days of completing the assessment of the beneficiary.

(b) Standard: Accuracy of encoded OASIS data. The encoded OASIS data must accurately reflect the patient's status at the time of the assessment.

(c) Standard: Transmittal of OASIS data. The HHA must:

(1) For all completed assessments, transmit OASIS data in a format that meets the requirements of paragraph (d) of this section.

(2) Successfully transmit test data to the State agency or CMS OASIS contractor.

(3) Transmit data using electronics communications software that provides a direct telephone connection from the HHA to the State agency or CMS OASIS contractor.

(4) Transmit data that includes the CMS-assigned branch identification number, as applicable.

(d) Standard: Data format. The HHA must encode and transmit data using the software available from CMS or software that conforms to CMS standard electronic record layout, edit
Subpart C — Furnishing of Services

§484.30 Condition of participation: Skilled nursing services.

The HHA furnishes skilled nursing services by or under the supervision of a registered nurse and in accordance with the plan of care.

(a) Standard: Duties of the registered nurse. The registered nurse makes the initial evaluation visit, regularly reevaluates the patient's nursing needs, initiates the plan of care and necessary revisions, furnishes those services requiring substantial and specialized nursing skill, initiates appropriate preventive and rehabilitative nursing procedures, prepares clinical and progress notes, coordinates services, informs the physician and other personnel of changes in the patient's condition and needs, counsels the patient and family in meeting nursing and related needs, participates in in-service programs, and supervises and teaches other nursing personnel.

(b) Standard: Duties of the licensed practical nurse. The licensed practical nurse furnishes services in accordance with agency policies, prepares clinical and progress notes, assists the physician and registered nurse in performing specialized procedures, prepares equipment and materials for treatments observing aseptic technique as required, and assists the patient in learning appropriate self-care techniques.

§484.32 Condition of participation: Therapy services.

Any therapy services offered by the HHA directly or under arrangement are given by a qualified therapist or by a qualified therapy assistant under the supervision of a qualified therapist and in accordance with the plan of care. The qualified therapist assists the physician in evaluating level of function, helps develop the plan of care (revising it as necessary), prepares clinical and progress notes, advises and consults with the family and other agency personnel, and participates in in-service programs.

(a) Standard: Supervision of physical therapy assistant and occupational therapy assistant. Services furnished by a qualified physical therapy assistant or qualified occupational therapy assistant may be furnished under the supervision of a qualified physical or occupational therapist. A physical therapy assistant or occupational therapy assistant performs services planned, delegated, and supervised by the therapist, assists in preparing clinical notes and progress reports, and participates in educating the patient and family, and in in-service programs.

(b) Standard: Supervision of speech therapy services. Speech therapy services are furnished only by or under supervision of a qualified speech pathologist or audiologist.

§484.34 Condition of participation: Medical social services.

If the agency furnishes medical social services, those services are 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. The social worker assists the physician and other team members in understanding the significant social and emotional factors related to the health problems, participates in the development of the plan of care, prepares clinical and progress notes, works with the family, uses appropriate community resources, participates in discharge planning and in-service programs, and acts as a consultant to other agency personnel.

§484.36 Condition of participation: Home health aide services.

Home health aides are selected 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 are closely supervised to ensure their competence in providing care. For home health services furnished
(either directly or through arrangements with other organizations) after August 14, 1990, the HHA must use individuals who meet the personnel qualifications specified in §484.4 for “home health aide.”

(a) Standard: Home health aide training.
   (1) Content and duration of training. The aide training program must address each of the following subject areas through classroom and supervised practical training totaling at least 75 hours, with at least 16 hours devoted to supervised practical training. The individual being trained must complete at least 16 hours of classroom training before beginning the supervised practical training.
      (i) Communications skills.
      (ii) Observation, reporting and documentation of patient status and the care or service furnished.
      (iii) Reading and recording temperature, pulse, and respiration.
      (iv) Basic infection control procedures.
      (v) Basic elements of body functioning and changes in body function that must be reported to an aide’s supervisor.
      (vi) Maintenance of a clean, safe, and healthy environment.
      (vii) Recognizing emergencies and knowledge of emergency procedures.
      (viii) The physical, emotional, and developmental needs of and ways to work with the populations served by the HHA, including the need for respect for the patient, his or her privacy and his or her property.
      (ix) Appropriate and safe techniques in personal hygiene and grooming that include:
         (A) Bed bath.
         (B) Sponge, tub, or shower bath.
         (C) Shampoo (sink, tub, or bed).
         (D) Nail and skin care.
         (E) Oral hygiene.
         (F) Toileting and elimination.
         (x) Safe transfer techniques and ambulation.
         (xi) Normal range of motion and positioning.
         (xii) Adequate nutrition and fluid intake.
         (xiii) Any other task that the HHA may choose to have the home health aide perform.
   “Supervised practical training” means training in a laboratory or other setting in which the trainee demonstrates knowledge while performing tasks on an individual under the direct supervision of a registered nurse or licensed practical nurse.

