



ACHC STANDARDS

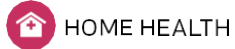
PROGRAM

Home Health

SERVICES

Home Health Aide Services, Medical Social Services, Occupational Therapy Services, Physical Therapy Services, Skilled Nursing Services, Speech Therapy Services

ACHC ACCREDITATION STANDARDS



The following packet contains the 2022 ACHC Home Health Accreditation Standards.

Release Date: February 1, 2022

Accreditation Commission for Health Care (ACHC) has updated Home Health Accreditation Standards to incorporate regulatory changes by the Centers for Medicare & Medicaid Services (CMS), including CMS COVID-19 vaccination requirements for certain staff at organizations that participate in Medicare and Medicaid programs.

New or revised ACHC Home Health Accreditation Standards are HH4-2K, HH4-14A, HH5-2B, HH5-2C, and HH5-6A. Effective dates vary, in accordance with CMS guidance. Please visit Customer Central for more information.

ACHC is committed to providing healthcare organizations with comprehensive standards that facilitate the highest level of performance. To ensure each standard is clear, concise, and relevant, ACHC conducts annual reviews by compiling feedback from providers, industry consultants, and regulatory bodies.

Based on the annual review, ACHC has made the following changes:

- No standards were updated during ACHC's annual review.

The following accreditation distinctions are offered to providers accredited for ACHC Home Health services:

- Behavioral Health
- Palliative Care
- Telehealth

The accreditation packet contains:

- Preliminary Evidence Report Checklist (if applying for ACHC Accreditation for the first time)
- ACHC Home Health Accreditation Standards
- Items Needed for Survey form
- Glossary of Terms
- Glossary of Personnel Qualification

PRELIMINARY EVIDENCE REPORT CHECKLIST



FOR PROVIDERS.
BY PROVIDERS.



HOME HEALTH

This checklist constitutes the requirements of the Preliminary Evidence Report (PER), which is mandatory for organizations applying for initial Home Health accreditation.

Review and acknowledge that all of the following requirements have been met and submit this signed checklist with the required items listed below.

Verification of the following is required for organizations seeking an initial Medicare Provider Number:

- The organization has completed the CMS-855 application and received written confirmation the application has been “processed” and “the application is being forwarded with a recommendation to the state and CMS Regional Office.”
 - **Submit a copy of the letter from CMS or the Medicare Administrative Contractor (MAC). This is applicable for companies seeking an initial Medicare Provider Number.**
 - **Please follow up with your MAC if the approval letter is greater than 6 months. It is the responsibility of the agency to make sure your 855a is still active. It is the responsibility of the agency to report any changes that would affect the status of your 855a to your MAC and/or CMS.**
- The organization can demonstrate they are able to provide all services needed by patients being served and is able to demonstrate operational capacity of all facets of the organization
- The organization must be providing nursing and at least one other therapeutic service (Physical Therapy [PT], Speech Language Pathology [SLP], Occupational Therapy [OT], Medical Social Services [MSS], or Home Health Aide [HHA])
 - At least one of these services must be offered solely by W-2/W-4 employees
- The organization must have provided care to a minimum of 10 patients requiring skilled care (not required to be Medicare patients)
 - At least 7 of the required 10 patients should be receiving skilled care from the Home Health Agency (HHA) at the time of the initial Medicare survey
 - If the HHA is located in a medically underserved area, as determined by the CMS Regional Office (RO), please contact ACHC for further guidance
- The organization has a full and current license, NOT PROVISIONAL, in the state it is currently doing business, if applicable.
 - **Please note: not all states require a license therefore this only pertains to organizations that reside in states that require a license**

Confirmation of the following (initial in spaces provided):

_____ I attest that this organization possesses all policies and procedures as required by the ACHC Accreditation Standards

_____ I acknowledge that this organization was/is/will be in compliance with ACHC Accreditation Standards as of _____ date.

Your organization will be placed into scheduling once this document, the Agreement for Accreditation Services and Business Associate Agreement are submitted to your Account Advisor and payments are up-to-date. ACHC will strive to conduct your survey as soon as possible.

ACCREDITATION COMMISSION *for* HEALTH CARE

**PLEASE NOTE: YOUR ORGANIZATION MUST ALWAYS BE IN COMPLIANCE WITH MEDICARE REGULATIONS, CONDITIONS OF PARTICIPATION, AND APPROPRIATE STATE REGULATIONS.

I, having the authority to represent this organization, verify that _____ (organization's legal name) has met the above requirements for survey. If this organization fails to meet any of the aforementioned requirements when the ACHC Surveyor arrives for your survey, the survey performed by ACHC will not be accepted as a legitimate Initial Medicare Certification Survey by CMS. This will result in additional charges to the organization for a subsequent survey to be performed when the organization has notified ACHC it has met all of the above requirements.

(Name)

(Title)

(Date)

(Signature)

ACHC ACCREDITATION STANDARDS

Customized for Home Health Aide Services, Medical Social Services, Occupational Therapy Services, Physical Therapy Services, Skilled Nursing Services, Speech Therapy Services

Section 1: ORGANIZATION AND ADMINISTRATION

The standards in this section apply to the leadership and organizational structure of the organization. All items referring to business licensure, including federal, state, and local licenses that affect the day-to-day operations of the organization, should be addressed. This section includes information on the organization's leadership structure, including board of directors, advisory committees, management, and employees. Also included is information about leadership responsibilities, conflicts of interest, chain of command, program goals, and regulatory compliance.

Standard HH1-1A: The Home Health Agency (HHA) is in compliance with federal, state and local laws. 484.100 (G848), 484.100(b) (G860).

The Home Health Agency (HHA) and its personnel must operate and furnish services in compliance with all applicable federal, state, and local laws and regulations related to the health and safety of patients. If state or local law provides for licensing of HHAs, the HHA must be licensed.

The HHA, its branches, and all persons furnishing services to patients must be licensed, certified, or registered, as applicable, in accordance with the state licensing authority as meeting those requirements.

The HHA has a physical location and all required license(s) and/or permit(s) are current and posted in a prominent location accessible to public view in all locations/branches and/or in accordance with appropriate regulations or law.

The HHA is an established entity with legal authority to operate and has the appropriate Articles of Incorporation or other documentation of legal authority. Legal authority is granted to one individual, members of a limited liability corporation, a board of directors, or a board of health (usually referred to as the governing body), and as allowed in state statutes for the appropriate type and structure of the organization. The entity, individual or HHA has a copy of the appropriate documentation or authorization(s) to conduct business.

Evidence: Copy of all current applicable licenses/permits for each location and copy of Articles of Incorporation/Bylaws and all applicable amendments

Evidence: Observation

Evidence: Personnel Files

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.100 and 484.100(b). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: OT, PT, SN, ST, HHA, MSS

Standard HH1-1A.01: The HHA is in compliance with all applicable federal, state, and local laws and regulations.

This standard requires compliance with all laws and regulations including but not limited to:

- Local and state licensure
- The Americans with Disabilities Act
- Equal Employment Opportunities Act
- Fair Labor Standards Act
- Title VI of the Civil Rights Act of 1964
- Occupational Safety and Health Administration (OSHA)
- Medicare regulations
- Medicaid regulations
- Health Insurance Portability and Accountability Act (HIPAA)
- US Food and Drug Administration (FDA), if applicable
- Drug Enforcement Administration (DEA), if applicable
- Home Health Agency's policies and procedures
- ACHC Accreditation Process
- Section 1557 of the Patient Protection and Affordable Care Act
- Other laws and regulations as applicable to the care/service provided by the HHA

Copies of all required federal and state posters are placed in a prominent location for easy viewing by personnel.

Evidence: Written Policies and Procedures

Evidence: Copies of Required Posters in a prominent location
Evidence: Observation
Evidence: Patient Records
Evidence: Personnel Files

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH1-1B: Written policies and procedures are established and implemented by the HHA in regard to the disclosure of ownership and management information as required in 42 CFR Part 420, Subpart C and action required for a request of information. 484.100(a) (G850) (G852), 484.100(a)(1) (G854), 484.100(a)(2) (G856), 484.100(a)(3) (G858).

Written policies and procedures are established and implemented by the HHA regarding the action required and time frames for a change in ownership, governing body, or management.

The HHA 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 42CFR 420.201, 420.202 and 420.206
 - Disclosure of persons having controlling interest or ownership of greater than 5%.
 - Disclosure of persons with controlling interest, or managing employees convicted of criminal offenses against Medicare, Medicaid, or the title V (Maternal and Child Health Services) and title XX (Social Services) programs.
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 42CFR 420.201, 420.202, and 420.206
3. The name and business 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.

A disclosing entity must furnish updated information to CMS, state agencies, and ACHC at intervals between recertification, re-enrollment, or contract renewals, within 30 days of a written request or change in authority, ownership, or management.

Evidence: Written Policies and Procedures
Evidence: Organizational Chart/Current CMS 855A
Evidence: Response to Interviews
Evidence: Observation

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.100(a), 484.100(a)(1), 484.100(a)(2) and 484.100(a)(3). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH1-1C: The HHA is in compliance with accepted professional standards and principles. 484.105(f)(2) (G984).

All HHA services must be provided in accordance with current clinical practice guidelines and accepted professional standards of practice which include, but are not limited to:

- HHA federal regulation
- State Practice Act
- Commonly accepted health standards established by national organizations, boards, and councils (e.g., the American Nurses Association standards)

Evidence: Observation
Evidence: Written Policies and Procedures

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.105(f)(2). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH1-2A: The HHA is directed by a governing body/owner (if no governing body is present, owner suffices), which assumes full legal authority and responsibility for the operation of the HHA. The governing body/owner duties and accountabilities are clearly defined. 484.105(a) (G942).

A governing body/owner (or designated persons so functioning) must assume full legal authority and responsibility for the agency's overall management and operation, the provision of all home health services, its fiscal operations, review of the agency's budget and its operational plans, and its Quality Assessment and Performance Improvement program. Activities of the governing body/owner include, but are not limited to:

- Decision making
- Appointing a qualified Administrator
- Adopting and periodically reviewing written bylaws or equivalent
- Establishing or approving written policies and procedures governing operations
- Human resource management
- Quality Assessment and Performance Improvement (QAPI)
- Community-needs planning, if applicable
- Oversight of the management, operation plans and fiscal affairs of the HHA
- Annual review of the policies and procedures

Although many governing bodies/owners delegate authority for some of these functions to individual personnel members or to an advisory committee, the ultimate responsibility continues to rest with the governing body/owner. In situations where the board of directors serves as the governing body for a large, multi-service organization, board activities will address the overall HHA; however, oversight of the HHA's program is evidenced in some manner such as in reports to the board or documented in minutes of board meetings.

Evidence: Written Policies and Procedures

Evidence: Governing Body Meeting Minutes, if applicable

Evidence: Response to Interviews

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.105(a). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH1-2A.03: Governing body members receive an orientation to their responsibilities and accountabilities.

There is evidence that the governing body members received an orientation to their responsibilities and accountabilities as defined by the HHA. Governing body members are provided the opportunity to evaluate the orientation process.

Orientation includes, but is not limited to:

- Organizational structure
- Confidentiality practices and signing of a confidentiality agreement
- Review of the HHA's values, mission, and/or goals
- Overview of programs, operational plans, services and initiatives
- Personnel and patient grievance policies and procedures
- Responsibility for the Quality Assessment and Performance Improvement Program (QAPI)
- Organizational ethics
- Conflict of interest

The HHA has a list of governing body members that includes name, address and telephone number. This criterion would not apply to a single owner who serves as the governing body.

Evidence: Orientation Records

Evidence: List of Governing Body Members, if applicable

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH1-4A.01: Written policies and procedures are established and implemented by the HHA in regard to conflicts of interest and the procedure for disclosure.

The HHA's policies and procedures define conflicts of interest and the procedure for disclosure and conduct in relationships with personnel, customers, and patients. The policies and procedures include the required conduct of any affiliate or representative of the following:

- Governing body/owner
- Personnel having an outside interest in an entity providing services to the HHA
- Personnel having an outside interest in an entity providing services to patient

In the event of proceedings that require input, voting, or decisions, the individual(s) with a conflict of interest are excluded from the

activity.

Governing board members and personnel demonstrate understanding of conflict of interest policies and procedures.

Evidence: Written Policies and Procedures

Evidence: Response to Interviews

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH1-5A: There is an individual who is designated as responsible for the overall operation and services of the HHA. The Administrator organizes and directs the HHA's ongoing functions and maintains ongoing liaison among the governing body/owner and the personnel. 484.105(b) (G944), 484.105(b)(1) (G944), 484.105(b)(1)(i) (G946), 484.105(b)(1)(ii) (G948), 484.105(b)(1)(iii) (G950), 484.105(b)(1)(iv) (G952), 484.105(b)(2) (G954), 484.105(b)(3) (G956).

The Administrator is responsible for all programs and services and is appointed and accountable to the governing body/owner. There is a job description that specifies the responsibilities and authority of this individual. The Administrator:

- Is responsible for all day-to-day operations of the HHA
- Ensures that a clinical manager as described in 42 CFR 484.105(c) is available during all operating hours
- Ensures that the HHA employs qualified personnel, including assuring the development of personnel qualifications and policies
- When the Administrator is not available, a qualified, pre-designated person, who is authorized in writing by the Administrator and the governing body, assumes the same responsibilities and obligations as the Administrator. The pre-designated person may be the clinical manager as described in 42 CFR 484.105(c)
- The Administrator or a pre-designated person is available during all operating hours

The Administrator meets the qualifications outlined in the ACHC Glossary of Personnel Qualifications as defined by the Medicare Conditions of Participation.

The resume/application of the current Administrator verifies that the individual who holds this position possesses the appropriate education and experience requirements as defined by the governing board/owner and any applicable state and federal laws and regulations.

Evidence: Job Description

Evidence: Administrator Resume or Application

Evidence: Observation

Evidence: Personnel Files

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.105(b), 484.105(b)(1)(i), 484.105(b)(1)(ii), 484.105(b)(1)(iii), 484.105(b)(1)(iv), 484.105(b)(2) and 484.105(b)(3). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH1-5A.01: The governing body, or its designee, writes and conducts annual evaluations of the Administrator.

The HHA conducts annual reviews of the Administrator's performance. The governing body/owner may delegate the evaluation function to a specific person or entity such as an advisory or personnel committee. The evaluation is reviewed with the Administrator and documented.

This criterion does not apply to sole proprietorships or to limited liability corporations (LLC), where the president and Administrator is also the owner and governing body.

This criterion is not applicable if the HHA has been in operation less than one year at the time of accreditation survey.

Evidence: Written and Dated Evaluation of the Administrator or other documentation

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH1-6A: Responsibility and accountability for programs are defined. The organizational chart shows the relationship of all positions within the HHA with identifiable lines of authority. 484.105 (G940).

The HHA must organize, manage, and administer its resources to attain and maintain the highest practicable functional capacity, including providing optimal care to achieve the goals and outcomes identified in the patient's plan of care, for each patient's medical,

nursing, and rehabilitative needs. The HHA must assure that administrative and supervisory functions are not delegated to another agency or organization, and all services not furnished directly are monitored and controlled.

The services furnished by the HHA, administrative control, and lines of authority for the delegation of responsibility down to the patient care level are clearly defined in writing.

The governing body/owner and all positions are identified on the organizational chart. The organizational chart shows the position responsible for each program or service the HHA provides.

Evidence: Organizational Chart
Evidence: Response to Interviews

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.105. See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH1-6B: There is one or more individual who is qualified to act as clinical manager. A clinical manager is a licensed physician, physical therapist, speech-language pathologist, occupational therapist, audiologist, social worker, or a Registered Nurse. A clinical manager must provide oversight of all patient care services and personnel. This person, or a similarly qualified alternate, is available at all times during business hours and participates in all activities relevant to the professional services furnished. Administrative and supervisory functions are not delegated to another agency or organization. 484.105(c) (G958), 484.105(c)(1) (G960), 484.105(c)(2) (G962), 484.105(c)(3) (G964), 484.105(c)(4) (G966), 484.105(c)(5) (G968).

All skilled nursing and other therapeutic services are furnished under the supervision and direction of a qualified clinical manager with sufficient education and experience in the scope of services offered. A minimum of 2 years of home care experience and at least one year of supervisory experience is required.

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.

The policies and procedures specify the responsibilities and authority of this individual(s).

The clinical managers are responsible for the direction, coordination, and supervision of services. The clinical manager's oversight must include the following:

- Making patient and personnel assignments
- Coordinating patient care
- Coordinating referrals
- Assuring that patient needs are continually assessed,
- Assuring the development, implementation, and updates of the individualized plan of care

Evidence: Written Policies and Procedures
Evidence: Observation
Evidence: Resume/Application of Qualified Professional

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.105(c), 484.105(c)(1), 484.105(c)(2), 484.105(c)(3), 484.105(c)(4) and 484.105(c)(5). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH1-6C: Written policies and procedures are established and implemented that define the responsibilities of the parent agency in relation to coordination of care provided through branches. All services not furnished directly are monitored and controlled by the parent agency. 484.105(d) (G970), 484.105(d)(1) (G972), 484.105(d)(2) (G974).

The policies and procedures define that the parent HHA is responsible for reporting all branch locations of the HHA to the state survey agency at the time of the HHA's request for initial certification, at each survey and at the time the parent proposes to add or delete a branch.

Regardless of the formal organizational structure, the overall responsibility for all services provided, whether directly, through arrangements or contracts, rests with the HHA that has assumed responsibility for admitting patients and implementing plans of care.

A parent and branch are defined by the Medicare Conditions of Participation and outlined in the ACHC Glossary of Terms.

The parent HHA provides direct support and administrative control of its branches. A branch office, as an extension of the parent HHA, may not offer services that are different than those offered by the parent HHA.

Evidence: Written Policies and Procedures

Evidence: Observation

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.14. See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH1-7A: The HHA provides part-time or intermittent skilled nursing services and at least one other therapeutic service (physical therapy, speech language pathology or occupational therapy; medical social services; or home health aide services) that are made available on a visiting basis, in a place of residence used as a patient's home. 484.105(f) (G982), 484.105(f)(1) (G982) .

An HHA must provide at least one of the services described in this standard directly, but may provide the second service and additional services under arrangements with another HHA or organization.

An HHA is considered to be providing a service directly when the person providing the service is an employee of the HHA. An individual who works for a Home Health Agency on an hourly or per-visit basis may be considered an HHA employee if the HHA is required to issue a W-2 form in their name.

Evidence: Observation

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.105(f) and 484.105(f)(1). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH1-8A: The HHA electronically reports all OASIS data collected from the comprehensive assessment. 484.45 (G370).

HHA's must electronically report all OASIS data collected in accordance with 42 CFR 484.55.

HHA's must, electronically report OASIS data on all applicable patients in a format that meets CMS electronic data and edit specifications. For purposes of this requirement, the term "reporting" means electronic reporting.

HHAs must continue to collect, encode, and transmit OASIS data for their non-maternity Medicare (traditional and HMO/managed care) and Medicaid (traditional and HMO/Managed Care) patients that are age 18 and over and receiving skilled services. Medicare (HMO/managed care) does include Medicare Advantage (MA), formerly known as Medicare+Choice (M+C) plans and Medicare PPO plans.

Evidence: OASIS Validation Report

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.45. See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH1-8B: The HHA's policies and procedures describe activities and the implementation to ensure safe, timely and accurate collection and transmission of OASIS data. 484.45(a) (G372), 484.45(b) (374), 484.45(c) (G376), 484.45(c)(1) (G378), 484.45(c)(2) (G380), 484.45(c)(3) (G382), 484.45(d) (G386) .

The HHA's policies and procedures include, but are not limited to:

- Conducting clinical and data entry audits and following a process to verify that collected OASIS data is consistent with reported OASIS data
- Identifying and addressing any discrepancies in data collected and reported
- Alternate plan when it is unable to submit OASIS data to the State agency

An HHA must encode and electronically transmit each completed OASIS assessment to the CMS system regarding each beneficiary

with respect to which information is required to be transmitted (as determined by the Secretary), within 30 days of completing the assessment of the beneficiary. The encoded OASIS data must accurately reflect the patient's status at the time of assessment.

The HHA must encode and transmit data using the software available from CMS or software that conforms to CMS standard electronic record layout, edit specifications, and data dictionary, and that includes the required OASIS data set.

The HHA must:

- For all completed assessments, transmit OASIS data in a format that meets the requirements of 42 CFR 484.45(d)
- Transmit data using electronic communications software that complies with the Federal Information Processing Standard (FIPS 140-2, issued May 24, 2001) from the HHA or the HHA contractor to the CMS collection site
- Transmit data that includes the CMS-assigned branch identification number, as applicable

Evidence: Written Policies and Procedures

Evidence: Patient Records

Evidence: OASIS Validation Report

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.45(a), 484.45(b), 484.45(c), 484.45(c)(1), 484.45(c)(2), 484.45(c)(3), 484.45(c)(4) and 484.45(d). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH1-9A.01: The HHA informs the accrediting body and other state/federal regulatory agencies, as appropriate, of negative outcomes from sanctions, regulatory inspection and/or audits.

Negative outcomes affecting accreditation, licensure, or Medicare/Medicaid certification are reported to ACHC within 30 days. The report includes all action taken and plans of correction.

Incidents that must be reported to ACHC include, but are not limited to:

- License suspension(s)
- License probation; conditions/restrictions to license(s)
- Non-compliance with Medicare (condition level deficiency)/Medicaid regulations identified during survey by another state/regulatory body
- Revocation of Medicare/Medicaid/third-party provider number
- Any open investigation by any regulatory or governmental authority
- HHA agrees to a Corporate Integrity Agreement

Evidence: Governing Body Meeting Minutes

Evidence: Response to Interviews

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH1-10A: An HHA that uses outside personnel/organization to provide care/services on behalf of the HHA has a written contract/agreement for care furnished. The contract/agreement contains all requirements and is kept on file within the HHA. 484.105(e) (G976), 484.105(e)(1) (G976), 484.105(e)(2) (G978), 484.105(e)(2)(i) (G978), 484.105(e)(2)(ii) (G978), 484.105(e)(2)(iii) (G978), 484.105(e)(2)(iv) (G978), 484.105(e)(3) (G980).