   (2) Conduct of training.
      (i) Organizations. A home health aide training program may be offered by any organization except an HHA that, within the previous 2 years, has been found:
         (A) Out of compliance with requirements of this paragraph (a) or paragraph (b) of this section;
         (B) To permit an individual that does not meet the definition of “home health aide” as specified in §484.4 to furnish home health aide services (with the exception of licensed health professionals and volunteers);
         (C) Has been subject to an extended (or partial extended) survey as a result of having been found to have furnished substandard care (or for other reasons at the discretion of the CMS or the State);
         (D) Has been assessed a civil monetary penalty of not less than $5,000 as an intermediate sanction;
         (E) Has been found to have compliance deficiencies that endanger the health and safety of the HHA’s patients and has had a temporary management appointed to oversee the management of the HHA;
         (F) Has had all or part of its Medicare payments suspended; or
         (G) Under any Federal or State laws within the 2-year period beginning on October 1, 1988;
      (1) Has had its participation in the Medicare program terminated;
      (2) Has been assessed a penalty of not less than $5,000 for deficiencies in Federal or State standards for deficiencies in Federal or State standards for HHAs;
      (3) Was subject to a suspension of Medicare payments to which it otherwise would have been entitled;
      (4) Had operated under a temporary management that was appointed to oversee the operation of the HHA and to ensure the health and safety of the HHA’s patients; or
      (5) Was closed or had its residents transferred by the State.
      (ii) Qualifications for instructors. The training of home health aides and the supervision of home health aides during the supervised practical portion of the training must be performed by or under the general supervision of a registered nurse who possesses a minimum of 2 years of nursing experience, at least 1 year of which must be in the provision of home health care. Other individuals
may be used to provide instruction under the supervision of a qualified registered nurse.

(3) Documentation of training. The HHA must maintain sufficient documentation to demonstrate that the requirements of this standard are met.

(b) Standard: Competency evaluation and in-service training. (1) Applicability. An individual may furnish home health aide services on behalf of an HHA only after that individual has successfully completed a competency evaluation program as described in this paragraph. The HHA is responsible for ensuring that the individuals who furnish home health aide services on its behalf meet the competency evaluation requirements of this section.

(2) Content and frequency of evaluation and amount of in-service training.

(i) The competency evaluation must address each of the subjects listed in paragraph (a)(1)(ii) through (xiii) of this section.

(ii) The HHA must complete a performance review of each home health aide no less frequently than every 12 months.

(iii) The home health aide must receive at least 12 hours of in-service during each 12 month period. The in-service training may be furnished while the aide is furnishing care to patients.

(3) Conduct of evaluation and training.

(i) Evaluators and instructors. The competency evaluation must be performed by a registered nurse. The in-service training generally must be supervised by a registered nurse who possesses a minimum of 2 years of nursing experience, at least 1 year of which must be in the provision of home health care.

(ii) Subject areas. The subject areas listed at paragraphs (a)(1)(iii), (ix), (x), and (xi) of this section must be evaluated after observation of the aide’s performance of the tasks with a patient. The other subject areas in paragraph (a)(1) of this section may be evaluated through written examination, oral examination, or after observation of a home health aide with a patient.

(4) Competency determination.

(i) A home health aide is not considered competent in any task for which he or she is evaluated as “unsatisfactory.” The aide must not perform that task without direct supervision by a licensed nurse until after he or she receives training in the task for which he or she was evaluated as “unsatisfactory” and passes a subsequent evaluation with “satisfactory.”

(ii) A home health aide is not considered to have successfully passed a competency evaluation if the aide has an “unsatisfactory” rating in more than one of the required areas.

(5) Documentation of competency evaluation. The HHA must maintain documentation which demonstrates that the requirements of this standard are met.

(6) Effective date. The HHA must implement a competency evaluation program that meets the requirements of this paragraph before February 14, 1990. The HHA must provide the preparation necessary for the individual to successfully complete the competency evaluation program. After August 14, 1990, the HHA may use only those aides that have been found to be competent in accordance with §484.36(b).

(c) Standard: Assignment and duties of the home health aide.

(1) Assignment. The home health aide is assigned to a specific patient by the registered nurse. Written patient care instructions for the home health aide must be prepared by the registered nurse or other appropriate professional who is responsible for the supervision of the home health aide under paragraph (d) of this section.

(2) Duties. The home health aide provides services that are ordered by the physician in the plan of care and that the aide is permitted to perform under State law. The duties of a home health aide include the provision of hands-on personal care, performance of simple procedures as an extension of therapy or nursing services, assistance in ambulation or exercises, and assistance in administering medications that are ordinarily self-administered. Any home health aide services offered by an HHA must be provided by a qualified home health aide.

(d) Standard: Supervision.

(1) If the patient receives skilled nursing care, the registered nurse must perform the supervisory
visits required by paragraph (d)(2) of this section. If
the patient is not receiving skilled nursing care,
but is receiving another skilled service (that is,
physical therapy, occupational therapy, or speech-
language pathology services), supervision may be
provided by the appropriate therapist.

(2) The registered nurse (or another professional
described in paragraph (d)(1) of this section) must
make an on-site visit to the patient’s home no less
frequently than every 2 weeks.

(3) If home health aide services are provided
to a patient who is not receiving skilled nursing
care, physical or occupational therapy or speech-
language pathology services, the registered nurse
must make a supervisory visit to the patient’s
home no less frequently than every 60 days. In
these cases, to ensure that the aide is properly caring
for the patient, each supervisory visit must occur
while the home health aide is providing patient
care.

(4) If home health aide services are provided by
an individual who is not employed directly by the
HHA (or hospice), the services of the home health
aide must be provided under arrangements, as
defined in Section 1861(w)(1) of the Act. If the HHA
(or hospice) chooses to provide home health aide
services under arrangements with another
organization, the HHA’s (or hospice’s) responsibilities
include, but are not limited to:

(i) Ensuring the overall quality of the care
provided by the aide;

(ii) Supervision of the aide’s services as described
in paragraphs (d)(1) and (d)(2) of this section; and

(iii) Ensuring that home health aides are
providing services under arrangements have met the
training requirements of paragraphs (a) and (b) of this
section.

(e) Standard: Personal care attendant:
evaluation requirements.

(1) Applicability. This paragraph applies to
individuals who are employed by HHAs
exclusively to furnish personal care attendant services
under a Medicaid personal care benefit.

(2) Rule. An individual may furnish personal care
services, as defined in §440.170 of this chapter, on
behalf of an HHA after the individual has been found
competent by the State to furnish those services for
which a competency evaluation is required by
paragraph (b) of this section and which the individual
is required to perform. The individual need not be
determined competent in those services listed in
paragraph (a) of this section that the individual is not
required to furnish.

§484.38 Condition of participation:
Qualifying to furnish outpatient physical
therapy or speech pathology services.

An HHA that wishes to furnish outpatient
physical therapy or speech pathology services must
meet all the pertinent conditions of this part and also
meet the additional health and safety requirements
set forth in §§485.711, 485.713, 485.715, 485.719,
485.723, and 485.727 of this chapter to implement
section 1861(p) of the Act.

§484.48 Condition of participation:
Clinical records.

A clinical record containing pertinent past and
current findings in accordance with accepted
professional standards is maintained for every patient
receiving home health services. In addition to the
plan of care, the record contains appropriate
identifying information; name of physician; drug,
dietary, treatment, and activity orders; signed and
dated clinical and progress notes; copies of
summary reports sent to the attending physician;
and a discharge summary. The HHA must inform
the attending physician of the availability of a
discharge summary. The discharge summary must be
sent to the attending physician upon request and
must include the patient’s medical and health status
at discharge.

(a) Standard: Retention of records. Clinical
records are retained for 5 years after the month the
cost report to which the records apply is filed with the
intermediary, unless State law stipulates a longer
period of time. Policies provide for retention even if
the HHA discontinues operations. If a patient is
transferred to another health facility, a copy of the
record or abstract is sent with the patient.

(b) Standard: Protection of records. Clinical
record information is safeguarded against loss or
unauthorized use. Written procedures govern use
and removal of records and the conditions for release
of information. Patient’s written consent
is required for release of information not authorized
by law.
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