Arranged care/services are supported by written agreements that require that all care/services are:

- Authorized by the HHA
- Furnished in a safe and effective manner by qualified personnel/organizations
- Delivered in accordance with the patient's plan of care

An HHA must have a written agreement with another agency, with an organization, or with an individual when that entity or individual furnishes services under arrangement to the HHA's patients. The HHA must maintain overall responsibility for the services provided under arrangement, as well as the manner in which they are furnished. The agency, organization, or individual providing services under arrangement may not have been:

- Denied Medicare or Medicaid enrollment
- Been excluded or terminated from any federal health care program or Medicaid
- Had its Medicare or Medicaid billing privileges revoked; or
- Been debarred from participating in any government program

The HHA must ensure that all services furnished under arrangement provided by other entities or individuals meet the requirements of this standard and the requirements of section 1861(w) of the Act (42 U.S.C. 1395x (w)).

HHA that utilize personnel/organizations under hourly or per visit have a written contract/agreement that includes, but is not limited to:

- Patients are accepted for care only by the primary HHA
- The care/services to be furnished
- The necessity to conform to all applicable HHA policies and procedures, including personnel qualifications, orientation, competencies and required background checks
- The responsibility for participating in developing plans of care
- The manner in which care/services will be controlled, coordinated, and evaluated by the HHA
- The procedures for submitting clinical and progress notes, scheduling of visits, periodic patient evaluation
- The procedures for payment for care/services furnished under the contract
- Duration of contract/agreement
- Requirements to meet the Medicare Conditions of Participation
- Overall responsibility for supervision of personnel
- Other applicable laws and regulations
- Liability insurance for individuals providing direct care and HHAs providing shared responsibility of patient care

The HHA has an established process to review and renew contracts/agreements as required in the contract. A mechanism to indicate that the review/renewal has been accomplished may be evidenced by either a notation of the review dates on the initial contract/agreement or development of an updated contract/agreement.

Evidence: Written Contracts/Agreements

Evidence: Observation

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.105(e), 484.105(e)(1), 484.105(e)(2), 484.105(e)(2)(i), 484.105(e)(2)(ii), 484.105(e)(2)(iii), 484.105(e)(2)(iv) and 484.105(e)(3). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH1-11A: 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 Food and Drug Administration (FDA), the testing must be in compliance with all applicable requirements of 42 CFR 493 (Laboratory Requirements). 484.100(c) (G862), 484.100(c)(1) (G862), 484.100(c)(2) (G864).

The HHA follows procedures for waived tests under the Clinical Laboratory Improvement Amendment (CLIA) and state regulations when personnel perform waived tests. The HHA obtains and maintains a current certificate of waiver from the Department of Health and Human Services. If the HHA refers specimens for laboratory testing, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the applicable requirements of 42 CFR 493.

Examples of several waived tests are:

- Dipstick/tablet reagent urinalysis
- Blood glucose by glucose monitoring devices cleared by the Food and Drug Administration (FDA) specifically for home use
- Some prothrombin time tests
- Some glycosylate hemoglobin tests

Assisting individuals in administering their own tests, such as fingerstick blood glucose or prothrombin testing, is not considered testing subject to the CLIA regulations. However, if the HHA staff is actually responsible for measuring the blood glucose level or prothrombin times of patients with an FDA approved blood glucose or prothrombin time monitor, and no other tests are being performed, the agency must have evidence of a CLIA waiver.

The HHA may not substitute its equipment for a patient's equipment when assisting with self-administered tests.

Evidence: Observation

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.100(c), 484.100(c)(1) and 484.100(c)(2). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH1-12A.01: Prior to adding additional locations, HHAs must obtain Medicare approval before providing care/

service to Medicare patients.

When an existing provider intends to add an additional location, it notifies CMS, the state survey agency (SA) and ACHC in writing of the proposed location if it expects this location to participate in Medicare or Medicaid. The provider must also submit a CMS Form-855A change of information request (including all supporting documentation) to its Medicare Administrative Contractor (MAC) before CMS approval can be granted. The provider must obtain CMS approval of the new location before it is permitted to bill Medicare for services provided from the new location. All providers must also follow the ACHC Branch Addition process.

A provider may not bill Medicare for services provided from an additional location until the new site or location has been approved by CMS and ACHC. The fact that a national accreditation organization with deeming authority has approved a new site or location will not affect CMS' decision. CMS' determination will be based on its independent application of its regulations to the facts in the case. Services provided before the effective date of approval should not be billed to Medicare.

The additional location(s) must be part of the HHA and must share administration, supervision, and services with the HHA issued the certification number. The lines of authority and professional and administrative control must be clearly delineated in the provider's organizational structure and in practice, and must be traced to the location issued the certification number.

The provider must continually monitor and manage all services provided at all of its locations to ensure that services are delivered in a safe and effective manner and to ensure that each patient receives the necessary care and services outlined in the plan of care.

If the provider does operate at multiple branches, a deficiency found at any branch will result in a compliance issue for the entire HHA.

Evidence: CMS Letter of Approval for Branch Addition

Services applicable: HHA, MSS, OT, PT, SN, ST

Section 2: PROGRAM/SERVICE OPERATIONS

The standards in this section apply to the specific programs and services an organization is supplying. This section addresses rights and responsibilities, complaints, incidents, Protected Health Information (PHI), cultural diversity, and compliance with laws to prevent fraud and abuse.

Standard HH2-1A.01: Written policies and procedures are established and implemented in regard to the HHA's descriptions of care/services and its distribution to personnel, patients, and the community.

The HHA's written policies and procedures include, but are not limited to:

- Types of care/service available
- Care/service limitations
- Charges or patient responsibility for care/service
- Eligibility criteria
- Hours of operation, including on-call availability
- Contact information and referral procedures

Written descriptions of care/services with detailed information are available. Marketing and instructional materials use lay language and provide a more general description of care/services offered.

Patients will receive information about the services covered under the HHA benefit and the scope of services that the HHA will provide and specific limitations on those services. The patient and/or family will receive this information prior to receiving care/service with evidence documented in the patient record.

Evidence: Written Policies and Procedures

Evidence: Marketing Materials Including Electronic Media

Evidence: Patient Records

Evidence: Home Visits

Evidence: Observation

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH2-2A: Written policies and procedures are established and implemented by the HHA in regard to the creation and distribution of the Patient Rights and Responsibilities statement. 484.50 (G406), 484.50(a) (G408), 484.50(a)(1) (G410), 484.50(a)(i) (G6412), 484.50(a)(ii) (G414), 484.50(a)(iii) (G416), 484.50(a)(2) (G418), 484.50(a)(4) (G422), 484.50(b) (G424), 484.50(b)(1) (G424), 484.50(b)(2) (G424), 484.50(b)(3) (G424), 484.50(c) (G426), 484.50(c)(1) (G428), 484.50(c)(2) (G430), 484.50(c)(3) (G432), 484.50(c)(4) (G434), 484.50(c)(4)(i) (G434), 484.50(c)(4)(ii) (G434), 484.50(c)(4)(iii) (G434), 484.50(c)(4)(iv) (G434), 484.50(c)(4)(v) (G434), 484.50(c)(4)(vi) (G434), 484.50(c)(4)(vii) (G434), 484.50(c)(4)(viii) (G434), 484.50(c)(5) (G436), 484.50(c)(6) (G438), 484.50(c)(7) (G440), 484.50(c)(7)(i) (G440), 484.50(c)(7)(ii) (G440), 484.50(c)(7)(iii) (G440), 484.50(c)(7)(iv) (G440), 484.50(c)(8) (G442), 484.50(c)(9) (G444), 484.50(c)(10) (G446), 484.50(c)(10)(i) (G446), 484.50(c)(10)(ii) (G446), 484.50(c)(10)(iii) (G446), 484.50(c)(10)(iv) (G446), 484.50(c)(10)(v) (G446), 484.50(c)(11) (G448), 484.50(c)(12) (G450), (Standard HH2-2A is in regard to the creation and distribution of the statement of the Patient Rights and Responsibilities and the standard reference next to the right is the standard that demonstrates the implementation of the right.)

Written policies and procedures outline the patient's rights and responsibilities. The HHA must provide the patient and the patient's legal representative (if any) with a written notice of the patient's rights during the initial evaluation visit, in advance of furnishing care to the patient, along with:

- Contact information for the HHA Administrator, including the Administrator's name, business address, and business phone number in order to receive complaints
- An OASIS privacy notice to all patients for whom the OASIS data is collected
- Written notice of the patient's rights and responsibilities under this rule and the HHA's transfer and discharge policies as set forth in 42 CFR 484.50(d)(1-7) to a patient-selected representative within 4 business days of the initial evaluation visit

The patient and representative (if any) have the right to be informed of the patient's rights:

- Must be written in a language and manner the individual understands
- Written notice must be understandable to persons who have limited English proficiency and accessible to individuals with disabilities

An HHA provides written information concerning its policies on Advance Directives, prior to care being provided.

The HHA obtains the patient's or legal representative's signature confirming that he or she has received a copy of the notice of rights and responsibilities.

The written statement of Patient Rights and Responsibilities includes, but is not limited to, the patient's right to:

1. Have his or her property and person treated with respect (HH2-2C)
2. Be free from verbal, mental, sexual, and physical abuse, including injuries of unknown source, neglect and misappropriation of property; (HH2-3A)
3. Make complaints to the HHA regarding treatment or care that is (or fails to be) furnished, and the lack of respect for property and/or person by anyone who is furnishing services on behalf of the HHA; (HH2-4A)
4. Participate in, be informed about, and consent or refuse care in advance of and during treatment, where appropriate, with respect to: (HH2-6A)
 - i. Completion of all assessments;
 - ii. The care to be furnished, based on the comprehensive assessment;
 - iii. Establishing and revising the plan of care;
 - iv. The disciplines that will furnish the care;
 - v. The frequency of visits;
 - vi. Expected outcomes of care, including patient-identified goals, and anticipated risks and benefits;
 - vii. Any factors that could impact treatment effectiveness; and
 - viii. Any changes in the care to be furnished
5. Receive all services outlined in the plan of care.(HH5-3B)
6. Have a confidential clinical record. Access to or release of patient information and clinical records is permitted in accordance with 45 CFR parts 160 and 164.(HH2-5A)
7. Be advised, orally and in writing of: (HH3-4C)
 - i. The extent to which payment for HHA services may be expected from Medicare, Medicaid, or any other federally-funded or federal aid program known to the HHA;
 - ii. The charges for services that may not be covered by Medicare, Medicaid, or any other federally-funded or federal aid program known to the HHA;
 - iii. The charges the individual may have to pay before care is initiated; and
 - iv. Any changes in the information provided in accordance with 42 CFR 484.50(c)(7) of this section when they occur. The HHA must advise the patient and representative (if any), of these changes as soon as possible, in advance of the next home health visit. The HHA must comply with the patient notice requirements at 42 CFR 411.408(d)(2) and 42 CFR 411.408(f)
8. Receive proper written notice, in advance of a specific service being furnished, if the HHA believes that the service may be non-covered care; or in advance of the HHA reducing or terminating on-going care. The HHA must also comply with the requirements of 42 CFR 405.1200 through 405.1204.(HH5-6A)
9. Be advised of the state toll free home health telephone hot line, its contact information, its hours of operation, and that its purpose is to receive complaints or questions about local HHAs.(HH2-4B)
10. Be advised of the names, addresses, and telephone numbers of the following federally-funded and state-funded entities that serve the area where the patient resides: (HH2-4B)
 - i. Agency on Aging
 - ii. Center for Independent Living
 - iii. Protection and Advocacy Agency
 - iv. Aging and Disability Resource Center
 - v. Quality Improvement Organization
11. Be free from any discrimination or reprisal for exercising his or her rights or for voicing grievances to the HHA or an outside entity. (HH2-4A)
12. Be informed of the right to access auxiliary aids and language services as described in paragraph (f) of this section, and how to access these services (HH2-8A)
13. Be able to identify visiting personnel members through agency generated photo identification (HH2-2C)
14. Choose a health care provider, including an attending physician or allowed practitioner (HH2-2C)
15. Receive appropriate care without discrimination in accordance with physician or allowed practitioner orders (HH2-2C)
16. Be informed of any financial benefits when referred to an HHA (HH2-2C)

When additional state or federal regulations exist regarding patient rights, the HHA's Patient Rights and Responsibilities statement must include those components. The patient has the right to be informed and exercise their rights as a patient of the HHA.

If the patient has been adjudged to lack legal capacity to make health care decisions as established by state law by a court of proper jurisdiction, the rights of the patient may be exercised by the person appointed to act on the patient's behalf. If a state court has not adjudged a patient to lack legal capacity to make health care decisions as defined by state law, the patient's representative may exercise the patient's rights. If a patient has been adjudged to lack legal capacity to make health care decisions under state law by a court of proper jurisdiction, the patient may exercise his or her rights to the extent allowed by court order.

The HHA must protect and promote the exercise of these rights. The HHA also develops a statement of patient responsibilities.

Personnel are provided training during orientation and at least annually thereafter concerning the HHA's policies and procedures on the Patient Rights and Responsibilities.

Evidence: Written Policies and Procedures

Evidence: Statement of Patient's Rights and Responsibilities

Evidence: Patient Records

Evidence: Home Visits

Evidence: Observation

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.50, 484.50(a), 484.50(a)(1), 484.50(a)(2), 484.50(a)(3), 484.50(a)(4), 484.50(a)(i), 484.50(a)(ii), 484.50(a)(iii), 484.50(b), 484.50(b)(1), 484.50(b)(2), 484.50(b)(3), 484.50(c), 484.50(c)(1), 484.50(c)(10)(iii), 484.50(c)(10)(iv), 484.50(c)(10)(v), 484.50(c)(11), 484.50(c)(12), 484.50(c)(2), 484.50(c)(3), 484.50(c)(4), 484.50(c)(4)(i), 484.50(c)(4)(ii), 484.50(c)(4)(iii), 484.50(c)(4)(iv), 484.50(c)(4)(v), 484.50(c)(4)(vi), 484.50(c)(4)(vii), 484.50(c)(4)(viii), 484.50(c)(5), 484.50(c)(6), 484.50(c)(7), 484.50(c)(7)(i), 484.50(c)(7)(ii), 484.50(c)(7)(iii), 484.50(c)(7)(iv), 484.50(c)(8) and 484.50(c)(9). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH2-2C: The HHA protects and promotes the exercise of the Patient's Rights. 484.50 (G406), 484.50(c) (G426), 484.50(c)(1) (G428).

Personnel honor the patient right to:

- To exercise his or her rights as a patient of the HHA
- Have his or her property and person treated with respect
- Be able to identify visiting personnel members through agency-generated photo identification
- Choose a health care provider, including an attending physician or allowed practitioner
- Receive appropriate care without discrimination in accordance with physician or allowed practitioner orders
- Be informed of any financial benefits when referred to an HHA
- Be fully informed of one's responsibilities

Evidence: Home Visits

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.50, 484.50(a), 484.50(a)(1), 484.50(a)(1)(i), 484.50(a)(1)(ii), 484.50(a)(1)(iii), 484.50(a)(2), 484.50(a)(3), 484.50(a)(4), 484.50(b), 484.50(b)(1), 484.50(b)(2), 484.50(b)(3) and 484.50(c). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH2-3A: Written policies and procedures are established and implemented by the HHA in regard to reporting and investigating all alleged violations involving mistreatment, neglect, or verbal, mental, sexual and physical abuse, including injuries of unknown source and misappropriation of patient property by anyone furnishing services on behalf of the HHA. 484.50(c)(2) (G430), 484.50(e)(1)(i)(B) (G482), 484.50(e)(2) (G488) .

The patient has the right to be free of mistreatment; neglect; or verbal, mental, sexual and physical abuse, including injuries of unknown source; and misappropriation of patient property.

Any HHA staff (whether employed directly or under arrangements) in the normal course of providing services to patients, who identifies, notices, or recognizes incidences or circumstances of mistreatment; neglect; verbal, mental, sexual, and/or physical abuse, including injuries of unknown source, or misappropriation of patient property, must report these findings immediately to the HHA and other appropriate authorities in accordance with state law.

The HHA ensures this right and investigates all alleged violations involving mistreatment; neglect; verbal, mental, sexual and physical abuse, including injuries of unknown source; and misappropriation of patient property by anyone furnishing services on behalf of the HHA. Alleged violations are reported immediately to the Administrator or appropriate designee.

The HHA immediately investigates all alleged violations involving anyone furnishing services on behalf of the HHA and immediately takes action to prevent further potential violations while the alleged violation is being verified. Investigations and/or documentation of all alleged violations are conducted in accordance with established policies and procedures.

The HHA takes appropriate corrective action in accordance with state law if the alleged violation is verified by the HHA's administration or an outside body having jurisdiction, such as ACHC, the state survey agency or local law enforcement agency. The HHA ensures that verified violations are reported to ACHC, state and local bodies having jurisdiction (including to the state survey and certification agency) within 5 working days of becoming aware of the verified violation unless state regulations are more stringent.

Evidence: Written Policies and Procedures

Evidence: Incident Reports/Investigation Results

Evidence: Response to Interviews

Evidence: Observation

Evidence: Home Visits

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.50(c)(2), 484.50(e)(1)(i) (B) and 484.50(e)(2). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH2-4A: Written policies and procedures are established and implemented by the HHA requiring that the patient be informed at the initiation of care/service how to report grievances/complaints. 484.50(c)(3) (G432), 484.50(e) (G476), 484.50(e)(1) (G476), 484.50(e)(1)(i) (G478), 484.50(e)(1)(i)(A) (G480), 484.50(e)(1)(ii) (G484), 484.50(e)(1)(iii) (G486).

The patient has the right to voice grievances/complaints regarding treatment or care that is (or fails to be) furnished and lack of respect of property by anyone who is furnishing care/service on behalf of the HHA. The HHA will take action to prevent further potential violations, including retaliation, while the complaint is being investigated. Be free from any discrimination or reprisal for exercising his or her rights or for voicing grievances to the HHA or an outside entity.

The HHA ensures this right and investigates all grievances/complaints. Written policies and procedures include, but are not limited to:

- The appropriate person to be notified of the grievance/complaint
- Time frames for investigation activities, to include after hours
- Reporting of information
- Review and evaluation of the collected information
- Communication with the patient/family
- Documentation of all activities involved with the grievance/complaint, investigation, analysis and resolution

The HHA must investigate complaints made by a patient, the patient's representative (if any), and the patient's caregivers and family including, but not limited to, the following topics: treatment or care that is (or fails to be) furnished, or is furnished inconsistently, or is furnished inappropriately. The HHA must document both the existence of the complaint and the resolution of the complaint.

The HHA investigates and attempts to resolve all patient grievances/complaints and document the results within a described time frame as defined in policies and procedures.

The HHA maintains records of grievances/complaints and their outcomes, submitting a summary report quarterly to the governing body/owner. This information is included in the Quality Assessment and Performance Improvement (QAPI) annual report.

Personnel are oriented and familiar with the grievance/complaint policies and procedures. Personnel assist in implementing the resolution process when needed.

Evidence: Written Policies and Procedures
Evidence: Grievance/Complaint Log
Evidence: Governing Body Meeting Minutes
Evidence: Response to Interviews
Evidence: Home Visits

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.50(c)(3), 484.50(e), 484.50(e)(1), 484.50(e)(1)(i), 484.50(e)(1)(i)(A), 484.50(e)(1)(ii) and 484.50(e)(1)(iii). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH2-4B: The HHA provides the patient with written information concerning how to contact the HHA, appropriate state agencies, and ACHC concerning grievances/complaints at time of admission. 484.50(c)(9) (G444), 484.50(c)(10) (G446).

The HHA provides all patients with written information listing a telephone number, contact person, and the HHA's process for receiving, investigating, and resolving grievances/complaints about its care/service.

The agency advises patients in writing of the state's toll free Home Health telephone hot line, its contact information, its hours of operation, and that its purpose is to receive complaints and questions about local HHAs. This may be a separate information sheet given to the patient or incorporated with the Patient Rights information. If the agency is Medicare certified, the patients must also be made aware that they can use the hotline to lodge complaints concerning the implementation of Advance Directives requirements.

The patient should be advised of the names, addresses, and telephone numbers of the following federally-funded and state-funded entities that serve the area where the patient resides:

- (i) Agency on Aging
- (ii) Center for Independent Living
- (iii) Protection and Advocacy Agency

- (iv) Aging and Disability Resource Center
- (v) Quality Improvement Organization

ACHC's telephone number must be provided. The ACHC phone number requirement is not applicable to HHAs undergoing their first ACHC survey.

Evidence: Admission/New Patient Packet
Evidence: Home Visits
Evidence: Patient Records

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.50(c)(10), 484.50(c)(10)(i), 484.50(c)(10)(ii), 484.50(c)(10)(iii), 484.50(c)(10)(iv), 484.50(c)(10)(v) and 484.50(c)(9). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH2-5A: Written policies and procedures are established and implemented by the HHA in regard to the securing and releasing of confidential and Protected Health Information (PHI) and Electronic Protected Health Information (EPHI). 484.40 (G350), 484.50(c)(6) (G438).

The patient has the right to a confidential patient record. Access to or release of patient information and clinical records is permitted in accordance with 45 CFR parts 160 and 164. The HHA ensures this right and follows all policies and procedures to secure patient information.

Confidentiality policies and procedures include, but are not limited to:

- A definition of protected health and confidential information, the types of information that are covered by the policy, including electronic information, telephone and cell phone communications, and verbal and faxed information
- Persons/positions authorized to release PHI/EPHI and confidential information
- Conditions which warrant its release
- Persons to whom it may be released
- Signature of the patient or someone legally authorized to act on the patient's behalf
- A description of what information the patient is authorizing the HHA to disclose
- Securing patient records and identifying who has authority to review or access clinical records
- When records may be released to legal authorities
- The storage and access of records to prevent loss, destruction or tampering of information
- The use of confidentiality/privacy statements and who is required to sign a confidentiality/privacy statement
- The HHA and agent 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 information to the public

The HHA has clearly established written policies and procedures that address the areas listed above which are clearly communicated to all personnel.

There is a signed confidentiality statement for all personnel and governing body/owner. Personnel and the governing body/owner abide by the confidentiality statement and the HHA's policies and procedures. The HHA designates an individual responsible for seeing that the confidentiality and privacy policies and procedures are adopted and followed.

Evidence: Written Policies and Procedures
Evidence: Signed Confidentiality Agreements
Evidence: Observation
Evidence: Response to Interviews

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.40 and 484.50(c)(6). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH2-5C.01: The HHA has Business Associate Agreements for all Business Associates that may have access to Protected Health Information as required by HIPAA and other applicable laws and regulations.

A copy of all Business Associate Agreements will be on file at the HHA for all non-covered entities as defined by the Health Insurance Portability and Accountability Act (HIPAA).

Examples of non-covered entities include, but are not limited to:

- A CPA firm whose accounting services to a health care provider involves access to protected health information

- An attorney whose legal services to a health plan involve access to protected health information
- A consultant that has access to protected health information
- An independent medical transcriptionist that provides transcription services to a physician

A Business Associate Agreement is not required with persons or organizations (e.g., janitorial service or electrician) whose functions or services do not involve the use or disclosure of protected health information, and where any access to protected health information by such persons would be incidental, if at all.

Evidence: Business Associates Agreement

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH2-6A: Written policies and procedures are established by the HHA in regard to the patient's right to make decisions about medical care, accept or refuse medical care, patient resuscitation, and surgical treatment. 484.50(c)(4) (G434), 484.50(c)(4)(i) (G434), 484.50(c)(4)(ii) (G434), 484.50(c)(4)(iii) (G434), 484.50(c)(4)(iv) (G434), 484.50(c)(4)(v) (G434), 484.50(c)(4)(vi) (G434), 484.50(c)(4)(vii) (G434), 484.50(c)(4)(viii) (G434) .

The patient has the right to, participate in, be informed about, and consent or refuse care in advance of and during treatment, where appropriate, with respect to:

- (i) Completion of all assessments
- (ii) The care to be furnished, based on the comprehensive assessment
- (iii) Establishing and revising the plan of care
- (iv) The disciplines that will furnish the care
- (v) The frequency of visits
- (vi) Expected outcomes of care, including patient-identified goals, and anticipated risks and benefits
- (vii) Any factors that could impact treatment effectiveness
- (viii) Any changes in the care to be furnished

The HHA's policies and procedures must describe the patient's rights under law to make decisions regarding medical care, including the right to accept or refuse care/service.

Evidence: Written Policies and Procedures
 Evidence: Patient Records

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.50(c)(4), 484.50(c)(4)(i), 484.50(c)(4)(ii), 484.50(c)(4)(iii), 484.50(c)(4)(iv), 484.50(c)(4)(v), 484.50(c)(4)(vi), 484.50(c)(4)(vii) and 484.50(c)(4)(viii). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH2-6B.01: Written policies and procedures are established and implemented by the HHA in regard to resuscitative guidelines and the responsibilities of personnel.

The HHA has written policies and procedures for personnel responsibilities regarding patient resuscitation and the response in the event of a medical emergency. The policies and procedures identify which personnel perform resuscitative measures, respond to medical emergencies and utilization of 911 services (EMS) for emergencies. Successful completion of appropriate training, such as a CPR certification course is defined in the policies and procedures. Online CPR certification is acceptable with in-person verification of competency. Patients are provided information about the HHA's policies and procedures for resuscitation, medical emergencies and accessing 911 services (EMS).

Evidence: Written Policies and Procedures
 Evidence: Personnel Files
 Evidence: Response to Interviews

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH2-6B.02: Written policies and procedures are established and implemented in regard to the HHA providing advance directive information to the patient/responsible party orally and in writing prior to the initiation of care/services and documented in the patient record.

Advance Directive information is provided to the patient/responsible party prior to the initiation of care/services. The patient's decision regarding an Advance Directive is documented in the patient record.

The HHA's personnel respect the patient's wishes and assist the patient in completing an Advance Directive, if requested.

Written policies and procedures include, but are not limited to:

- Providing all adult individuals with written information about their rights under state law to:
 - Make decisions about their medical care
 - Accept or refuse medical or surgical treatment
 - Formulate, at the individual's option, an Advance Directive
- Informing patients about the HHA's written policies on implementing Advance Directives
- Documenting in the patient's medical record whether he or she has executed an Advance Directive
- Not limiting the provision of care or otherwise discriminating against an individual based on whether he or she has executed an Advance Directive
- Ensuring compliance with the related state requirements on Advance Directives
- Providing staff and community education on issues concerning Advance Directives

Evidence: Patient Records

Evidence: Response to Interviews

Evidence: Written Policies and Procedures

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.10(c)(2)(ii). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH2-7A.01: Written policies and procedures are established and implemented by the HHA in regard to the identification, evaluation, and discussion of ethical issues.

The HHA provides care/service within an ethical framework that is consistent with applicable professional and regulatory bodies. Written policies and procedures address the mechanisms utilized to identify, address, and evaluate ethical issues in the HHA. Examples of forums utilized to consider and discuss ethical issues may include:

- Ethics Committees
- Ethics forums
- Access to professional experts
- Performance Improvement Committee

The HHA monitors and reports all ethical issues and actions to the governing body/organizational leaders as outlined in policies and procedures.

Orientation and annual training of personnel includes examples of potential ethical issues and the process to follow when an ethical issue is identified.

Evidence: Written Policies and Procedures

Evidence: Governing Body Meeting Minutes

Evidence: Responses to Interviews

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH2-8A: Written policies and procedures are established and implemented by the HHA in regard to the provision of care/service to patients and families with communication or language barriers. 484.50(f) (G490), 484.50(f)(1) (G490), 484.50(f)(2) (G490).

Information must be provided to patients in plain language and in a manner that is accessible and timely to:

1. Persons with disabilities, including accessible web sites and the provision of auxiliary aids and services at no cost to the individual in accordance with the Americans with Disabilities Act and Section 504 of the Rehabilitation Act.
2. Persons with limited English proficiency through the provision of language services at no cost to the individual, including oral interpretation and written translations.

Personnel can communicate with the patient and/or family in the appropriate language or form understandable to the patient. Mechanisms are in place to assist with language and communication barriers. This may include the availability of bilingual personnel, interpreters, or assistive technologies. Personnel can communicate with the patient/family by using special telephone devices for the deaf or other communication aids such as picture cards or written materials in the patient's language.

All personnel are knowledgeable regarding the written policies and procedures for the provision of care/service to patients and

families with communication barriers.

Evidence: Written Policies and Procedures

Evidence: Observation

Evidence: Response to Interviews

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.50(f), 484.50(f)(1) and 484.50(f)(2). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH2-8B.01: Written policies and procedures are established and implemented for the provision of care/service to patients and families from various cultural backgrounds, beliefs and religions.

Written policies and procedures describe the mechanism the HHA utilizes to provide care for patients and families of different cultural backgrounds, beliefs and religions. The policies and procedures also describe any actions expected for personnel providing care to patients who have different cultural backgrounds, beliefs and religions.

Different cultural backgrounds, beliefs and religions impact the patient's lifestyles, habits, and view of health, healing and illness. Personnel identify differences in their own beliefs and the patient's beliefs and find ways to support the patient. Personnel make efforts to understand how the patient's and family's cultural beliefs impact their perception of the illness

All personnel are provided with annual education and resources to increase their cultural awareness of the patients/families they serve.

Evidence: Written Policies and Procedures

Evidence: Response to Interviews

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH2-9A.01: Written policies and procedures are established and implemented by the HHA in regard to a Compliance Program aimed at preventing fraud and abuse.

The HHA has an established Compliance Program that provides guidance for the prevention of fraud and abuse. The Compliance Program identifies numerous compliance risk areas particularly susceptible to fraud and abuse.

The Compliance Program details actions the HHA takes to prevent violations of fraud and abuse. The guidelines include, but are not limited to:

- Implementation of written policies, procedures, and standards of conduct
- Designation of a Compliance Officer and Compliance Committee
- Conducting effective training and education programs
- Developing open lines of communication between the Compliance Officer and/or Compliance Committee and HHA personnel for receiving complaints and protecting callers from retaliation
- Performance of internal audits to monitor compliance
- Establishing and publicizing disciplinary guidelines for failing to comply with policies and procedures, applicable statutes and regulations
- Prompt response to detected offenses through corrective action

Evidence: Written Policies and Procedures

Evidence: Performance Improvement Reports

Evidence: Response to Interviews

Evidence: Observation

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH2-10A.01: Supervision is available during all hours that care/service is provided.

There is administrative and clinical supervision of personnel in all care/service areas provided 24 hours per day, 7 days a week, as applicable. Supervision is consistent with state laws and regulations.

Evidence: Observation

Evidence: Response to Interviews

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH2-11A.01: Nursing services are provided according to the patient's plan of care with access available 24 hours a day, 7 days per week.

The HHA provides nursing services 24 hours a day, seven days a week as necessary to meet patient needs. An on-call coverage system for nursing services must be used to provide this coverage during evenings, nights, weekends and holidays. Supervision is consistent with state laws and regulations.

Evidence: On-Call Schedule

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH2-12A.01: Written policies and procedures are established and implemented that identify the approved treatments, procedures and patient care activities.

Written policies and procedures list the procedures or treatments, approved by the governing board/owner, that may be provided by clinical personnel. The policies and procedures include any exceptions as well as and any special criteria for the acceptance of patients for this service.

The HHA has written guidelines defining any special education, experience or licensure/certification requirements necessary for the clinical personnel to provide any special procedures or treatments, which include, but are not limited to:

- Wound VAC
- Vital-Stim
- Anodyne Therapy

Qualifications may vary based upon the national and state clinical board requirements.

Evidence: Written Policies and Procedures

Evidence: Observation

Services applicable: HHA, MSS, OT, PT, SN, ST

Section 3: FISCAL MANAGEMENT

The standards in this section apply to the financial operations of the organization. These standards address the annual budgeting process, business practices, accounting procedures, and the company's financial processes.

Standard HH3-1A: Written policies and procedures are established and implemented that address the budgeting process. The HHA under the direction of the governing body/owner prepares an overall plan and a budget that includes an annual operating budget and capital expenditure. 484.105(h) (G988), 484.105(h)(1) (G988), 484.105(h)(3) (G988).

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.

The HHA has a budget that includes projected revenue and expenses for all programs and care/service it provides. The budget is reflective of the HHA's care/service and programs.

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.

Evidence: Written Policies and Procedures

Evidence: Current Annual Budget

Evidence: Governing Body Meeting Minutes, if applicable

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.105(h), 484.105(h)(1) and 484.105(h)(3). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH3-1B: Written policies and procedures are established and implemented by the HHA in regard to a Capital Expenditure Plan. The HHA's Capital Expenditure Plan is developed in collaboration with management and personnel and under the direction of the governing body/owner, if applicable. 484.105(h)(2) (G988), 484.105(h)(2)(i) (G988), 484.105(h)(2)(ii) (G988), 484.105(h)(2)(ii)(A) (G988), 484.105(h)(2)(ii)(B) (G988), 484.105(h)(2)(ii)(C) (G988) .

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.

If the anticipated source of financing is, in any part, the anticipated payment from Title V (Maternal and Child Health Services Block Grant) or Title XVIII (Medicare) or Title XIX (Medicaid) of the Social Security Act, the plan specifies the following:

- 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
- 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 implementing regulations
- Whether the designated planning agency has approved or disapproved the proposed capital expenditure if it was presented to that agency

Evidence: Written Policies and Procedures

Evidence: Capital Expenditure Plan

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.105(h)(2), 484.105(h)(2)(i), 484.105(h)(2)(ii), 484.105(h)(2)(ii)(A), 484.105(h)(2)(ii)(B) and 484.105(h)(2)(ii)(C). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH3-1C: The HHA performs an annual review and update of the budget. 484.105(h)(4) (G988)

The over plan and budget is reviewed and updated at least annually by the committee referred to in 42 CFR 484.105(h)(3) under the direction of the governing body/owner of the HHA.

Evidence: Governing Body Meeting Minutes, if applicable

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.105(h)(4). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH3-2A.01: The HHA implements financial management practices that ensure accurate accounting and billing.

These practices include, but are not limited to:

- Receipt and tracking of revenue
- Billing of patients and third-party payors
- Notification to the patient/family of changes in reimbursement from third-party payors
- Collection of accounts
- Reconciliation of accounts
- Extension of credit, if applicable
- Financial Hardship, if applicable
- Consequences of non-payment
- Acceptance of gifts and/or funds, if applicable
- Process for receiving, recording and acknowledging contributions, if applicable
- Assignment of revenue to the appropriate program

Evidence: Observation

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH3-3A.01: Written policies and procedures are established and implemented by the HHA in regard to the time frames financial records are kept.

Written policies and procedures reflect applicable statutes and IRS regulations in regard to the time frame requirements for the retention of financial records. Medicare/Medicaid-certified programs are required to maintain financial records for at least five years after the last audited cost report.

Evidence: Written Policies and Procedures

Evidence: Observation

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH3-3B.02: The HHA will have a qualified individual conduct a financial review annually which includes identification of recommendations and a written report.

The financial review report demonstrates the ability of the organization to accumulate financial information and statistics required for the completion of the Medicare Cost Report including:

- Number of patients served and number of patient visits by discipline and payor source (Medicare, Medicaid, and other)
- Unduplicated number of patients served by payor (Medicare, Medicaid and other)
- Standard charge structure for all services
- Square footage by Medicare cost center
- Patient visits by discipline by CBSA code
- Medical supply charges by payor source (Medicare, Medicaid and other)
- Related party transactions
- Segregation of non-reimbursable activities - cost and utilization statistics
- Having up-to-date access to IACS
- Full time equivalent by discipline from payroll records

Evidence: Observation

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH3-4A.01: Written policies and procedures are established and implemented by the HHA that develop rates for care/service and that describe the methods for conveying charges to the patient, the public and referral sources.

There are written policies and procedures for establishing and conveying the charges for care/services provided to patients. Written charges for care/services are available upon request.

Personnel responsible for conveying charges are oriented and provided with education concerning the conveying of charges.

Evidence: Written Policies and Procedures

Evidence: Response to Interviews

Evidence: Observation

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH3-4C: The patient is advised orally and in writing of the charges for care/service at, or prior to, the receipt of care/services. The HHA must advise the patient of charges both orally and in writing as soon as possible, in advance of the next home visit. Patients who are Medicare or Medicaid eligible are informed when Medicare/Medicaid assignment is accepted. (484.50(c)(7) (G440), 484.50(c)(7)(i) (G440), 484.50(c)(7)(ii) (G440), 484.50(c)(7)(iii) (G440), 484.50(c)(7)(iv) (G440) .

Before the care is initiated, the HHA must inform the patient, orally and in writing, of:

- The extent to which payment may be expected from Medicare, Medicaid, or any other federally funded or aided program known to the HHA
- The charges for services that will not be covered by Medicare, Medicaid, or any other federally funded or federal aid program known to the HHA
- The charges that the individual may have to pay before care is initiated
- Any changes in the information provided in accordance with 42 CFR 484.50(c)(7) when they occur. The HHA must advise the patient and representative (if any) of these changes as soon as possible, in advance of the next home health visit. The HHA must comply with the patient notice requirements at 42 CFR 411.408(d)(2) and 42 CFR 411.408(f)

The patient is provided written information concerning the charges for care/service at or prior to the receipt of care/service. Patient records contain written documentation that the patient was informed of the charges, the expected reimbursement for third-party payors, and the financial responsibility of the patient.

Evidence: Patient Records

Evidence: Observation

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.50(c)(7), 484.50(c)(7)(i), 484.50(c)(7)(ii), 484.50(c)(7)(iii) and 484.50(c)(7)(iv). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH3-4D.01: There is verification that the care/service(s) billed for reconciles with the care/service(s) provided by the HHA.

The HHA verifies that patients and/or third-party payors are properly billed for care/service provided.

Evidence: Observation

Services applicable: HHA, MSS, OT, PT, SN, ST

Section 4: HUMAN RESOURCE MANAGEMENT

The standards in this section apply to all categories of personnel in the organization unless otherwise specified. Personnel may include, but are not limited to, support personnel, licensed clinical personnel, unlicensed clinical personnel, administrative and/or supervisory employees, contracted personnel, independent contractors, volunteers, and students completing clinical internships. This section includes requirements for personnel records, including skill assessments and competencies.

Standard HH4-1A.01: Written policies and procedures are established and implemented that describe the procedures to be used in the management of personnel files and confidential personnel records.

The written policies and procedures include, but are not limited to:

- Positions having access to personnel file
- Proper storage
- The required contents
- Procedures to follow for employees who wish to review their personnel file
- Time frames for retention of personnel files

The HHA has a personnel record for all employees of the HHA that is available for inspection by federal, state regulatory agencies and accreditation organizations.

Evidence: Written Policies and Procedures

Evidence: Observation

Evidence: Response to Interviews

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH4-1A.02: Prior to or at the time of hire all personnel complete appropriate documentation.

Prior to or at the time of hire all personnel complete the appropriate documentation, which includes, but is not limited to:

- Position application
- Dated and signed withholding statements
- Form I-9 (employee eligibility verification which confirms citizenship or legal authorization to work in the United States)

Evidence: Personnel Files

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH4-1B.01: All personnel files at a minimum contain or verify the following items. (Informational Standard Only)

Please refer to the standard listed for a detailed description of these requirements.

Description:	Standard:
Position application	HH4-1A.02
Dated and signed Withholding Statements	HH4-1A.02
Form I-9 (employee eligibility verification which confirms citizenship or legal authorization to work in the United States)	HH4-1A.02
Personnel credentialing	HH4-2B.01
TB Screening	HH4-2C.01
Hepatitis B vaccination	HH4-2D.01
Job description	HH4-2E.01
Motor vehicle license, if applicable	HH4-2F.01
Criminal background check	HH4-2H.01
National sex offender	HH4-2H.01
OIG's exclusion list	HH4-2H.01
Personnel policies review or employee handbook	HH4-2I.01
Annual performance	HH4-2J.01
Verification of qualifications	HH4-4A.01
Orientation	HH4-5A.01
Confidentiality agreement	HH2-5A
Competency assessments	HH4-6A.01, HH4-12G
Annual evaluation of job duties	HH4-6A.01

- Personnel includes, but is not limited to: support personnel, licensed clinical personnel, unlicensed clinical personnel, administrative and/or supervisory personnel, contract personnel, and volunteers.
- For contract staff the organization must have access to all of the above items, except position application, withholding statement, I-9, and personnel handbook. The remainder of items must be available for review during survey but do not need to be kept on site.
- Direct patient care - care of a patient provided personally by a staff member or contracted individual/organization in a patient's residence or healthcare facility. Direct patient care may involve any aspects of the health care of a patient, including treatments, counseling, self-care, patient education, and administration of medication

Evidence: Informational Standard Only

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH4-2B.01: Licensed personnel credentialing activities are conducted at the time of hire and prior to expiration of the credentials to verify qualifications of all personnel.

The personnel file or other personnel records contain validation that primary source credentialing information is obtained at the time of hire and prior to expiration of credentials, or in accordance with specific state practice act requirements.

Credentialing information includes a review of professional occupational licensure, certification, registration or other training as required by state boards and/or professional associations for continued credentialing.

Evidence: Personnel Files (Primary Source Verification)

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH4-2C.01: Written policies and procedures are established and implemented in regard to all direct care personnel having a baseline Tuberculosis (TB) test at any point in the past or in accordance with state requirements. Prior to patient contact, an individual TB risk assessment and a symptom evaluation are completed.

Prior to patient contact, direct care personnel provide or have:

- Upon hire personnel provide evidence of a baseline TB skin or blood test.
- Prior to patient contact, an individual TB risk assessment and symptom evaluation are completed to determine if high risk exposures have occurred since administration of the baseline TB test.
- If there is no evidence of a baseline TB skin or blood test, TB testing is conducted by the organization.

An organization conducts an annual TB risk assessment to determine the need, type, and frequency of testing/assessment for direct care personnel.

Annual TB testing of health care professionals is not recommended unless there is a known exposure or ongoing transmission.

Evidence: Written Policies and Procedures

Evidence: Personnel Files or other Confidential Employee Records

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH4-2D.01: Written policies and procedures are established and implemented for all direct care personnel to have access to the Hepatitis B vaccine as each job classification indicates and as described in federal CDC and OSHA standards.

Hepatitis B vaccination program and post-vaccination antibody titer are performed in accordance with CDC and OSHA guidelines. Personnel sign a declination statement for the Hepatitis B vaccination within 10 working days of employment if they choose not to become vaccinated.

The following are circumstances under which an organization is exempted from making the vaccination available:

- The complete Hepatitis B vaccination series was previously received
- Antibody testing shows the employee to be immune
- The vaccine cannot be given to the individual for medical reasons or the individual cannot receive antibody testing

Evidence: Written Policies and Procedures
Evidence: Personnel Records or other Confidential Employee Records

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH4-2E.01: There is a job description for each position within the HHA which is consistent with the organizational chart with respect to function and reporting responsibilities.

The job description lists:

- Job duties
- Reporting responsibilities
- Minimum job qualifications, experience requirements, education, and training
- Requirements for the job
- Physical and environmental requirements with or without reasonable accommodation

The HHA's job descriptions are consistent with the organizational chart with respect to function and reporting responsibilities. Review of the job description with personnel is conducted as part of the orientation process and whenever the job description changes.

There is documentation of receipt of the job description at time of orientation and whenever the job description changes (e.g., signed job description, orientation checklist, electronic verification).

Evidence: Job Descriptions
Evidence: Personnel Files

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH4-2F.01: All personnel who transport patients in the course of their duties, have a valid state driver's license appropriate to the type of vehicle being operated and are in compliance with state laws.

There is evidence that all personnel who transport patients as part of their job duties have a valid driver's license, appropriate to the type of vehicle being operated. The HHA conducts a Motor Vehicle Records (MVR) check on all personnel who are required to transport patients as part of their job duties, at time of hire and annually.

Evidence: Personnel Files

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH4-2H.01: Written policies and procedures are established and implemented in regard to background checks being completed on personnel that have direct patient care and/or access to patient records. Background checks include: Office of Inspector General exclusion list, criminal background record and national sex offender registry.

The HHA obtains a criminal background check, Office of Inspector General (OIG) exclusion list check and national sex offender registry check on all HHA employees who have direct patient care. HHA contracts require that all contracted entities obtain criminal background check, Office of Inspector General exclusion list check and national sex offender registry check on contracted employees who have direct patient care.

The HHA obtains a criminal background check and OIG exclusion list check on all HHA employees who have access to patient records. HHA contracts require that all contracted entities obtain criminal background checks and OIG exclusion list check on contracted employees who have access to patient records.

Criminal background checks are obtained in accordance with state requirements. In the absence of state requirements, criminal background checks are obtained within three months of the date of employment for all states in which the individual has lived or worked during past three years.

The HHA has policies and procedures regarding special circumstances, if any, for hiring a person convicted of a crime. The policies and procedures include, but are not limited to:

- Documentation of special considerations
- Restrictions
- Additional supervision

Evidence: Written and Procedures

Evidence: Personnel Files
Evidence: Response to Interviews

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH4-2I.01: Written personnel policies and procedures and/or an Employee Handbook are established and implemented describing the activities related to personnel management.

Personnel policies and procedures and/or an Employee Handbook include, but are not limited to:

- Wages
- Benefits
- Grievances and complaints
- Recruitment, hiring and retention of personnel
- Disciplinary action/termination of employment
- Professional boundaries and conflict of interest
- Performance expectations and evaluations

Personnel policies and procedures and/or Employee Handbook are reviewed at least annually, updated as needed, and are in accordance with applicable law and regulations. Personnel policies and procedures show evidence of non-discriminatory practices.

Wages

Information is available on overtime, on-call, holiday pay, and exempt versus non-exempt status.

Benefits

An explanation of benefits is shared with all benefit-eligible personnel. HHAs, which provide no benefits to some categories of personnel, communicate this fact in writing to affected personnel. For example, the contract/agreement with personnel who are utilized on an “as needed” basis may address that benefits are not available to persons employed in that classification.

Grievances and complaints

Written grievance information addresses options available to personnel who have work-related complaints, including steps involved in the grievance process.

Recruitment, Hiring and Retention of Personnel

The HHA has written policies and procedures on its recruitment, hiring, and retention of personnel which demonstrate non-discriminatory practices.

Disciplinary Action and Termination of Employment

Disciplinary action and termination of employment policies and procedures define time frames for probationary actions, conditions warranting termination, steps in the termination process, and appeal process.

Professional Boundaries

Written policies and procedures are established and implemented that define professional boundaries.

Conflict of Interest

Written policies and procedures are established and implemented that define a conflict of interest.

Performance Expectations and Evaluations

The organization's policies and procedures outline general performance expectations of all personnel (e.g., dress code, professional conduct), along with the schedule for performance evaluations.

Written documentation is kept verifying that the employee has reviewed and has access to personnel policies and procedures.

Evidence: Written Policies and Procedures and/or Employee Handbook
Evidence: Observation
Evidence: Personnel Files

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH4-2J.01: Written policies and procedures are established and implemented in regard to written annual performance evaluations being completed for all personnel based on specific job descriptions. The results of annual performance evaluations are shared with personnel.

Written policies and procedures are established and implemented addressing individual performance evaluations for all personnel. These policies and procedures describe how performance evaluations are conducted, who conducts them, and when they are to be conducted. The policies and procedures also identify any deviations to their policy.

Personnel evaluations are completed, shared, reviewed and signed by the supervisor and employee on an annual basis.

Evidence: Written Policies and Procedures

Evidence: Personnel Files

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH4-2K: Written policies and procedures are developed and implemented in regard to the requirement of all personnel to receive the COVID-19 vaccine. 484.70(d)(1-3)

The HHA must develop and implement policies and procedures to ensure that all personnel are fully vaccinated for COVID-19.

Regardless of clinical responsibility or patient contact, the policies and procedures must apply to the following HHA personnel, who provide any care, treatment, or other services for the HHA and/or its patients:

- HHA employees.
- Licensed practitioners.
- Students, trainees, and volunteers; and
- Individuals who provide care, treatment, or other services for the HHA and/or its patients, under contract or by other arrangement.

The policies and procedures of 42 CFR 484.70(d) do not apply to the following HHA personnel:

- Personnel who exclusively provide telehealth or telemedicine services outside of the settings where HHA services are provided to patients and who do not have any direct contact with patients, patient families and caregivers, and other personnel specified in 42 CFR 484.70(d)(1); and
- Personnel who provide support services for the HHA that are performed exclusively outside of the settings where HHA services are provided to patients and who do not have any direct contact with patients, patient families and caregivers, and other personnel specified in 42 CFR 484.70(d)(1).

The policies and procedures must include, at a minimum, the following components:

- A process for ensuring all personnel specified in 42 CFR 484.70(d)(1) (except for those personnel who have pending requests for, or who have been granted, exemptions to the vaccination requirements of 42 CFR 484.70(d), or those personnel for whom COVID-19 vaccination must be temporarily delayed, as recommended by CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID-19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID-19 vaccine prior to personnel providing any care, treatment, or other services for the HHA and/or its patients.
- A process for ensuring that all personnel specified in 42 CFR 484.70(d)(1) are fully vaccinated, except for those personnel who have been granted exemptions to the vaccination requirements of 42 CFR 484.70(d), or those personnel for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations.
- A process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID-19, for all personnel who are not fully vaccinated for COVID-19.
- A process for tracking and securely documenting the COVID-19 vaccination status of all personnel specified in 42 CFR 484.70(d)(1).
- A process for tracking and securely documenting the COVID-19 vaccination status of any personnel who have obtained any booster doses as recommended by CDC.
- A process by which personnel may request an exemption from the personnel COVID-19 vaccination requirements based on an applicable federal law.
- A process for tracking and securely documenting information provided by those personnel who have requested, and for whom the HHA has granted, an exemption from the personnel COVID-19 vaccination requirements.
- A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID-19 vaccines, and which supports personnel requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable state and local laws, and for further ensuring that such documentation contains:
 - All information specifying which of the authorized COVID-19 vaccines are clinically contraindicated for the personnel member to receive and the recognized clinical reasons for the contraindications; and
 - A statement by the authenticating practitioner recommending that the personnel member be exempted from the HHA's COVID-19 vaccination requirements for based on the recognized clinical contraindications.
- A process for ensuring the tracking and secure documentation of the vaccination status of personnel for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID-19, and individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment; and
- Contingency plans for personnel who are not fully vaccinated for COVID-19.

Evidence: Written Policies and Procedures

Evidence: Personnel Files or other Confidential Employee Records

Evidence: Observation

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH4-4A.01: Non-licensed personnel are qualified for the positions they hold by meeting the education, training, and experience requirements defined by the HHA.

Personnel hired for specific positions within the HHA meet the minimum qualifications for those positions in accordance with applicable laws or regulations and the HHA's job descriptions.

Education, training and experience are verified prior to employment. This can be accomplished by obtaining copies of resumes, applications, references, diplomas, licenses, certificates, and workshop attendance records.

Evidence: Personnel Files

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH4-5A.01: Written policies and procedures are established and implemented that describe the orientation process. Documentation reflects that all personnel have received an orientation.

Written policies and procedures are established and implemented, which include, but are not limited to:

- Review of the individual's job description and duties performed and their role in the HHA
- Organizational chart
- HHA philosophy
- Record keeping and reporting
- Confidentiality and privacy of Protected Health Information (PHI)
- Patient rights
- Advance Directives
- Conflict of interest
- Written policies and procedures
- Emergency Plan
- Training specific to job requirements
- Additional training for special populations, if applicable (e.g., pediatrics, disease processes with specialized care, substance abuse)
- Cultural diversity
- Communication barriers
- Ethical issues
- Professional boundaries
- Quality Assessment and Performance Improvement (QAPI) program
- Compliance Program
- Conveying of charges for care/service
- OSHA requirements, safety and infection control
- Orientation to equipment, if applicable as outlined in job description
- Incident/variance reporting
- Handling of patient grievances/complaints
- Medicare certified home health agencies must include OASIS and other required documentation in the orientation

The HHA creates and completes checklist or other method to verify that the topics have been reviewed with all personnel.

Evidence: Written Policies and Procedures

Evidence: Personnel Files

Evidence: Response to Interviews

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH4-5B.01: The HHA designates an individual who is responsible for conducting orientation activities.

The HHA designates an individual to coordinate the orientation activities ensuring that instruction is provided by qualified personnel.

Evidence: Orientation Schedule

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH4-6A.01: Written policies and procedures are established and implemented requiring the HHA to design a

competency assessment program based on the care/services provided for all direct care personnel.

The HHA designs and implements a competency assessment program based on the care/service provided for all direct care personnel. Competency assessments are an ongoing process and focuses on the primary care/service, and/or therapies being provided. Competency assessments are conducted initially during orientation, prior to providing a new task and annually thereafter. Validation of skills is specific to the employee's role and job responsibilities.

Policies and procedures for determining that direct care personnel are competent to provide quality care/service are in place and may be accomplished through clinical observation, skills lab review, supervisory visits, knowledge-based tests, situational analysis/case studies, and self-assessment. All competency assessments and training are documented. A self-assessment tool alone is not acceptable.

Peer review of clinical personnel competency by a like disciplines is acceptable if defined by the HHA. There is a plan in place for addressing performance and education of personnel when they do not meet competency requirements.

Evidence: Written Policies and Procedures

Evidence: Personnel Files

Evidence: Response to Interviews

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH4-6C.01: Written policies and procedures are established and implemented that define utilization purposes and personnel training requirements for using waived tests.

The HHA identifies which personnel may perform waived tests, and conducts and documents appropriate training for these individuals.

Evidence: Written Policies and Procedures

Evidence: Training Logs/Files

Services applicable: SN

Standard HH4-7C.01: Written policies and procedures are established and implemented in regard to the observation and evaluation of direct care personnel performing their job duties by qualified personnel prior to providing care independently and at least annually and/or in accordance with state or federal regulations.

Qualified personnel observe and evaluate each direct care personnel performing their job duties prior to providing care independently and at frequencies required by state or federal regulations. If no regulation exists, the evaluation is performed initially and at least once annually in the home care setting to assess that quality care is being provided. Written policies and procedures define the evaluation criteria. This activity may be performed as part of a supervisory visit and is included as part of the personnel record.

Evidence: Written Policies and Procedures

Evidence: Personnel Files

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH4-8A: Written policies and procedures are established and implemented defining the number of hours of in-service or continuing education for each Home Health Aide and supervision requirements of the education. 484.80(d) (G774), 484.80(d)(1) (G776), 484.80(d)(2) (G778) (This standard only applies to Home Health Aide requirements)

A Home Health Aide must receive at least 12 hours of in-service training during each 12-month period. In-service training may occur while an aide is furnishing care to a patient.

In-service training for Home Health Aides may be offered by any organization, and must be supervised by a Registered Nurse. The HHA must maintain documentation that demonstrates the requirements of this standard have been met.

The HHA must maintain a written description of the in-service training provided during the previous 12 months.

Evidence: Written Policies and Procedures

Evidence: Personnel Files and/or Training Logs

Evidence: Response to Interviews

Evidence: Observation

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.80(d), 484.80(d)(1) and

484.80(d)(2). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA

Standard HH4-8A.01: A written education plan is developed and implemented which defines the content, frequency of evaluations and amount of in-service training for each classification of personnel.

The education plan includes training provided during orientation as well as ongoing in-service education. HHAs provide this training directly or arrange for personnel to attend sessions offered by outside sources.

The on-going education plan is a written document that outlines the education to be offered for personnel throughout the year. The plan is based on reliable and valid assessment of needs relevant to individual job responsibilities. Education activities also include a variety of methods for providing personnel with current relevant information to assist with their learning needs. These methods include provision of journals, reference materials, books, internet learning, in house lectures and demonstrations, and access to external learning opportunities.

Non-direct care personnel have a minimum of 8 hours of on-going education per year. Direct care personnel must have a minimum of 12 hours of on-going education during each 12-month period.

The HHA has an on-going education plan that annually addresses, but is not limited to:

- How to handle grievances/complaints
- Infection control training
- Cultural diversity
- Communication barriers
- Ethics training
- Work place (OSHA), patient safety and components of HH7-2A.01
- Patient Rights and Responsibilities
- Compliance Program

There is written documentation confirming attendance at on-going education programs.

Evidence: Written Policies and Procedures

Evidence: Personnel Files

Evidence: Response to Interviews

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH4-10A.01: Written policies and procedures are established and implemented in regard to special education, experience or certification requirements for nursing personnel to administer pharmaceuticals and/or perform special treatments.

Written policies and procedures define any special education, experience, or licensure/certification requirements necessary for nursing personnel to administer pharmaceuticals and/or perform special treatments.

Personnel files contain documentation of completion of all special education, experience, or licensure/certification requirements. Qualifications may vary based upon Board of Nursing requirements for Licensed Practical Nurses and Registered Nurses.

Evidence: Written Policies and Procedures

Evidence: Personnel Files

Services applicable: SN

Standard HH4-11H: All Home Health Aide Services are provided by qualified personnel in accordance with the state's occupational certification regulations, where applicable, federal regulations and the HHA's policies and procedures and/or job descriptions and ACHC Glossary of Personnel Qualifications as defined by Medicare's Conditions of Participation 484.80 (G750) , 484.80(a) (G752), 484.80(a)(1) (G754), 484.80(a)(1)(i) (G754), 484.80(a)(1)(ii) (G754), 484.80(a)(1)(iii) (G754), 484.80(a)(1)(iv) (G754), 484.80(a)(2) (G756) .

All home health aide services must be provided by individuals who meet the personnel requirements specified in 42 CFR 484.80(a). A qualified Home Health Aide is a person who has successfully completed:

- A training and competency evaluation program as specified in 42 CFR 484.80 (b) and (c); or
- A competency evaluation program that meets the requirements of 42 CFR 484.80(c); or
- A nurse aide training and competency evaluation program approved by the state as meeting the requirements of 42 CFR

- 483.151 through 42 CFR 483.154, and is currently listed in good standing on the state nurse aide registry; or
- The requirements of a state licensure program that meets the provisions of 42 CFR 484.80(b) and (c).

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.

A Home Health Aide or nurse aide is not considered to have completed a program, as specified in 42 CFR 484.80(a)(1), if, since the individual's most recent completion of the program(s), there has been a continuous period of 24 consecutive months during which none of the services furnished by the individual as described in 42 CFR 409.40 were for compensation. If there has been a 24-month lapse in furnishing services for compensation, the individual must complete another program, as specified in 42 CFR 484.80(a)(1), before providing services.

Written policies and procedures define the minimum personnel qualifications, experience and educational requirements for each level of aide services, as well as the tasks that can be performed at each level.

Evidence: Written Policies and Procedures

Evidence: Observation

Evidence: Personnel File

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.80, 484.80(a), 484.80(a)(1), 484.80(a)(1)(i), 484.80(a)(1)(ii), 484.80(a)(1)(iii), 484.80(a)(1)(iv) and 484.80(a)(2). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA

Standard HH4-12A: For HHAs that conduct a Home Health Aide training program, the HHA meets all of the requirements of the Medicare Conditions of Participation. 484.80(b) (G758), 484.80(b)(1) (G760), 484.80(b)(2) (G762), 484.80(b)(3) (G764), 484.80(b)(3)(i) (G764), 484.80(b)(3)(ii) (G764), 484.80(b)(3)(iii) (G764), 484.80(b)(3)(iv) (G764), 484.80(b)(3)(v) (G764), 484.80(b)(3)(vi) (G764), 484.80(b)(3)(vii) (G764), 484.80(b)(3)(viii) (G764), 484.80(b)(3)(ix)(A) (G764), 484.80(b)(3)(ix)(B) (G764), 484.80(b)(3)(ix)(C) (G764), 484.80(b)(3)(ix)(D) (G764), 484.80(b)(3)(ix)(E) (G764), 484.80(b)(3)(ix)(F) (G764), 484.80(b)(3)(x) (G764), 484.80(b)(3)(xi) (G764), 484.80(b)(3)(xii) (G764), 484.80(b)(3)(xiii) (G764), 484.80(b)(3)(xiv) (G764), 484.80(b)(3)(xv) (G764), 484.80(b)(4) (G766).

The HHA ensures that the Home Health Aide training program consists of the following:

- The Home Health aide training must include classroom and supervised practical training in a practicum laboratory or other setting in which the trainee demonstrates knowledge while providing services to an individual under the direct supervision of a Registered Nurse, or a Licensed Practical Nurse who is under the supervision of a Registered Nurse. Classroom and supervised practical training must total at least 75 hours. A minimum of 16 hours of classroom training must precede a minimum of 16 hours of supervised practical training as part of the 75 hours.

A home health aide training program must address each of the following subject areas:

- Communication skills , including the ability to read, write, and verbally report clinical information to patients, representatives, and caregivers, as well as to other HHA staff
- Observation, reporting and documentation of patient status and the care or service furnished.
- Reading and recording temperature, pulse, and respiration
- Basic infection control procedures.
- Basic elements of body functioning and changes in body function that must be reported to an aide's supervisor.
- Maintenance of a clean, safe, and healthy environment.
- Recognizing emergencies and knowledge of instituting emergency procedures and their application
- 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.
- Appropriate and safe techniques in personal hygiene and grooming that include:
 - Bed bath
 - Sponge, tub, and shower bath
 - Hair shampooing in sink, tub, and bed
 - Nail and skin care
 - Oral hygiene
 - Toileting and elimination
 - Safe transfer techniques and ambulation
 - Normal range of motion and positioning
 - Adequate nutrition and fluid intake
 - Recognizing and reporting changes in skin condition;
 - Any other task that the HHA may choose to have the Home Health Aide perform as permitted under state law

The HHA is responsible for training Home Health Aides, as needed, for skills not covered in the basic checklist, as described in 42 CFR 484.80(b)(3)(ix).

"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.

A mannequin may be used for training purposes only.

This standard applies to all Home Health Aides providing care who are directly employed by the HHA or through a contractual agreement.

The HHA must maintain documentation that demonstrates that the requirements of this standard have been met.

Evidence: Home Health Aide Training Program

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.80(b), 484.80(b)(1), 484.80(b)(2), 484.80(b)(3), 484.80(b)(3)(i), 484.80(b)(3)(ii), 484.80(b)(3)(iii), 484.80(b)(3)(iv), 484.80(b)(3)(ix), 484.80(b)(3)(v), 484.80(b)(3)(vi), 484.80(b)(3)(vii), 484.80(b)(3)(viii), 484.80(b)(3)(x), 484.80(b)(3)(xi), 484.80(b)(3)(xii), 484.80(b)(3)(xiii), 484.80(b)(3)(xiv), 484.80(b)(3)(xv) and 484.80(b)(4). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA

Standard HH4-12B: A Home Health Aide training program and competency evaluation program may be offered by any organization except an HHA that, within the previous two years, has been found out of compliance with Medicare Conditions of Participation. 484.80(c)(2) (G768), 484.80(f) (G782), 484.80(f)(1) (G784), 484.80(f)(2) (G786), 484.80(f)(3) (G788), 484.80(f)(4) (G790), 484.80(f)(5) (G792), 484.80(f)(6) (G794), 484.80(f)(7) (G796), 484.80(f)(7)(i) (G796), 484.80(f)(7)(ii) (G796), 484.80(f)(7)(iii) (G796), 484.80(f)(7)(iv) (G796), 484.80(f)(7)(v) (G796), 484.80(f)(7)(vi) (G796) .

A Home Health Aide training program and competency evaluation program may be offered by any organization except an HHA that, within the previous two years, has been found:

- Out of compliance with requirements of 42 CFR 484.80(b), (c), (d) or (e); or
- Permitted an individual that does not meet the definition of "a qualified Home Health Aide" as specified in 42 CFR 484.80(a) to furnish home health aide services (with the exception of licensed health professionals and volunteers); or
- Was 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 CMS or the State); or
- Was assessed a civil monetary penalty of not less than \$5,000 or more as an intermediate sanction; or
- Was 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; or
- Has had all or part of its Medicare payments suspended; or
- Was found under any federal or state law to have:
 - Had its participation in the Medicare program terminated; or
 - Been assessed a penalty of \$5,000 or more for deficiencies in federal or state standards for HHAs; or
 - Been subject to a suspension of Medicare payments to which it otherwise would have been entitled; or
 - 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
 - Been closed or had its residents transferred by the state; or
 - Been excluded from participating in federal health care programs or debarred from participating in any government program

Evidence: Observation

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.80(c)(2), 484.80(f), 484.80(f)(1), 484.80(f)(2), 484.80(f)(3), 484.80(f)(4), 484.80(f)(5), 484.80(f)(6), 484.80(f)(7), 484.80(f)(7)(i), 484.80(f)(7)(ii), 484.80(f)(7)(iii), 484.80(f)(7)(iv), 484.80(f)(7)(v) and 484.80(f)(7)(vi). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA

Standard HH4-12C: Home Health Aide training and competency evaluation programs are conducted by qualified instructors. 484.80(c)(3) (G768), 484.80(e) (G780).

Classroom and supervised practical training must be performed by a Registered Nurse who possesses a minimum of 2 years' nursing experience, at least 1 year of which must be in home health care, or by other individuals under the general supervision of the Registered Nurse.

The required 2 years of nursing experience for the instructor should be "hands on" clinical experience such as providing care and/or supervising nursing services or teaching nursing skills in an organized curriculum or in-service program.

The competency evaluation must be performed by a Registered Nurse in consultation with other skilled professionals, as appropriate.

Other individuals may be used to provide instruction under the supervision of a qualified Registered Nurse in consultation with other skilled professionals, as appropriate.

"Other individuals" who may help with aide training would include health care professionals such as Physical Therapists, Occupational Therapists, Medical Social Workers, and Speech-Language Pathologists. Experienced aides, nutritionists, pharmacists, lawyers and consumers might also be teaching resources.

Evidence: Personnel Files

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.80(c)(3) and 484.80(e). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA

Standard HH4-12F: For HHAs that conduct a Home Health Aide competency evaluation program, the HHA meets all of the requirements of the Medicare Conditions of Participation. 484.80(c) (G768), 484.80(c)(1) (G768).

An individual may furnish home health services on behalf of an HHA only after that individual has successfully completed a competency evaluation program as described below.

The competency evaluation must address each of the subjects listed in 42 CFR 484.80 (b)(3). Subject areas specified under 42 CFR 484.80(b)(3)(i), (iii), (ix), (x), and (xi) must be evaluated by observing an aide's performance of the task with patient or pseudo-patient. The remaining subject areas may be evaluated through written examination, oral examination, or after observation of a Home Health Aide with a patient or with a pseudo-patient as part of a simulation.

The competency evaluation program includes, but is not limited to 42 CFR 484.80(b)(3):

- Communication skills, including the ability to read, write, and verbally report clinical information to patients, representatives, and caregivers, as well as to other HHA staff
- Observation, reporting and documentation of patient status and the care or service furnished
- Reading and recording temperature, pulse, and respiration
- Basic infection control procedures
- Basic elements of body functioning and changes in body function that must be reported to an aide's supervisor
- Maintenance of a clean, safe, and healthy environment
- Recognizing emergencies and knowledge of instituting emergency procedures and their applications
- 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
- Appropriate and safe techniques in personal hygiene and grooming tasks that include:
 - Bed bath
 - Sponge, tub, and shower bath
 - Hair shampooing in sink, tub, and bed
 - Nail and skin care
 - Oral hygiene
 - Toileting and elimination
- Safe transfer techniques and ambulation
- Normal range of motion and positioning
- Adequate nutrition and fluid intake
- Any other task that the HHA may choose to have the Home Health Aide perform as permitted under state law

The competency evaluation must address each of the subjects listed in 42 CFR 484.80(b)(3). Subject areas specified under 42 CFR 484.80(b)(3)(i), (iii), (ix), (x), and (xi) must be evaluated by observing an aide's performance of the task with patient or pseudo-patient which include:

- Communication skills, including the ability to read, write, and verbally report clinical information to patients, representatives, and caregivers, as well as to other HHA staff 42 CFR 484.80(b)(3)(i).
- Reading and recording temperature, pulse and respiration 42 CFR 484.80(b)(3)(iii)
- Appropriate and safe techniques in personal hygiene and grooming 42 CFR 484.80(b)(3)(ix) that include:
 - Bed bath
 - Sponge, tub, and shower bath
 - Hair shampooing in sink, tub, and bed
 - Nail and skin care
 - Oral hygiene

- Toileting and elimination
- Safe transfer techniques and ambulation 42 CFR 484.80(b)(3)(x)
- Normal range of motion and positioning 42 CFR 484.80(b)(3)(xi)

The remaining subject areas may be evaluated through written examination, oral examination, or after observation of a Home Health Aide with a patient or pseudo-patient as part of a simulation.

This standard applies to all Home Health Aides providing care/service who are directly employed by the HHA or through a contractual agreement.

Evidence: Home Health Aide Competency Program

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.80(c) and 484.80(c)(1). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA

Standard HH4-12G: The HHA determines if the Home Health Aide successfully completes competency evaluations. 484.80(c)(4) (G770), 484.80(c)(5) (G772) .

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 Registered 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.

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.

The HHA must maintain documentation which demonstrates that the requirements of this standard have been met.

Evidence: Personnel Files

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.80(c)(4) and 484.80(c)(5). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA

Standard HH4-13A: Personal Care Attendants (PCA) who are employed by HHAs to furnish services under a Medicaid personal care benefit must abide by all other requirements for Home Health Aides for the services the PCA perform. 484.80(i) (G828).

An individual may furnish Medicaid personal care aide only services, under a Medicaid personal care benefit. An individual may furnish personal care services as defined in 42 CFR 440.167 on behalf of an HHA. Before the individual may furnish personal care services, the individual must meet all qualification standards established by the state. The individual only needs to demonstrate competency in the services the individual is required to furnish.

Evidence: Personnel Files

Evidence: Observation

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.80(i). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA

Standard HH4-14A: Aides providing skilled or personal care services are supervised in those tasks in the patient's home as appropriate to the service level provided. 484.80(h) (G806), 484.80(h)(1)(i) (G808), 484.80(h)(1)(i)(A), 484.80(h)(1)(i)(B), 484.80(h)(1)(ii) (G810), 484.80(h)(1)(iii) (G812), 484.80(h)(2) (G814), 484.80(h)(3) (G816), 484.80(h)(4) (G818), 484.80(h)(4)(i) (G818), 484.80(h)(4)(ii) (G818), 484.80(h)(4)(iii) (G818), 484.80(h)(4)(iv) (G818), 484.80(h)(4)(v) (G818), 484.80(h)(4)(vi) (G818), 484.80(h)(5) (G820), 484.80(h)(5)(i) (G822), 484.80(h)(5)(ii) (G824), 484.80(h)(5)(iii) (G826) .

If home health aide services are provided to a patient who is receiving skilled nursing, physical or occupational therapy, or speech-language pathology services, a Registered Nurse or other appropriate skilled professional who is familiar with the patient, the patient's plan of care, and the written patient care instructions described in 42 CFR 484.80(g), must complete a supervisory assessment of the aide services being provided no less frequently than every 14 days. The Home Health Aide does not need to be present during supervisory assessment described in 42 CFR 484.80(h)(1)(i)(A). The supervisory assessment must be completed onsite (that is, an in-person visit), or on the rare occasion by using two-way audio-video telecommunications technology that allows

for real-time interaction between the registered nurse (or other appropriate skilled professionals) and the patient, not to exceed one virtual supervisory assessment per patient in a 60-day episode.

If an area of concern in aide services is noted by the supervising Registered Nurse or other appropriate skilled professional, then the supervising individual must make an on-site visit to the location where the patient is receiving care in order to observe and assess the aide while he or she is performing care.

A Registered Nurse or other appropriate skilled professional must make an annual on-site visit to the location where a patient is receiving care in order to observe and assess each aide while he or she is performing care.

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 an onsite in person visit every 60 days to assess the quality of care and services provided by the home health aide and to ensure that services meet the patient's needs and the home health aide does not need to be present during the visit.

Semi-annually the registered nurse must make an onsite visit to the location there each patient is receiving care in order to observe and assess each home health aide while he or she is performing non-skilled care.

If a deficiency in aide services is verified by the Registered Nurse or other appropriate skilled professional during an on-site visit, then the agency must conduct, and the Home Health Aide must complete, a retraining and a competency evaluation for the deficient and related skill(s).

Home Health Aide supervision must ensure that aides furnish care in a safe and effective manner, including, but not limited to, the following elements:

- Following the patient's plan of care for completion of tasks assigned to a Home Health Aide by the Registered Nurse or other appropriate skilled professional
- Maintaining an open communication process with the patient, representative (if any), caregivers, and family
- Demonstrating competency with assigned tasks
- Complying with infection prevention and control policies and procedures
- Reporting changes in the patient's condition
- Honoring patient rights

If the Home Health Agency chooses to provide home health aide services under arrangements, as defined in the Social Security Act 1861(w)(1), the HHA's responsibilities also include, but are not limited to:

- Ensuring the overall quality of care provided by an Aide
- Supervising aide services as described in 42 CFR 484.80 (h)(1) and (2); and
- Ensuring that Home Health Aides who provide services under arrangement have met the training or competency evaluation requirements, or both, of this part.

Evidence: Patient Records

Evidence: Response to Interviews

Evidence: Observation

Evidence: Personnel Files

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.80(h), 484.80(h)(1)(i), 484.80(h)(1)(ii), 484.80(h)(1)(iii), 484.80(h)(2), 484.80(h)(3), 484.80(h)(4), 484.80(h)(4)(i), 484.80(h)(4)(ii), 484.80(h)(4)(iii), 484.80(h)(4)(iv), 484.80(h)(4)(v), 484.80(h)(4)(vi), 484.80(h)(5), 484.80(h)(5)(i), 484.80(h)(5)(ii) and 484.80(h)(5)(iii). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA

Section 5: PROVISION OF CARE AND RECORD MANAGEMENT

The standards in this section apply to documentation and requirements for the service recipient/client/patient/resident record. These standards also address the specifics surrounding the operational aspects of care/services provided.

Standard HH5-1A: There is a patient record for each individual who receives care/service that contains all required documentation. All entries are legible, clear, complete, and appropriately authenticated, dated, and timed. Authentication must include a signature and a title (occupation), or a secured computer entry by a unique identifier, of a primary author who has reviewed and approved the entry. 484.110 (G1008), 484.110(a) (G1010), 484.110(a)(1) (G1012), 484.110(a)(2) (G1014), 484.110(a)(3) (G1016), 484.110(a)(4) (G1018), 484.110(a)(5) (G1020), 484.110(b) (G1024).

A separate patient record is maintained for each patient. The HHA must maintain a clinical record containing past and current information for every patient accepted by the HHA and receiving home health services. Information contained in the clinical record must be accurate, adhere to current clinical record documentation standards of practice, and be available to the physician(s) or allowed practitioner issuing orders for the home health plan of care, and appropriate HHA staff. This information may be maintained electronically.

The patient record contains documentation of all care/service provided, which includes, but is not limited to:

- Comprehensive assessment:
 - Current comprehensive assessment
 - All of the assessments from the most recent home health admission, clinical notes, plans of care, and physician or allowed practitioner orders
- Plans of care
 - Goals in the patient's plans of care and the patient's progress toward achieving them
- Physician or allowed practitioner orders
- All interventions:
 - Medication administration
 - Treatments and services
 - Response to those interventions
- Identifying information
 - Contact information for the patient, patient's representative and patient's primary caregiver(s)
- Contact information for the primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA
- Signed and dated clinical and progress notes
- Copies of summary reports sent to the attending physician or allowed practitioner
- Discharge summary
- Transfer summary
- All other items required by ACHC standard HH5-1A.01

Each home visit, treatment, or care/service is documented in the patient record and signed by the individual who provided the care/service. Signatures are legible, legal and include the proper designation of any credentials. Electronic signatures are acceptable as long as the HHA is following appropriate safeguards to prevent unauthorized access to the patient records.

Stamped physician, allowed practitioner or clinical personnel signatures on orders, treatments, or other documents that are part of the patient's record are not accepted.

Filing of documents into clinical record is current according to the HHA's policy and any applicable state filing timelines.

When comprehensive assessments are corrected, the HHA maintains the original assessment as well as all subsequent corrected assessments.

Evidence: Patient Records

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.110, 484.110(a), 484.110(a)(1), 484.110(a)(2), 484.110(a)(3), 484.110(a)(4), 484.110(a)(5), 484.110(a)(6)(i), 484.110(a)(6)(ii), 484.110(a)(6)(iii) and 484.110(b). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH5-1A.01: Written policies and procedures are established relating to the required content of the patient record.

Written policies and procedures define the required content of the patient record. The patient record includes, but is not limited to:

- Source of referral
- Diagnosis

- Signed release of information and other documents for Protected Health Information
- Admission and informed consent documents
- Assessment of the home, if applicable
- Signed notice of receipt of Patient Rights and Responsibilities
- Advance Directives, if applicable
- Admission and discharge dates from a hospital or other institution, if applicable
- Names of power of attorney and/or healthcare power of attorney, if applicable
- Evidence of coordination of care/service provided by the HHA with others who may be providing care/service, if applicable
- Copies of summary reports sent to physicians or allowed practitioner, if applicable
- Patient/family response to care/service provided

If the HHA has electronic medical records (EMR), the HHA has written policies and procedures and a mechanism to maintain all patient records in an electric format. The EMR is in compliance with federal and state EMR requirements.

Evidence: Written Policies and Procedures

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH5-1B: Written policies and procedures are established and implemented that address access, storage, removal, and retention of patient records and information. 484.110(c) (G1026), 484.110(c)(1) (G1026), 484.110(c)(2) (G1026), 484.110(d) (G1028), 484.110(e) (G1030).

Written policies and procedures are consistent with Health Insurance Portability and Accountability Act (HIPAA) standards. Written policies and procedures include:

- Who can have access to patient records
- Personnel authorized to enter information and review the records
- Any circumstances and the procedure to be followed to remove patient records from the premises or designated electronic storage areas
- A description of the protection and access of computerized records and information
- Back-up procedures, which include, but are not limited to:
 - Electronic transmission procedures
 - Storage of back-up disks and tapes
 - Methods to replace information if necessary
- Conditions for release of information

All active patient records are kept in a secure location. Current electronic patient records are stored in an appropriate secure manner, to maintain the integrity of the patient data through routine backups on- or off-site. The clinical record, its contents, and the information contained therein must be safeguarded against loss or unauthorized use. The HHA must be in compliance with the rules regarding protected health information set out at 45 CFR parts 160 and 164. An HHA has written consent from the patient to release information not authorized by law.

All patient records are retained for a minimum of five years after the discharge of the patient, unless state law stipulates a longer period of time. Records of minor patients are retained until at least five years following the patient's eighteenth birthday or according to state laws and regulations. The HHAs policies and procedures provide for retention of clinical records even if the HHA discontinues operations. When an HHA discontinues operation, it must inform the state agency where clinical records will be maintained.

Portions of patient records may be copied and removed from the licensed premises to ensure that appropriate personnel have information readily accessible to them to enable them to provide the appropriate level of care. The HHA has specific written policies and procedures delineating how these copies will be transported and stored to preserve confidentiality of information.

A patient's clinical record (whether hard copy or electronic form) must be made available to a patient, free of charge, upon request at the next home visit, or within 4 business days (whichever comes first).

The patient record, whether hard copy or in electronic form, is made readily available on request by an appropriate authority.

Evidence: Written Policies and Procedures

Evidence: Patients Records

Evidence: Observation

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.110(c), 484.110(c)(1), 484.110(c)(2), 484.110(d) and 484.110(e). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH5-2A.01: Written policies and procedures are established that describe the process for assessment and the development of the plan of care.

Written policies and procedures describe the process for a patient assessment, the development of the plan of care and the frequency and process for the plan of care review. A Registered Nurse, Physical Therapist, or Speech Language Pathologist conducts an initial assessment to determine eligibility, immediate care and support needs of the patient. The plan of care should be appropriate for the type of care that is needed. Care planning is directed toward driving positive patient outcomes.

Written policies and procedures address the following:

- Medicare patients must have documented eligibility for Medicare benefits and determination of homebound status.
- The initial assessment visit must be held either within 48 hours of referral, or within 48 hours of the patient's return home, or on the physician or allowed practitioner ordered start of care date.
- A comprehensive assessment is completed in a timely manner, consistent with the patient's immediate needs, but no later than five (5) calendar days after the start of care.

The HHA develops written assessment policies and procedures and/or protocols that define specific assessment techniques, specify when outside consultation is needed and provides detailed guidelines for factors to be considered in assessing each component.

Evidence: Written Policies and Procedures

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH5-2B: All patients referred for services have an initial assessment. The initial assessment is conducted within 48 hours of referral and/or within 48 hours of the patient's return home or on the physician's or allowed practitioner's ordered start of care date. 484.55(a) (G512), 484.55(a)(1) (G514), 484.55(a)(2) (G516), 484.60 (G570).

A Registered Nurse must conduct an initial assessment visit to determine the immediate care and support needs of the patient; and, for Medicare patients, to determine eligibility for the Medicare home health benefit, including homebound status. The initial assessment visit must be held either within 48 hours of referral or within 48 hours of the patient's return home, or on the physician or allowed practitioner ordered start of care date.

Patients are accepted for treatment on the basis of a reasonable expectation that an HHA can meet the patient's medical, nursing, rehabilitative, and social needs in the patient's place of residence.

For patients receiving only nursing services or both nursing and therapy services, a Registered Nurse must conduct the initial assessment visit.

When rehabilitation therapy service (speech language pathology, physical therapy, or occupational therapy) is the only service ordered by the physician or allowed practitioner who is responsible for the home health plan of care, the initial assessment visit may be made by the appropriate rehabilitation skilled professional.

For Medicare patients, an occupational therapist may complete the initial assessment when occupational therapy is ordered with another qualifying rehabilitation therapy service (speech-language pathology or physical therapy) that establishes program eligibility.

A patient who requires short term nursing determined at the start of care in addition to ongoing therapy is not considered a therapy-only case, i.e., a one-time visit by a nurse scheduled to remove sutures. Therefore, the RN must do the initial assessment.

Evidence: Patient Records

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.55(a), 484.55(a)(1), 484.55(a)(2) and 484.60. See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH5-2C: Written policies and procedures are established and implemented in regard to the comprehensive assessment being completed in a timely manner, consistent with patient's immediate needs, but no later than 5 calendar days after the start of care. 484.55 (G510), 484.55(b) (G518), 484.55(b)(1) (G520), 484.55(b)(2) (G522), 484.55(b)(3) (G524), 484.55(c) (G526), 484.55(c)(1) (G528), 484.55(c)(2) (G530), 484.55(c)(3) (G532), 484.55(c)(4) (G534), 484.55(c)(6)(i) (G538) 484.55(c)(6)(ii) (G538), 484.55(c)(7) (G540), 484.55(c)(8) (G542).

Each patient must receive, and an HHA must provide, a patient-specific comprehensive assessment that accurately reflects the patient's current health; psychosocial, functional, and cognitive status; and the patient's strengths, goals, and care preferences. The assessment includes information that may be used to demonstrate the patient's progress toward achievement of the goals identified

by the patient and the measurable outcomes identified by the HHA.

The comprehensive assessment is performed on patients referred for services and documented in the patient's record. The comprehensive assessment is conducted and documented whether services continue or not. The comprehensive assessment is appropriate to the patient age and diagnosis (e.g., infant, older adult, prenatal, post-partum, and mental health patient). The comprehensive assessment must identify the patient's continuing need for home care and meet the patient's medical, nursing, rehabilitative, social, and discharge planning needs.

Except as provided in 42 CFR 484.55(b)(3), a Registered Nurse (RN) must complete the comprehensive assessment and for Medicare beneficiaries, determine eligibility for the Medicare home health benefit including homebound status, both at the time of the initial assessment visit and at the time of the comprehensive assessment.

When physical therapy, speech-language pathology, or occupational therapy is the only service ordered by the physician or allowed practitioner, a Physical Therapist, Speech-Language Pathologist or Occupational Therapist may complete the comprehensive assessment, and for Medicare patients, determine eligibility for the Medicare home health benefit, including homebound status. For Medicare patients the Occupational Therapist may complete the comprehensive assessment when occupational therapy is ordered with another qualifying rehabilitation therapy service (speech-language pathology or physical therapy) that establishes program eligibility. If it is the HHA's policy for the RN to perform a comprehensive assessment before the therapist's start of care visit, the nurse could perform a comprehensive assessment on or after the therapist's start-of-care date or the therapist could perform the start of care comprehensive assessment if this is a therapy only case.

HHAs incorporate the use of the current version of the Outcomes and Assessment Information Set (OASIS) items, using the language and groupings of the OASIS items into their comprehensive assessments. The OASIS data items must include: clinical record items, demographics and patient history, living arrangements, supportive assistance, sensory status, integumentary status, respiratory status, elimination status, neuro/emotional/behavioral status, activities of daily living, medications, equipment management, emergent care, and data items collected at inpatient facility admission or discharge only.

The comprehensive assessment must accurately reflect the patient's status, and must include, at a minimum, the following information:

Patient information:

- Patient demographics

The physical health component:

- Diagnosis
- Vital signs
- Identification of additional health problems or pertinent health history
- Data items collected at inpatient facility admission or discharge only
- Review of medications
- Allergies
- Special nutritional needs or dietary requirements and weight loss
- Complete pain and other symptoms assessment
- Head to toe assessment:
 - Respiratory status
 - Elimination status
 - Sensory status
 - Integumentary status
 - Emergent care
- Equipment and supply needs
- Patient/family preferences for treatment and concerns
- Other needed information that could impact the level of services required to meet the patient and family needs

The mental component:

- Orientation/memory
- Reasoning/judgment
- Neuro/emotional/behavioral status
- Depression and suicide risk
- Substance abuse
- Coping mechanisms

The social component:

- The patient's primary caregiver(s), if any, and other available supports, including their:
 - Willingness and ability to provide care
 - Availability and schedules
- Identification of the patient's representative, if any
- Identification of an emergency contact
- Role changes and family dynamics
- language preference

- Communication strengths and barriers, literacy and language skills
- The patient's involvement with social and community resources
- Financial, economic and community resources
- Advance Directive decisions
- Supportive assistance

The environmental component:

- Identification of safety and health hazards
- Presence of adequate living arrangements (no heat, electricity or water)
- Home environmental assessments, which include, the potential for safety and security hazards (e.g., throw rugs, furniture layout, bathroom safety, cluttered stairways and blocked exits, unsecured doors, lack of smoke detectors, and fire risks)
- Emergency preparedness

The economic component:

- A review of the financial resources

Functional limitations:

- The patient's ability to ambulate
- Documentation of all functional limitations
- Documentation of ability to complete Activities of Daily Living (ADL) and Instrumental Activities of Daily Living (IADL) that include:
 - Bathing
 - Dressing
 - Feeding
 - Toileting
 - Transferring
 - Ambulation
 - Use of telephone
 - Shopping
 - Meal preparation
 - Housework
 - Money management
 - Ability to take medication, as appropriate

A complete pain and symptom assessment is conducted at the time of admission based on policies and procedures and/or protocols for assessment and management of pain. The assessment includes, but is not limited to:

- History of pain and its treatment (including non-pharmacological and pharmacological treatment)
- Characteristics of pain, such as:
 - Intensity of pain (e.g., as measured on a standardized pain scale)
 - Descriptors of pain (e.g., burning, stabbing, tingling, aching)
 - Pattern of pain (e.g., constant or intermittent)
 - Location and radiation of pain
 - Frequency, timing and duration of pain
 - Impact of pain on quality of life (e.g., sleeping, functioning, appetite, and mood)
 - Factors such as activities, care, or treatment that precipitate or exacerbate pain
 - Strategies and factors that reduce pain
 - Patient's/family's goals for pain management and their satisfaction with the current level of pain control

Common physical symptoms other than pain are assessed at the time of admission and on an ongoing basis based on policies and procedures/protocols for symptom identification and management. Common symptoms include, but are not limited to:

- Nausea and vomiting
- Anorexia
- Constipation
- Anxiety
- Restlessness
- Dyspnea
- Dehydration
- Skin breakdown
- Sleep disorders

Assessment findings are communicated to all personnel. A physician or allowed practitioner order is obtained if the assessment indicates additional disciplines are needed.

Evidence: Written Policies and Procedures

Evidence: Patient Records

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.55, 484.55(b), 484.55(b)(1), 484.55(b)(2), 484.55(b)(3), 484.55(c), 484.55(c)(1), 484.55(c)(2), 484.55(c)(3), 484.55(c)(4), 484.55(c)(6), 484.55(c)(6)(i),

484.55(c)(6)(ii), 484.55(c)(7) and 484.55(c)(8). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH5-2C.01: Written policies and procedures are established and implemented that address the need for all patients that are admitted with therapy orders to have a discipline specific assessment completed.

The evaluation assessment will be performed on patients referred for services and documented in patient records. The assessment is based on patient need or perceived need and addresses physical and functional status. The evaluation assessment will be documented whether services continue or not. The assessment should be appropriate to the patient diagnosis and age.

The therapy assessment includes, but is not limited to:

The environmental component:

- Identification of safety or health hazards and presence of adequate living arrangements
- Home environmental assessments include the potential for safety and security hazards (e.g. throw rugs, furniture layout, bathroom safety, cluttered stairways and blocked exits, unsecured doors, lack of smoke detectors, fire risks)
- Instructions and interventions are directed to minimizing safety risks and preventing injury

Functional limitations component:

- Patient's mobility
- Patient's restrictions
- Assistive devices
- Medical equipment

The physical health component:

- Patient diagnosis
- Other needed information that could impact the level of services required to meet the patient's needs

The HHA develops written assessment policies and procedures and/or protocols that define specific assessment techniques, specify when outside consultation is needed and provides detailed guidelines for factors to be considered in assessing each component.

Evidence: Written Policies and Procedures

Evidence: Patient Records

Services applicable: OT, PT, ST

Standard HH5-2C.02: Written policies and procedures are established and implemented that address the need for all patients that are admitted for Medical Social Services to have a discipline specific assessment completed.

A Medical Social Services evaluation assessment will be performed on patients referred for Medical Social Services and documented in the patient's record. The assessment is based on patient need or perceived need and addresses financial and social status. The evaluation assessment will be documented whether services continue or not.

The assessment includes, but is not limited to:

The social component:

- Identification of the responsible party
- An emergency contact
- The patient's involvement with social and community activities

The economic component:

- A review of the financial resources available to pay for the care/services provided
- A review of the financial resources to maintain current independent status

Functional limitations:

- Resources needed to manage functional limitations

The mental health component:

- Orientation
- Memory
- Reasoning
- Judgment

The physical health component:

- Identification of health problems and other needed information that could impact the level of services required to meet the patient's needs.

The HHA develops written assessment policies and procedures and/or protocols that define specific assessment techniques, specify when outside consultation is needed and provides detailed guidelines for factors to be considered in assessing each component.

Evidence: Written Policies and procedures
Evidence: Patient Records

Services applicable: MSS

Standard HH5-2E: The comprehensive assessment is updated and revised (including the administration of the OASIS) as frequently as the patient's condition warrants due to a major decline or improvement in the patient's health status, but no less frequently than described in interpretive guidelines. 484.55(d) (G544), 484.55(d)(1) (G546), 484.55(d)(1)(i) (G546), 484.55(d)(1)(ii) (G546), 484.55(d)(1)(iii) (G546), 484.55(d)(2) (G548), 484.55(d)(3) (G550) .

A comprehensive assessment is conducted by a qualified clinician to identify the patient's current health status and continued need (s) for home health services. A comprehensive assessment is updated and revised no less frequently than:

- The last five (5) days of every 60-days beginning with the start of care date unless there is a:
 - Beneficiary elected transfer
 - Significant change in condition or
 - Discharge and return to the same HHA during the 60-day episode
- Within 48 hours of the patient's return to the home from a hospital admission of 24 hours or more for any reason except diagnostic tests or physician or allowed practitioner ordered resumption date
- At discharge
- A significant change in condition as defined by the Home Health Agency

The patient plan of care is updated when the comprehensive assessment is revised.

Evidence: Patient Records

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.55(d), 484.55(d)(1), 484.55(d)(1)(i), 484.55(d)(1)(ii), 484.55(d)(1)(iii), 484.55(d)(2) and 484.55(d)(3). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH5-2F: The comprehensive assessment includes a review of all medications the patient is currently using, both prescription and non-prescription. The drug regimen review occurs as an ongoing part of the care to the patient. 484.55(c) (5) (G536)

A medication profile is part of the patient-specific comprehensive assessment. A Registered Nurse (RN) or Physical Therapist, Occupational Therapist or Speech-Language Pathologist (for therapy only cases) reviews all of the patient's prescription and over-the-counter drugs, herbal remedies and other alternative treatments that could affect drug therapy on an ongoing basis.

A Registered Nurse (RN) or Physical Therapist, Occupational Therapist or Speech-Language Pathologist (for therapy only cases) reviews all medications that the patient is currently using in order to identify any potential adverse effects, drug reactions and are accountable for evaluating the following, which includes, but is not limited to:

- Ineffective drug therapy
- Effectiveness of drug therapy
- Significant drug side effects
- Immediate desired effects
- Unusual and unexpected effects
- Significant drug interactions
- Duplicate drug therapy

- Non-compliance with drug therapy
- Drug therapy currently associated with laboratory monitoring
- Allergic reactions
- Changes in the patient's condition that contraindicates continued administration of the medication

A medication profile includes, but is not limited to:

- All current patient medications
- Date prescribed or taken
- Name of medication
- Dose
- Route
- Frequency
- Date discontinued
- Drug and/or food allergies

Conclusions of the medication review and other pertinent information are documented in the patient record as part of the comprehensive assessment and on an ongoing basis.

In addition, a Registered Nurse (RN) or Physical Therapist, Occupational Therapist or Speech-Language Pathologist (for therapy only cases) are able to anticipate those effects which may rapidly endanger a patient's life or wellbeing and instruct the patient, family members and/or caregiver, as necessary, in following the prescribed regimen.

The physician or allowed practitioner is notified promptly regarding any medication discrepancies, side effects, problems or reactions.

The label on the bottle of a prescription medication constitutes the pharmacist's transcription or documentation of the order. Such medications are noted in the patient's clinical record and listed on the plan of care. This is consistent with acceptable standards of practice.

Evidence: Patient Records

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.55(c)(5). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH5-2F.01: Written policies and procedures are established and implemented that identify the drugs or drug classifications and routes that are not approved for administration by HHA personnel.

Written policies and procedures identify the drugs or drug classifications and/or routes not approved by the governing board for administration by nursing personnel.

The policies and procedures also address any blood or blood products that may or may not be administered.

Evidence: Written Policies and Procedures

Evidence: Response to Interviews

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH5-2F.02: Written policies and procedures are established and implemented in regard to the requirements for agency staff administering the first dose of a medication in the home setting.

The HHA may elect not to administer the first dose of a medication in the home or may have specific written requirements that allow administration of the first dose. The HHA defines when first dose policies and procedures are appropriate based on the medication route and potential reaction.

The following are reviewed prior to administering the first dose in the home:

- The history of being allergic to this class of medication
- Orders have been received outlining the steps to take and the medication(s) to be given should an anaphylactic reaction occur
- Giving the first dose in the hospital, physician's or allowed practitioner's office or other medical facility has been considered and has been rejected
- The location and phone numbers for emergency support have been identified and a procedure to utilize these facilities has been developed
- The nurse administering the medication stays with the patient at least a half hour after the administration of the medication to ensure the patient has tolerated the medication well

- The appropriate monitoring of the patient after the first dose is administered

Evidence: Written Policies and Procedures

Evidence: Response to Interviews

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH5-3A: There is a written plan of care for each patient accepted to services. 484.60 (G570), 484.60(a) (G572), 484.60(a)(1) (G572), 484.60(a)(2) (G574), 484.60(a)(2)(i) (G574), 484.60(a)(2)(ii) (G574), 484.60(a)(2)(iii) (G574), 484.60(a)(2)(iv) (G574), 484.60(a)(2)(v) (G574), 484.60(a)(2)(vi) (G574), 484.60(a)(2)(vii) (G574), 484.60(a)(2)(viii) (G574), 484.60(a)(2)(ix) (G574), 484.60(a)(2)(x) (G574), 484.60(a)(2)(xi) (G574), 484.60(a)(2)(xii) (G574), 484.60(a)(2)(xiii) (G574), 484.60(a)(2)(xiv) (G574), 484.60(a)(2)(xv) (G574), 484.60(a)(2)(xvi) (G574), 484.60(a)(3) (G576) .

The plan of care is developed in consultation with the patient, physician, or allowed practitioner, and agency staff.

The initial plan of care includes, but is not limited to:

- Start of care date
- Certification period
- Patient demographics
- Principle diagnoses and other pertinent diagnoses
- Medications: dose/frequency/route
- Allergies
- Orders for therapy services, include specific procedures and modalities to be used
- Orders for all disciplines include amount, frequency, duration of visits to be made
- Equipment and supply needs
- Caregiver needs
- Functional limitations,
- Diet and nutritional requirements
- Safety measures to protect against injury
- Patient specific interventions and education, measurable outcomes and goals identified by the HHA and the patient
- Problems/needs
- Interventions
- Expected patient outcomes/goals
- Treatments/orders
- Mental/psychosocial/cognitive status
- Rehabilitation potential
- Activities permitted
- Prognosis
- Patient and caregiver education and training to facilitate timely discharge
- A description of the patient's risk for emergency department visits and hospital re-admission, and all necessary interventions to address the underlying risk factors
- Information related to any Advance Directives
- Any additional items the HHA or physician or allowed practitioner may choose to include

Each patient must receive an individualized written plan of care, including any revisions or additions. The individualized plan of care must specify the care and services necessary to meet the patient-specific needs as identified in the comprehensive assessment, including identification of the responsible discipline(s), and the measurable outcomes that the HHA anticipates will occur as a result of implementing and coordinating the plan of care. The individualized plan of care must also specify the patient and caregiver education and training. Services must be furnished in accordance with accepted standards of practice.

The HHA has a responsibility to obtain physician or allowed practitioner orders prior to initiation of the care and to notify the physician or allowed practitioner of any changes in the patient's condition.

All patient care orders, including verbal orders, must be recorded in the plan of care.

The plan of care will delineate specific services and assessments to be delivered based on the evaluation and will include amount, frequency, duration, and expected outcomes for the patient.

Physician or allowed practitioner orders are needed to provide any care requiring the administration of medication, treatment(s), on-going assessments or other activities governed by state law.

If a physician or allowed practitioner refers a patient under a plan of care that cannot be completed until after an evaluation visit, the physician or allowed practitioner is consulted to approve additions or modification to the original plan.

Evidence: Patient Records

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.60, 484.60(a), 484.60(a)(1), 484.60(a)(2), 484.60(a)(2)(i), 484.60(a)(2)(ii), 484.60(a)(2)(iii), 484.60(a)(2)(iv), 484.60(a)(2)(ix), 484.60(a)(2)(v), 484.60(a)(2)(vi), 484.60(a)(2)(vii), 484.60(a)(2)(viii), 484.60(a)(2)(x), 484.60(a)(2)(xi), 484.60(a)(2)(xii), 484.60(a)(2)(xiii), 484.60(a)(2)(xiv), 484.60(a)(2)(xv), 484.60(a)(2)(xvi) and 484.60(a)(3). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH5-3B: Care follows a written plan of care established and periodically reviewed by a Doctor of Medicine, osteopathy, or podiatric medicine. 484.60(a)(1) (G572), 484.60(b) (G578), 484.60(b)(1) (G580), 484.60(b)(2) (G582).

Each patient must receive the home health services that are written in an individualized plan of care that identifies patient-specific measurable outcomes and goals, and which is established, periodically reviewed, and signed by a doctor of medicine, osteopathy, podiatry or allowed practitioner acting within the scope of his or her state license, certification, or registration.

The plan of care conforms with physician or allowed practitioner orders: Drugs, services and treatments are administered only as ordered by the physician or allowed practitioner. Influenza and pneumococcal vaccines may be administered per agency policy developed in consultation with a physician or allowed practitioner, and after an assessment of the patient to determine any contraindications.

Evidence: Patient Records

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.60(a)(1), 484.60(b), 484.60(b)(1), 484.60(b)(2) and 484.60(c). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH5-3C: The HHA must provide the patient and caregiver with a copy of written instruction in regard to care to be provided. 484.60(e) (G612), 484.60(e)(1) (G614), 484.60(e)(2) (G616), 484.60(e)(3) (G618), 484.60(e)(4) (G620), 484.60(e)(5) (G622).

The HHA must provide the patient and caregiver with a copy of written instructions outlining:

- Visit schedule, including frequency of visits by HHA personnel and personnel acting on behalf of the HHA
- Patient medication schedule/instructions, including: medication name, dosage and frequency and which medications will be administered by HHA personnel and personnel acting on behalf of the HHA
- Any treatments to be administered by HHA personnel and personnel acting on behalf of the HHA, including therapy services
- Any other pertinent instruction related to the patient's care and treatments that the HHA will provide, specific to the patient's care needs
- Name and contact information of the HHA clinical manager

Evidence: Patient Records

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.60(e), 484.60(e)(1), 484.60(e)(2), 484.60(e)(3), 484.60(e)(4) and 484.60(e)(5). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH5-4A: All personnel involved in the patient's care are responsible for coordinating care effectively to support the objectives outlined in the patient's plan of care. 484.60(d) (G600), 484.60(d)(1) (G602), 484.60(d)(2) (G604), 484.60(d)(3) (G606), 484.60(d)(4) (G608), 484.60(d)(5) (G610) .

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 HHA coordinates care by:

- Ensuring communication with all physicians or allowed practitioner involved in the plan of care
- Integrating orders from all physicians or allowed practitioner involved in the plan of care to assure the coordination of all services and interventions provided to the patient
- Integrating services, whether services are provided directly or under arrangement, to assure the identification of patient needs and factors that could affect patient safety and treatment effectiveness and the coordination of care provided by all disciplines

- Coordinating care delivery to meet the patient's needs, and involve the patient, representative (if any), and caregiver(s), as appropriate, in the coordination of care activities
- Ensuring that each patient, and his or her caregiver(s) where applicable, receives ongoing education and training provided by the HHA, as appropriate, regarding the care and services identified in the plan of care. The HHA must provide training, as necessary, to ensure a timely discharge

The clinical record or minutes of case conferences establish that effective interchange, reporting, and coordination of patient care does occur.

Evidence: Patient Records

Evidence: Case Conference Notes or Similar Documentation of Coordination of Care

Evidence: Written Policies and Procedures

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.60(d), 484.60(d)(1), 484.60(d)(2), 484.60(d)(3), 484.60(d)(4) and 484.60(d)(5). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH5-5A: There is evidence that the plan of care is reviewed by personnel involved in the patient's care and the attending physician or allowed practitioner at least once every 60 days. 484.60(c)(1) (G588) (G590).

The individualized plan of care must be reviewed and revised by the physician or allowed practitioner who is responsible for the home health plan of care and the HHA as frequently as the patient's condition or needs requires, but no less frequently than once every 60 days, beginning with the start-of-care date or more frequently when there is a:

- Beneficiary elected transfer
- A significant change in condition
- Discharge and return to the same HHA during the 60-day episode

In addition, the plan of care is reviewed:

- When there are changes in patient's response to therapy
- When physician or allowed practitioner orders change
- At the request of the patient
- As defined in the HHA's policies and procedures

There is documentation in the patient record that reflects the plan of care is reviewed at least every 60 days for:

- Appropriateness (care being provided is still needed)
- Effectiveness (patient outcomes/response to care)
- To determine if all needed care is being provided
- Change in patient's condition

Included in this review is a discussion with the patient/responsible party to determine the level of satisfaction with the care being provided. The HHA follows program policies and procedures and any applicable laws and rules for the frequency of the plan of care review.

Evidence: Patient Records

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.60(c) and 484.60(c)(1). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH5-6A: Written policies and procedures are established and implemented in regard to the process for transferring or discharging a patient receiving Home Health Services. 484.50(c)(8) (G442), 484.50(d) (G452), 484.50(d)(1) (G454), 484.50(d)(2) (G456), 484.50(d)(3) (G458), 484.50(d)(4) (G460), 484.50(d)(5) (G462), 484.50(d)(5)(i) (G464), 484.50(d)(5)(ii) (G466), 484.50(d)(5)(iii) (G468), 484.50(d)(5)(iv) (G470), 484.50(d)(6) (G472), 484.50(d)(7) (G474), 484.58(a) (G562), 484.58(b)(1) (G564), 484.58(b)(2), 484.110(a)(6)(i) (G1022), 484.110(a)(6)(ii) (G1022), 484.110(a)(6)(iii) (G1022) .

The HHA's transfer and discharge policies and procedures define the circumstances when a patient would be transferred to another organization or discharged.

The patient and patient representative (if any), have the right to be informed of the HHA's policies and procedures on transfers and discharges. The HHA may only discharge or transfer a patient from the HHA if:

- The transfer or discharge is necessary for the patient's welfare because the HHA and the physician or allowed practitioner who is responsible for the home health plan of care agree that the HHA can no longer meet the patient's needs, based on the patient's acuity. The HHA must arrange a safe and appropriate transfer to other care entities when the needs of the patient exceed the HHA's capabilities;
- The patient or payor will no longer pay for the services provided by the HHA;
- The transfer or discharge is appropriate because the physician or allowed practitioner who is responsible for the home health plan of care and the HHA agree that the measurable outcomes and goals set forth in the plan of care in accordance with 42 CFR 484.60(a)(2)(xiv) have been achieved, and the HHA and the physician who is responsible for the home health plan of care agree that the patient no longer needs the HHA's services;
- The patient refuses services, or elects to be transferred or discharged
- The HHA determines, under a policy set by the HHA for the purpose of addressing discharge for cause that meets the requirements of 42 CFR 484.50(d)(5)(i) through (d)(5)(iii), that the patient's (or other persons in the patient's home) behavior is disruptive, abusive, or uncooperative to the extent that delivery of care to the patient or the ability of the HHA to operate effectively is seriously impaired. The HHA must do the following before it discharges a patient for cause:
 - Advise the patient, representative (if any), the physician(s) or allowed practitioner issuing orders for the home health plan of care, and the patient's primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA (if any) that a discharge for cause is being considered;
 - Make efforts to resolve the problem(s) presented by the patient's behavior, the behavior of other persons in the patient's home, or situation;
 - Provide the patient and representative (if any), with contact information for other agencies or providers who may be able to provide care; and
 - Document the problem(s) and efforts made to resolve the problem(s), and enter this documentation into its clinical records;
- The patient dies; or
- The HHA ceases to operate

The HHA must develop and implement an effective transfer and discharge planning process for patients who are transferred to another HHA or who are discharged to a Skilled Nursing Facility (SNF), Inpatient Rehabilitation Facility (IRF), or Long Term Care Hospital (LTCH), the HHA must assist patients and their caregivers in selecting a post-acute care provider by using and sharing data that includes, but is not limited to HHA, SNF, IRF, or LTCH data on quality measures and data on resource use measures. The HHA must ensure that the post-acute care data on quality measures and data on resource use measures is relevant and applicable to the patient's goals of care and treatment preferences.

The HHA must send all necessary medical information pertaining to the patient's current course of illness and treatment, post-discharge goals of care, and treatment preferences, to the receiving facility or health care practitioner to ensure the safe and effective transition of care.

The HHA must comply with requests for additional clinical information as may be necessary for treatment of the patient made by the receiving facility or health care practitioner.

A transfer summary is completed and a copy maintained in the patient record and a copy forwarded to the receiving service entity. A transfer summary includes, but is not limited to:

- Date of transfer
- Patient identifying information
- Emergency contact
- Destination of patient transferred
- Date and name of person receiving report
- Patient's physician or allowed practitioner and phone number
- Diagnosis related to the transfer
- Significant health history
- Transfer orders and instructions
- A brief description of services provided and ongoing needs that cannot be met
- Status of patient at the time of transfer

The discharge summary includes, but is not limited to:

- Date of discharge
- Patient identifying information
- Patient's physician or allowed practitioner and phone number
- Diagnosis
- Reason for discharge
- A brief description of care provided
- Patient's medical and health status at the time of discharge
- Any instructions given to the patient or responsible party

Discharge summary

- A completed discharge summary is sent to the primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA (if any) within 5 business days of the patient's discharge

Transfer summary

- A completed transfer summary is sent within 2 business days of a planned transfer, if the patient's care will be immediately continued in a health care facility; or
- A completed transfer summary is sent within 2 business days of becoming aware of an unplanned transfer, if the patient is still receiving care in a health care facility at the time when the HHA becomes aware of the transfer

Medicare and Medicare HMO patients are issued a Notice of Medicare Non-Coverage (NOMNC) at least 48 hours prior of termination of Home Health Services which explains the patients' right to an immediate independent review of the proposed discontinuation of services.

Patient has received proper written notice, in advance of a specific service being furnished, if the HHA believes that the service may be non-covered care; or in advance of the HHA reducing or terminating on-going care. The HHA must also comply with the requirements of 42 CFR 405.1200 through 405.1204.

Evidence: Written Policies and Procedures

Evidence: Patient Records

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.110(a)(6)(i), 484.110(a)(6)(ii), 484.110(a)(6)(iii), 484.50(c)(8), 484.50(d), 484.50(d)(1), 484.50(d)(2), 484.50(d)(3), 484.50(d)(4), 484.50(d)(5), 484.50(d)(5)(i), 484.50(d)(5)(ii), 484.50(d)(5)(iii), 484.50(d)(5)(iv), 484.50(d)(6) and 484.50(d)(7). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH5-8A: Written policies and procedures are established and implemented in regard to verbal orders only being accepted by personnel authorized to do so by applicable state and federal laws and regulations, as well as by the HHA's policies and procedures. 484.60(b)(3) (G584), 484.60(b)(4) (G584) .

When services are provided on the basis of a physician's or allowed practitioner's verbal orders a nurse acting in accordance with state licensure requirements, or other qualified practitioner responsible for furnishing or supervising the ordered services, in accordance with state law and the HHA's policies, must document the orders in the patient's clinical record, and sign, date and time the orders. (See ACHC Glossary of Personnel Qualifications as defined by the Medicare Conditions of Participation.)

Verbal orders must be authenticated and dated by the physician or allowed practitioner in accordance with applicable state law and regulations, as well as the HHA's internal policies.

Evidence: Written Policies and Procedures

Evidence: Patient Records

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.60(b)(3) and 484.60(b)(4). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH5-8B: The HHAs personnel promptly alert the physician(s) or allowed practitioner to any changes in the patient's condition or needs that suggest outcomes are not being achieved and/or that the plan of care should be altered. 484.60(c)(1) (G588) (G590), 484.60(c)(2) (G592), 484.60(c)(3) (G594), 484.60(c)(3)(i) (G596) 484.60(c)(3)(ii) (G598).

A revised plan of care must reflect current information from the patient's updated comprehensive assessment, and contain information concerning the patient's progress toward the measurable outcomes and goals identified by the HHA and patient in the plan of care.

Changes in the patient's condition that require a change in the plan of care should be documented in the patient's clinical record.

The clinical record should maintain documentation that the physician or allowed practitioner was notified of the discharge, but it does not need to contain a physician's or allowed practitioner's order for discharge unless required by the HHA's policies and procedures and/or state law.

Revisions to the plan of care must be communicated as follows:

- Any revision to the plan of care due to a change in patient health status must be communicated to the patient, representative (if any), caregiver, and all physicians or allowed practitioner issuing orders for the HHA plan of care

- Any revisions related to plans for the patient's discharge must be communicated to the patient, representative, caregiver, all physicians or allowed practitioner issuing orders for the HHA plan of care, and the patient's primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA (if any)

Evidence: Patient Records

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.60(c)(1), 484.60(c)(2), 484.60(c)(3), 484.60(c)(3)(i) and 484.60(c)(3)(ii). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH5-10A: Written policies and procedures are established and implemented in regard to how outpatient services are rendered. 484.105(g) (G986).

An HHA that wishes to furnish outpatient physical therapy or speech pathology services must meet all of the applicable conditions of this part and the additional health and safety requirements set forth in 42 CFR 485.711, 42 CFR 485.713, 42 CFR 485.715, 42 CFR 485.719, 42 CFR 485.723, and 42 CFR 485.727 to implement the Social Security Act, section 1861(p).

An HHA that furnishes outpatient therapy services on its own premises, including its branches, must comply with the listed citations as well as meet all other Medicare Conditions of Participation

The individual therapist may develop the plan of care for outpatient physical and speech pathology therapy services. For Medicare patients receiving outpatient physical and/or speech pathology therapy services, the plan of care and results of treatment must be reviewed by a physician or allowed practitioner. Non-Medicare patients are not required to be under the care of a physician or allowed practitioner, and therefore do not need a plan of care established by and reviewed by a physician or allowed practitioner. For non-Medicare patients, the plan of care may be reviewed by the therapist who established it or by a physician or allowed practitioner.

Evidence: Written Policies and Procedures

Evidence: Patient Records

Evidence: Observation

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.105(g). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: PT, ST

Standard HH5-11A: The HHA furnishes skilled professional services. Skilled professional services include skilled nursing services, physical therapy, speech-language pathology services, and occupational therapy, as specified in 42 CFR 409.44, and physician or allowed practitioner and medical social work services as specified in 42 CFR 409.45. 484.75 (G700), 484.75(a) (G702), 484.75(b) (G704), 484.75(b)(1) (G706), 484.75(b)(2) (G708), 484.75(b)(3) (G710), 484.75(b)(4) (G712), 484.75(b)(5) (G714), 484.75(b)(6) (G716), 484.75(b)(7) (G718), 484.75(b)(8) (G720), 484.75(b)(9) (G722), 484.75(c) (G724), 484.75(c)(1) (G726) 484.75(c)(2) (G728) 484.75(c)(3) (G730) .

The provision of services by skilled professionals are authorized, delivered, and supervised only by health care professionals who meet the appropriate qualifications specified under 42 CFR 484.115 (see ACHC Glossary of Personnel Qualifications) and who practice according to the HHA's policies and procedures.

Skilled professionals who provide services to HHA patients directly or under arrangement must participate in the coordination of care.

Skilled professionals must assume responsibility for, but not be restricted to, the following:

- Ongoing interdisciplinary assessment of the patient
- Development and evaluation of the plan of care in partnership with the patient, representative (if any), and caregiver(s)
- Providing services that are ordered by the physician or allowed practitioner as indicated in the plan of care
- Patient, caregiver, and family counseling
- Patient and caregiver education
- Preparing clinical notes
- Communication with all physicians or allowed practitioner involved in the plan of care and other health care practitioners (as appropriate) related to the current plan of care
- Participation in the HHA's QAPI program; and
- Participation in HHA-sponsored in-service training
- Supervision of skilled therapy professional assistants and licensed practical or vocational nurses:

- A visit to patient's home by qualified supervising professional, with or without the assistance present at least every 60 days, unless state laws requires more frequently
- Patient record reviews, conferences, ongoing communication
- Collaborative care planning
- Supervision of social worker assistants by master's degree prepared medical social worker:
 - Periodically approves the plan of care
 - Provides clinical supervision at least every 60 days, unless state laws requires more frequently
 - Case conferences, joint visits or both depending on the needs of the patient and skills of the assistant

Supervisory visits are documented in patient records.

Nursing services are provided under the direction of a Registered Nurse (RN), that meets the requirements of 42 CFR 484.115(k) and ACHC Glossary of Personnel Qualifications as defined by Medicare's Conditions of Participation.

Rehabilitative therapy services are provided under the supervision of an occupational therapist or physical therapist that meets the requirements of 42 CFR 484.115(f) or (h), respectively and ACHC Glossary of Personnel Qualifications as defined by Medicare's Conditions of Participation.

Medical social services are provided under the supervision of a social worker that meets the requirements of 42 CFR 484.115(m) and ACHC Glossary of Personnel Qualifications as defined by Medicare's Conditions of Participation.

Current copies of applicable rules and regulations and the state's Practice Acts are available to personnel.

Evidence: Job Description
 Evidence: Patient Records
 Evidence: Observation
 Evidence: Personnel Files

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.75, 484.75(a), 484.75(b), 484.75(b)(1), 484.75(b)(2), 484.75(b)(3), 484.75(b)(4), 484.75(b)(5), 484.75(b)(6), 484.75(b)(7), 484.75(b)(8), 484.75(b)(9), 484.75(c), 484.75(c)(1), 484.75(c)(2) and 484.75(c)(3). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: MSS, OT, PT, SN, ST

Standard HH5-11F: The HHA defines the duties of the Home Health Aide and ensures they are implemented in patient care. 484.80(g) (G798), 484.80(g)(1) (G798), 484.80(g)(2) (G800), 484.80(g)(2)(i) (G800), 484.80(g)(2)(ii) (G800), 484.80(g)(2)(iii) (G800), 484.80(g)(2)(iv) (G800), 484.80(g)(3)(i) (G802), 484.80(g)(3)(ii) (G802), 484.80(g)(3)(iii) (G802), 484.80(g)(3)(iv) (G802), 484.80(g)(4) (G804) .

The Home Health Aide is assigned to a specific patient by the Registered Nurse or other appropriate skilled professional with written patient care instructions for the Home Health Aide prepared by the Registered Nurse or other appropriate skilled professional (that is, physical therapist, speech-language pathologist, or occupational therapist).

The Registered Nurse or other qualified skilled professional must develop the plan of care; indicate what tasks are to be done by the Aide and the frequency of these tasks. The use of "PRN" or "per patient choice," for any task, whether personal care or non-personal care tasks, is not acceptable.

The Home Health Aide meets the qualifications outlined in the ACHC Glossary of Personnel Qualifications as defined by Medicare's Conditions of Participation.

The Home Health Aide provides services that are:

- Ordered by a physician or allowed practitioner
- Included in the plan of care
- Permitted to be performed under state law and
- Consistent with the home health aide training

The duties of the Home Health Aide include but are not limited to:

- The provision of hands-on care
- The performance of simple procedures as an extension of therapy or nursing services
- Assistance in ambulation or exercises and
- Assistance in administering medications ordinarily self-administered

Home Health Aides must be members of the interdisciplinary team, must report changes in the patient's condition to a Registered Nurse or other appropriate skilled professional, and must complete appropriate records in compliance with the HHA's policies and procedures.

Evidence: Job Description

Evidence: Patient Records
Evidence: Observation
Evidence: Personnel Files

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.80(g), 484.80(g)(1), 484.80(g)(2), 484.80(g)(2)(i), 484.80(g)(2)(ii), 484.80(g)(2)(iii), 484.80(g)(2)(iv), 484.80(g)(3), 484.80(g)(3)(i), 484.80(g)(3)(ii), 484.80(g)(3)(iii), 484.80(g)(3)(iv) and 484.80(g)(4). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA

Standard HH5-12A.01: Written policies and procedures are established in regard to the process for patient/caregiver education.

Written policies and procedures describe patient/caregiver education.

The policies and procedures include, but are not limited to:

- Treatment and disease management education
- Proper use, safety hazards, and infection control issues related to the use and maintenance of any equipment provided
- Plan of care
- Emergency preparedness information

Evidence: Written Policies and Procedures
Evidence: Observation

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH5-13A.01: Written policies and procedures are established and implemented in regard to the patient referral and acceptance process.

Written policies and procedures describe the referral process including the required information and the positions designated in the HHA that may receive referrals.

Referrals containing verbal orders are given to the designated professional for verification and documentation of verbal orders.

Care/service needs which cannot be met by the HHA are addressed by referring the patient to other organizations when appropriate.

The HHA maintains a referral log or other tool to record all referrals. Referral sources are notified when patient needs cannot be met and are not being admitted to the HHA.

Personnel are knowledgeable about other care/services available in the community.

Evidence: Written Policies and Procedures
Evidence: Observation

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH5-14B.01: The HHA obtains a statement of certification from the physician or allowed practitioner that the patient is eligible for the Medicare Home Health Care benefit.

The physician or allowed practitioner must certify, per the Medicare Benefits Policy Manual section 30.5.1 that the patient is eligible by using the following criteria:

- The home health services are or were needed because the patient is homebound as defined in section §30.1
- The patient needs or needed skilled nursing services on an intermittent basis, or physical therapy, or speech-language pathology services
- A plan of care has been established and is periodically reviewed by a physician or allowed practitioner
- The services are or were furnished while the patient is or was under the care of a physician or allowed practitioner
- A face-to-face encounter occurred no more than 90 days prior to or within 30 days after the start of the home health care, was related to the primary reason the patient requires home health services and was performed by an allowed provider type. The certifying physician or allowed practitioner must also document the date of the encounter
- The certification must be complete prior billing Medicare for reimbursement

Evidence: Patient Records

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH5-16A.01: Written policies and procedures are established and implemented in regard to the verification of the credentials of the referring physician or allowed practitioner prior to providing service/care.

Written policies and procedures describe the process for verification of physician or allowed practitioner credentials. Ongoing periodic assessments of current physician or allowed practitioner credentials are obtained from state and federal licensing/certification boards. The HHA has a mechanism to ensure that orders are only accepted from currently credentialed physicians or allowed practitioner.

Evidence: Written Policies and Procedures

Evidence: Observation

Services applicable: HHA, MSS, OT, PT, SN, ST

Section 6: QUALITY OUTCOMES/PERFORMANCE IMPROVEMENT

The standards in this section apply to the organization's plan and implementation of a Performance Improvement (PI) program. Items addressed in these standards include who is responsible for the program, activities being monitored, how data is compiled, and corrective measures being developed from the data and outcomes.

Standard HH6-1A: The HHA must develop, implement, evaluate and maintain an effective, on-going, HHA-wide, data-driven Quality Assessment and Performance Improvement (QAPI) program. The HHA's governing body must ensure that the program reflects the complexity of its organization and services; involves all HHA services (including those services provided under contract or arrangement); focuses on indicators related to improved outcomes, including the use of emergent care services, hospital admissions and re-admissions; and takes actions that address the HHA's performance across the spectrum of care, including the prevention and reduction of medical errors. The HHA must maintain documentary evidence of its QAPI program and be able to demonstrate its operation to CMS. The HHA measures, analyzes, and tracks quality indicators, including adverse patient events, and other aspects of performance that enable the HHA to assess processes of care, services, and operations. 484.65 (G640), 484.65(a) (G642), 484.65(a)(1) (G642), 484.65(a)(2) (G642), 484.65(b) (G644), 484.65(b)(1) (G644), 484.65(b)(2) (G644), 484.65(b)(2)(i) (G644), 484.65(b) (G644), (2)(ii) (G644), 484.65(b)(3) (G644), 484.65(c) (G646), 484.65(c)(1) (G648), 484.65(c)(1)(i) (G648), 484.65(c)(1)(ii) (G650), 484.65(c)(1)(iii) (G652), 484.65(c)(2) (G654), 484.65(c)(3) (G656), 484.65(d) (G658), 484.65(d)(1) (G658), 484.65(d)(2) (G658) .

Each HHA develops a program that is specific to its needs. The methods used by the HHA for reviewing data include, but are not limited to:

- Current documentation (e.g., review of clinical records, incident reports, complaints, patient satisfaction surveys, etc.)
- Patient care
- Direct observation of clinical performance
- Operating systems
- Interviews with patients and/or personnel

The program must at least be capable of showing measurable improvement in indicators for which there is evidence that improvement in those indicators will improve health outcomes, patient safety, and quality of care.

The program must utilize quality indicator data, including measures derived from OASIS, where applicable, and other relevant data, in the design of its program.

Ongoing means that there is a continuous and periodic collection and assessment of data. Assessment of such data enables identification of potential problems and indicates when additional data is needed.

The HHA must use the data collected to:

- Monitor the effectiveness and safety of services and quality of care; and
- Identify opportunities for improvement
- The frequency and detail of the data collection must be approved by the HHA's governing body

The HHA's performance improvement activities must:

- Focus on high risk, high volume, or problem-prone areas;
- Consider incidence, prevalence, and severity of problems in those areas; and
- Lead to an immediate correction of any identified problem that directly or potentially threaten the health and safety of patients.
- Performance improvement activities must track adverse patient and personnel events, analyze their causes, and implement preventive actions.
- The HHA must take actions aimed at performance improvement, and, after implementing those actions, the HHA must measure its success and track performance to ensure that improvements are sustained.

Beginning July 13, 2018 HHAs must conduct performance improvement projects:

- The number and scope of distinct improvement projects conducted annually must reflect the scope, complexity, and past performance of the HHA's services and operations
- The HHA must document the quality improvement projects undertaken, the reasons for conducting these projects, and the measurable progress achieved on these projects

Evidence: Written Policies and Procedures

Evidence: Observation

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.65, 484.65(a), 484.65(a)

(1), 484.65(a)(2), 484.65(b), 484.65(b)(1), 484.65(b)(2), 484.65(b)(2)(i), 484.65(b)(2)(ii), 484.65(b)(3), 484.65(c), 484.65(c)(1), 484.65(c)(1)(i), 484.65(c)(1)(ii), 484.65(c)(1)(iii), 484.65(c)(2), 484.65(c)(3), 484.65(d), 484.65(d)(1) and 484.65(d)(2). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH6-1B.01: The HHA ensures the implementation of an agency-wide Quality Assessment and Performance Improvement (QAPI) Program by the designation of a person responsible for coordinating QAPI activities.

Duties and responsibilities relative to QAPI coordination include:

- Assisting with the overall development and implementation of the QAPI program
- Assisting in the identification of goals and related patient outcomes
- Coordinating, participating and reporting of activities and outcomes

The position responsible for coordinating QAPI activities may be the owner, manager, supervisor, or other personnel and these duties are included in the individual's job description.

Evidence: Job Description

Evidence: Observation

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH6-1C: There is evidence of involvement of the governing body/owner and organizational leaders in the Quality Assessment and Performance Improvement (QAPI) process. 484.65(e) (G660), 484.65(e)(1) (G660), 484.65(e)(2) (G660), 484.65(e)(3) (G660), 484.65(e)(4) (G660) .

The governing body/owner are ultimately responsible for all actions and activities of the HHA QAPI program. The QAPI program includes, but is not limited to:

- That an ongoing program for QAPI and patient safety is defined, implemented, and maintained
- That the HHA-wide QAPI efforts address priorities for improved quality of care and patient safety, and that all improvement actions are evaluated for effectiveness;
- That clear expectations for patient safety are established, implemented, and maintained; and
- That any findings of fraud or waste are appropriately addressed

There is evidence that the results of QAPI activities are communicated to the governing body/owner and organizational Administrators.

The HHA's Administrators allocate resources for implementation of the QAPI program. Resources include, but are not limited to:

- Training and education programs regarding QAPI
- Personnel time
- Information management systems
- Computer support

Evidence: Governing Body Meeting Minutes, if applicable

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.65(e), 484.65(e)(1), 484.65(e)(2), 484.65(e)(3) and 484.65(e)(4). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH6-1D.01: There is evidence of personnel involvement in the Quality Assessment and Performance Improvement (QAPI) program.

Personnel receive training related to QAPI activities and their involvement. Training includes, but is not limited to:

- The purpose of QAPI activities
- Person(s) responsible for coordinating QAPI activities
- Individual's role in QAPI
- PI outcomes resulting from previous activities

Personnel are involved in the evaluation process through carrying out QAPI activities, evaluating findings, recommending action plans, and/or receiving reports of findings.

Evidence: Personnel Meeting Minutes/In-Service Records
Evidence: Response to Interviews

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH6-3A.01: There is an annual Quality Assessment and Performance Improvement (QAPI) report written.

There is a comprehensive, written annual report that describes the QAPI activities, findings and corrective actions that relate to the care/service provided. In a large multi-service organization, the report may be part of a larger document addressing all of the organization's programs.

While the final report is a single document, improvement activities must be conducted at various times during the year. Data for the annual report may be obtained from a variety of sources and methods, e.g., audit reports, patient questionnaires, feedback from referral sources, outside survey reports, etc.

The QAPI annual report includes, but is not limited to:

- The effectiveness of the QAPI program
- Summary of all QAPI activities, findings and corrective actions
- The effectiveness, quality and appropriateness of care/service provided to the patients, service areas and community served
- Effectiveness of all programs including care/service provided under contractual arrangements
- Review and revision of policies and procedures, and forms used by the HHA

Evidence: Performance Improvement Annual Report

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH6-4A.01: Each Quality Assessment and Performance Improvement (QAPI) activity contains the required items.

Each performance improvement activity/study includes the following items:

- A description of indicator(s) to be monitored/activities to be conducted
- Frequency of activities
- Designation of who is responsible for conducting the activities
- Methods of data collection
- Acceptable limits for findings/thresholds
- Written plan of correction when thresholds are not met
- Plans to re-evaluate if findings fail to meet acceptable limits
- Any other activities required under state or federal laws or regulations

The above criteria are used to develop each required QAPI activity.

Evidence: Performance Improvement Activities/Studies

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH6-4A.02: Quality Assessment and Performance Improvement (QAPI) activities include an assessment of processes that involve risks, including infections and communicable diseases.

A review of all variances, which includes, but is not limited to incidents, accidents, complaints/grievances, and worker compensation claims, are conducted at least quarterly to detect trends and create an action plan to decrease occurrences.

Evidence: Performance Improvement Reports

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH6-4A.04: Quality Assessment and Performance Improvement (QAPI) activities include ongoing monitoring of at least one important administrative function of the HHA.

The HHA conducts monitoring of at least one important administrative/operational function of the HHA.

Examples of QAPI activities include, but are not limited to:

- Monitoring compliance of conducting performance evaluations
- Number of in-service hours completed by personnel
- Conducting billing audits

Evidence: Performance Improvement Reports

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH6-4A.05: Quality Assessment and Performance Improvement (QAPI) activities include satisfaction surveys.

The QAPI plan identifies the process for conducting satisfaction surveys, which include, but are not limited to:

- Patient
- Personnel
- Referral source
- Home Health Care CAHPS Surveys, if applicable

Evidence: Performance Improvement Reports

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH6-4A.06: Quality Assessment and Performance Improvement (QAPI) activities include the ongoing monitoring of patient grievances/complaints.

QAPI activities include ongoing monitoring of patient complaints/grievances and the actions needed to resolve complaints/grievances and improve patient care/service.

Evidence: Performance Improvement Reports

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH6-4A.07: The Quality Assessment and Performance Improvement (QAPI) program includes a review of the patient record.

The patient record review consists of the following:

- At least quarterly, patient chart audits are completed representing the scope of the program, reviewing a sample of both active and closed patient records to determine if regulatory requirements are met and patient outcomes are achieved

Evidence: Performance Improvement Reports

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH6-5A: Quality Assessment and Performance Improvement (QAPI) activities focus on high-risk, high-volume, or problem-prone areas; considering incidence, prevalence and severity of problems in those areas. 484.65(c)(1)(i) (G648), 484.65(c)(1)(ii) (G650), 484.65(c)(1)(iii) (G652).

The HHA conducts monitoring of important aspects of the care/service provided by the HHA. An important aspect of care/service reflects a dimension of activity that may be high volume (occurs frequently or affects a large number of patients), high risk (causes a risk of serious consequences if the care/service is not provided correctly), or problem-prone (has tended to cause problems for personnel or patients in the past).

Performance activities that identify issues of this severity lead to an immediate correction of any identified problem that directly or potentially threaten the health and safety of patients.

Evidence: Performance Improvement Reports

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.65(c)(1)(i), 484.65(c)(1)(ii) and 484.65(c)(1)(iii). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH6-6A: The written policies and procedures established and implemented by the HHA identify, monitor, report, investigate and document all adverse events, incidents, accidents, variances, or unusual occurrences that involve patient care. 484.65(c)(2) (G654).

Written policies and procedures describe the process for identifying, reporting, monitoring, investigating and documenting all adverse events, incidents, accidents, variances, or unusual occurrences. Policies and procedures include, but are not limited to:

- Action to notify the supervisor or after hours' personnel
- Time frame for verbal and written notification
- Appropriate documentation and routing of information
- Guidelines for notifying the physician or allowed practitioner
- Follow-up reporting to the administration/board/owner

Written policies and procedures identify the person(s) responsible for collecting incident data and monitoring for trends, investigating all incidents, taking necessary follow-up actions and completing appropriate documentation.

The HHA investigates all adverse events, incidents, accidents, variances or unusual occurrences that involve patient care and develop a plan of correction to prevent the same or similar event from occurring again. Events include, but are not limited to:

- Unexpected death, including suicide of patient
- Any act of violence
- A serious injury
- Psychological injury
- Significant adverse drug reaction
- Significant medication error
- Other undesirable outcomes as defined by the HHA
- Adverse patient care outcomes
- Patient injury, (witnessed and un-witnessed) including falls

There are written policies and procedures for the HHA to comply with the FDA's Medical Device Tracking program and to facilitate any recall notices submitted by the manufacturer, if applicable.

There is a standardized form developed by the HHA used to report incidents.

This data is included in the Performance Improvement plan. The HHA assesses and utilizes the data for reducing further safety risks.

Evidence: Written Policies and Procedures

Evidence: Incident/Variance Reports

Evidence: Performance Improvement Reports

Evidence: Response to Interviews

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.65(c)(2). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH6-7A.01: The HHA utilizes reports generated from OASIS data to analyze agency performance and improve patient outcomes. (This is N/A for initial Medicare Certification Surveys)

The HHA utilizes the following OASIS reports:

- Outcome-Based Quality Monitoring (OBQM) Potentially Avoidable Events Report and Patient Listing
- Outcome-Based Quality Improvement (OBQI) Outcome Report
- Patient/Agency Characteristics Report
- Submission Statistics by Agency Report
- Error Summary Report by HHA

Quality Assessment and Performance Improvement (QAPI) activities include obtaining and systematically analyzing OASIS reports to:

- Collect and trend data to monitor performance

- Recognize statistically significant data
- Identify patient population trends
- Establish criteria for focused record review
- Identify and reduce risk
- Investigate factors that contribute to potentially avoidable events
- Determine staff education that can promote improved outcomes
- Use evidence-based practices in quality improvement initiatives

Evidence: Performance Improvement Reports

Services applicable: HHA, MSS, OT, PT, SN, ST

Section 7: RISK MANAGEMENT: INFECTION AND SAFETY CONTROL

The standards in this section apply to the surveillance, identification, prevention, control, and investigation of infections and safety risks. The standards also address environmental issues, such as fire safety, hazardous materials, and disaster and crisis preparation.

Standard HH7-1A: Written policies and procedures are established and implemented that address the surveillance, identification, prevention, control and investigation of infectious and communicable diseases and the compliance with regulatory standards. 484.70 (G680), 484.70(a) (G682), 484.70(c) (G686).

The HHA must maintain and document an infection control program which has as its goal the prevention and control of infections and communicable diseases. This program protects patients, families and personnel by preventing and controlling infections and communicable diseases.

The HHA's infection control program must identify risks for the acquisition and transmission of infectious agents in all care/service settings. There is a system to communicate with all personnel, patients, and families about infection prevention and control issues including their role in preventing the spread of infections and communicable diseases through daily activities.

Written policies and procedures are established and implemented that the HHA must follow accepted standards of practice, including the use of standard precautions, to prevent the transmission of infections and communicable diseases.

Accepted standards of practice for health care providers are typically developed by government agencies, professional organizations and associations. Examples include, but are not limited to:

- The Centers for Disease Control and Prevention (CDC)
- The Agency for Healthcare Research and Quality (AHRQ)
- State Practice Acts
- Commonly accepted health standards established by national organizations, boards, and councils (e.g., Association for Professionals in Infection Control and Epidemiology (APIC), American Nurses Association (ANA), etc.)

Written policies and procedures include, but are not limited to:

- General infection control measures appropriate for care/service provided
- Hand washing
- Use of standard precautions and personal protective equipment
- Needle-stick prevention and sharps safety
- Appropriate cleaning/disinfecting procedures
- Infection surveillance, monitoring and reporting of employees and patients
- Disposal and transportation of regulated waste, if applicable
- Precautions to protect immune-compromised patients
- Employee health conditions limiting their activities
- Assessment and utilization of data obtained about infections and the infection control program
- Protocols for addressing patient care issues and prevention of infection related to infusion therapy, urinary tract care, respiratory tract care, and wound care
- Guidelines on caring for patients with multi-drug-resistant organisms
- Policies on protecting patients and personnel from blood-borne or airborne pathogens
- Monitoring staff for compliance with HHA policies and procedures related to infection control
- Protocols for educating patient and personnel in standard precautions and the prevention and control of infection

Written policies and procedures detail OSHA Blood Borne Pathogen and TB Exposure Control Plan training for all direct care personnel. The exposure control plans are reviewed annually and updated to reflect significant modification in tasks or procedures that may result in occupational exposure. The Exposure Control Plan includes engineering and work practice controls that eliminate occupational exposure or reduce it to the lowest feasible extent (e.g., use of safer medical devices, and appropriate respiratory protection devices). Plans are available to the personnel at the workplace during the work shift.

The organization conducts an annual TB risk assessment to determine the need, type, and frequency of testing/assessments for direct care personnel.

Written policies and procedures identify the personnel who has the responsibility for the implementation of the infection control activities and personnel education.

The HHA must provide infection control education to employees, contracted providers, patients and caregiver(s) regarding basic and high-risk infection control procedures as appropriate to the care/services provided.

All personnel demonstrate infection control procedures in the process of providing care/service to patients as described in OSHA

and CDC standards and as adopted into program care/service policies and procedures.

Evidence: Written Policies and Procedures

Evidence: Observation

Evidence: Patient Records

Evidence: Home Visits

Evidence: Response to Interviews

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.70, 484.70(a) and 484.70(c). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH7-1D: The HHA reviews and evaluates the effectiveness of the infection control program. 484.70(b) (G684), 484.70(b)(1) (G684), 484.70(b)(2) (G684).

The HHA must maintain a coordinated agency-wide program for the surveillance, identification, prevention, control, and investigation of infectious and communicable diseases that is an integral part of the HHA's quality assessment and performance improvement (QAPI) program. The infection control program must include:

- The HHA has a method for identifying infectious and communicable disease problems and
- A plan for appropriate actions that are expected to result in improvement and disease prevention.

The HHA monitors infection statistics of both patients and personnel and implements other activities (such as infection tracking records or logs) to ensure that personnel follow infection control procedures and report infections.

The HHA has a method for identifying infectious and communicable disease problems and a plan for appropriate actions that are expected to result in improvement and disease prevention.

Infection control tracking is used to collect and trend data on infections of both personnel and patients. The HHA identifies what infections will be reported using criteria appropriate to the populations served and in accordance with applicable law and regulations.

Surveillance data is analyzed for trends and related factors that may contribute to the correlations between personnel, patients and infection control practices.

Data is utilized to assess the effectiveness of the infection control program. Corrective action plans and steps to improve are to be implemented as needed. Data and action plans must be included in the Quality Assessment and Performance Improvement reports and communicated to leadership and personnel.

The HHA reports all communicable diseases, as required by the local county health department, to the local county or state department of health.

Evidence: Reports of Infection Tracking Records or Logs

Evidence: Personnel Files

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.70(b), 484.70(b)(1) and 484.70(b)(2). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH7-2A.01: Written policies and procedures are established and implemented that address the education of personnel concerning safety.

Written policies and procedures include types of safety training as well as the frequency of training. Safety training is conducted during orientation and at least annually for all personnel.

Safety training activities include, but are not limited to:

- Body mechanics
- Safety management
 - Fire
 - Evacuation
 - Security
 - Office equipment
 - Environmental hazards
 - In-home safety

- Personal safety techniques

Evidence: Written Policies and Procedures

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH7-2B.01: Written policies and procedures are established and implemented that address patient safety in the home.

Written policies and procedures address patient safety in the home; the safety training activities include but are not limited to:

- Compliance monitoring measures relating to the patient's medication
- Patient medical equipment safety, if applicable
- Basic home safety measures (e.g., household chemicals, throw rugs, furniture layout, cluttered stairways, blocked exits, bathroom safety, electrical safety)

Evidence: Written Policies and Procedures

Evidence: Observation

Evidence: Response to Interviews

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH7-3A: An Emergency Preparedness Plan outlines the process for meeting patient and personnel needs in a disaster or crisis situation. Part of this process includes conducting a community based risk assessment and the development of strategies and collaboration with other health organization in the same geographic area. 484.102 (E-0001), 484.102(a), 484.102(a)(1-4) (E-0004), (E-0006), (E-0007), (E-0009)

The HHA must comply with all applicable federal, state and local emergency preparedness requirements. The HHA must establish and maintain an emergency preparedness program that meets the requirement of 42 CFR 484.102.

The emergency preparedness program includes, but is not limited to, the following elements:

- a. Emergency plan. The HHA must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every two years. The plan must do all of the following:
 1. Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach. The approach is specific to the location of the HHA and considers particular hazards most likely to occur in the surrounding area. These include, but are not limited to:
 - i. Natural disasters
 - ii. Man-made disasters
 - iii. Facility-based disasters that include, but are not limited to:
 - A. Care-related emergencies
 - B. Equipment and utility failures, including but not limited to power, water, gas, etc.
 - C. Interruptions in communication, including cyber attacks
 - D. Loss of all or portion of facility
 - E. Interruptions to the normal supply of essential resources, such as water, food, fuel (heating, cooking and generators) and in some cases, medication and medical supplies (including medical gas, if applicable)
 - F. Emerging infectious diseases (EIDs) such as Influenza, Ebola, Zika Virus and others:
 - a. These EIDs may require modifications to facility protocols to protect the health and safety of patients, such as isolation and personal protective equipment (PPE) measures
 - 2) Include strategies for addressing emergency events identified by the risk assessment
 - 3) Address patient population, including, but not limited to:
 - i. The type of services the HHA has
 - ii. The ability to provide in an emergency; and continuity of operations, including delegation of authority and succession plans
 - 4) Include a process for cooperation and collaboration with local, tribal, regional, state, and federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

Evidence: Risk Assessment

Evidence: Response to Interviews

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.102, 484.102(a), 484.102(a)(1), 484.102(a)(2), 484.102(a)(3) and 484.102(a)(4). See the Medicare Conditions of Participation for the full text of the regulation.

Standard HH7-3B: Written policies and procedures and an Emergency Preparedness Plan outline the process for meeting patient and personnel needs in a disaster or crisis situation. Part of this process is the development of specific policies and procedures and the review of them every two years. 484.102(b)(1-5) (E-0013) (E-0017) (E-0019) (E-0021) (E-0023) (E-0024)

Policies and procedures. The HHA must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in standard HH7-3A, risk assessment including an all hazards approach, and the communication plan set forth in standard HH7-3C. The policies and procedures are reviewed every two years.

Based on the emergency plan, the policies and procedures include, but are not limited to:

1. The plans for the HHA's patients during a natural or manmade disaster. Individual plans for each patient must be included as part of the comprehensive assessment, which must be conducted according to the provisions at .42 CFR 484.55.
2. The procedures to inform state and local emergency preparedness officials about HHA patients in need of evacuation from their residences at any time due to an emergency situation based on the patient's medical and psychiatric condition and home environment.
3. The procedures to follow up with on-duty staff and patients to determine services that are needed, in the event that there is an interruption in services during or due to an emergency. The HHA must inform State and local officials of any on-duty staff or patients that they are unable to contact.
4. A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains the availability of records.
5. The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of state or federally designated health care professionals to address surge needs during an emergency.

Evidence: Written Policies and Procedures

Evidence: Patient Records

Evidence: Response to Interviews

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.102(b), 484.102(b)(1), 484.102(b)(2), 484.102(b)(3), 484.102(b)(4) and 484.102(b)(5). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH7-3C: An Emergency Preparedness Plan includes the development of a communication plan that includes personnel, patients and other emergency and health care organization in same geographic area. 484.102(c)(1-6) (E-0029) (E-0030) (E-0031) (E-0032) (E-0033) (E-0034)

Communication plan. The HHA must develop and maintain an emergency preparedness communication plan that complies with federal, state, and local laws and must be reviewed and updated at least every two years. The communication plan must include all of the following:

1. Names and contact information for the following:
 - i. Staff
 - ii. Entities providing services under arrangement
 - iii. Patients' physicians or allowed practitioner
 - iv. Volunteers
2. Contact information for the following:
 - i. Federal, state, tribal, regional, or local emergency preparedness staff
 - ii. Other sources of assistance
3. Primary and alternate means for communicating with the HHA's staff, federal, state, tribal, regional, and local emergency management agencies
4. A method for sharing information and medical documentation for patients under the HHA's care, as necessary, with other health care providers to maintain the continuity of care.
5. A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4):
 - i. (4) *Use and disclosures for disaster relief purposes.* A covered entity may use or disclose protected health information to a public or private entity authorized by law or by its charter to assist in disaster relief efforts, for the purpose of coordinating with such entities the uses or disclosures permitted by paragraph (b)(1)(ii) of this section. The requirements in paragraphs (b)(2) and (3) of this section apply to such uses and disclosure to the extent that

the covered entity, in the exercise of professional judgment, determines that the requirements do not interfere with the ability to respond to the emergency circumstances

6. A means of providing information about the HHA's needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee

Evidence: Communication Plan

Evidence: Response to Interviews

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.102(c), 484.102(c)(1), 484.102(c)(1)(i), 484.102(c)(1)(ii), 484.102(c)(1)(iii), 484.102(c)(1)(v), 484.102(c)(2), 484.102(c)(2)(i), 484.102(c)(2)(ii), 484.102(c)(3), 484.102(c)(4), 484.102(c)(5) and 484.102(c)(6). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH7-3D: An Emergency Preparedness Plan includes the process of training and testing the emergency preparedness plan. 484.102(d)(1-2) (E-0036) (E-0037) (E-0039)

Training and testing. The HHA must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan and risk assessment set forth in standard HH7-3A, policies and procedures as defined in standard HH7-3B, and the communication plan describes in standard HH7-3C. The training and testing program must be reviewed and updated at least every two years.

1. Training program. The HHA must do all of the following:
 - i. Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles
 - ii. Provide emergency preparedness training at least every two years
 - iii. Maintain documentation of the training
 - iv. Demonstrate staff knowledge of emergency procedures
 - v. If the emergency preparedness policies and procedures are significantly updated, the HHA must conduct training on the updated policies and procedures
2. Testing. The HHA must conduct exercises to test the emergency plan at least annually. The HHA must do the following:
 - i. Participate in a full-scale exercise that is community-based; or
 - A. When a community-based exercise is not accessible, conduct an individual, facility-based functional exercise every two years; or
 - B. If the HHA experiences an actual natural or man-made emergency that requires activation of the emergency plan, the HHA is exempt from engaging in its next required full-scale community-based or facility-based full-scale exercise following the onset of the emergency event
 - ii. Conduct an additional exercise every two years, opposite the year the full-scale or functional exercise under 42 CFR 484.102(d)(2)(i) is conducted, that may include, but is not limited to the following:
 - A. A second full-scale exercise that is community-based or individual, facility-based functional exercise; or
 - B. A mock disaster drill; or
 - C. A tabletop exercise or workshop that is led by a facilitator and includes a group discussion, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan
 - iii. Analyze the HHA's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the HHA's emergency plan, as needed

Evidence: Training Logs

Evidence: Response to Interviews

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.102(d), 484.102(d)(1), 484.102(d)(1)(i), 484.102(d)(1)(ii), 484.102(d)(1)(iii), 484.102(d)(1)(iv), 484.102(d)(2), 484.102(d)(2)(i), 484.102(d)(2)(ii), 484.102(d)(2)(ii)(A), 484.102(d)(2)(ii)(B) and 484.102(d)(2)(iii). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH7-3E: The Emergency Preparedness Plan identifies each separately certified facility and how each facility participated in the development of the unified and integrated program. 484.102(e)(1-5) (E-0042)

Integrated healthcare systems. If a HHA is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the HHA may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must do all of the following:

1. Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program
2. Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered
3. Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance with the program
4. Include a unified and integrated emergency plan that meets the requirements of standard HH7-3A. The unified and integrated emergency plan must also be based on and include all of the following:
 - i. A documented community-based risk assessment, utilizing an all-hazards approach
 - ii. A documented individual facility based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach
5. Include integrated policies and procedures that meet the requirements set forth in standard HH7-3B, a coordinated communication plan and training and testing programs that meet the requirements of standards HH7-3C and HH7-3D, respectively

Evidence: Observation

Evidence: Response to Interviews

For Medicare-certified Home Health Agencies: The Home Health Agency must comply with CFR 484.102(e), 484.102(e)(1), 484.102(e)(2), 484.102(e)(3), 484.102(e)(4) and 484.102(e)(5). See the Medicare Conditions of Participation for the full text of the regulation.

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH7-5A.01: Written policies and procedures are established and implemented that address the HHA's fire safety and emergency power systems.

Written policies and procedures or a fire safety plan address fire safety and management for all office and worksite environments.

The written policies and procedures include, but are not limited to:

- Providing emergency power to critical areas such as:
 - Alarm systems, if applicable
 - Illumination of exit routes
 - Emergency communication systems
- Testing of emergency power systems (at least annually)
- A no-smoking policy and how it will be communicated
- Maintenance of:
 - Smoke detectors
 - Fire alarms
 - Fire extinguishers
- Fire drills
 - Conduct at least annually
 - Fire drills are evaluated and results communicated to all personnel

Personnel are trained on the fire safety plan and emergency power systems.

Evidence: Written Policies and Procedures

Evidence: Observation

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH7-6A.01: Written policies and procedures are established and implemented for the acceptance, transportation, pick-up, and/or disposal of hazardous chemicals and/or contaminated materials used in the provision of patient care.

Written policies and procedures include safe methods of handling, labeling, storage, transportation, disposal and pick-up of hazardous wastes, hazardous chemicals and/or contaminated materials used in the home/HHA. The HHA follows local, state and federal guidelines.

Evidence: Written Policies and Procedures

Evidence: Observation

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH7-6B.01: Written policies and procedures are established and implemented for following OSHA's Hazard Communication Standard that describe appropriate labeling of hazardous chemicals and/or materials, instructions for use,

and storage and disposal requirements.

Written policies and procedures and their implementation follow OSHA's Hazard Communication Standard detailing:

- The labeling of containers of hazardous chemicals and/or materials with the identity of the material and the appropriate hazard warnings
- Current Safety Data Sheet (SDS) must be accessible to personnel
- The proper use, storage, and disposal of hazardous chemicals and/or materials
- The use of appropriate personal protective equipment (PPE)

Written policies and procedures address how personnel handle an exposure to a hazardous product while in the home environment.

Evidence: Written Policies and Procedures

Evidence: Response to Interviews

Evidence: Observation

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH7-7A.01: Written policies and procedures are established and implemented for identifying, monitoring, reporting, investigating, and documenting all incidents, accidents, variances, or unusual occurrences involving personnel.

Written policies and procedures describe the process for reporting, monitoring, investigating and documenting a variance. Policies and procedures include, but are not limited to:

- Action to notify the supervisor or after hours' personnel
- Time frame for verbal and written notification
- Appropriate documentation and routing of information
- Guidelines for medical care
- Follow-up reporting to the administration/board/owner

Written policies and procedures address the compliance with OSHA guidelines regarding the recording of work-related injuries and illnesses that are diagnosed by a physician or licensed health care professional and any work-related injuries and illnesses that meet any of the specific recording criteria listed in 29 CFR 1904.8 through 1904.11, as applicable to the HHA.

Written policies and procedures identify the person responsible for collecting incident data and monitoring for patterns or trends, investigating all incidents, taking necessary follow-up actions and completing appropriate documentation.

Incidents to be reported include, but are not limited to:

- Personnel injury or endangerment
- Motor vehicle accidents when conducting agency business
- Environmental safety hazards
- Equipment safety hazards, malfunctions or failures
- Unusual occurrences

There is a standardized form developed by the HHA used to report incidents. The HHA documents all incidents, accidents, variances, and unusual occurrences. The reports are distributed to management and the governing body/owner and are reported as required by applicable law and regulation. This data is included in the Performance Improvement program. The HHA assesses and utilizes the data for reducing further safety risks.

The HHA educates all personnel on its policies and procedures for documenting and reporting incidents/variances.

Evidence: Written Policies and Procedures

Evidence: OSHA 300, 300A and 301 Forms, if applicable

Evidence: PI Reports

Evidence: Response to Interviews

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH7-8A.01: Written policies and procedures are established and implemented for the use of equipment in the performance of conducting waived tests.

Written policies and procedures address how waived tests will be utilized in patient care for screening, treatment, or diagnostic purposes.

Policies and procedures for the use of equipment in the performance of conducting waived tests include:

- Instructions for using the equipment
- The frequency of conducting equipment calibration, cleaning, testing and maintenance
- Quality control procedures

Evidence: Written Policies and Procedures

Evidence: Quality Control Logs

Services applicable: SN

Standard HH7-9A.01: Written policies and procedures are established and implemented for the use of equipment/supplies in the provision of care to the patient.

The written policies and procedures include, but are not limited to:

- Storage and transportation of equipment used to provide care/services
- Electrical safety of the equipment
- Use of cleaning and disinfecting agents
- Cleaning of equipment after each use
- Maintenance and repair of equipment used by HHA personnel
- Calibration per manufacturer's guidelines, if applicable
- Requirements for dispensing of any disposable supplies used in the provision of care/service
- Manufacturer recalls

Personnel implement the policies and procedures for the use of the HHA's equipment/supplies in the provision of care to the patient. The cleaning and maintenance of equipment used in the provision of care is documented. Supplies used in the provision of care are also documented.

Evidence: Written Policies and Procedures

Evidence: Observation

Services applicable: HHA, MSS, OT, PT, SN, ST

Standard HH7-10A.01: Written policies and procedures are established and implemented for participating in clinical research/experimental therapies and/or administering investigational drugs.

Written policies and procedures include, but are not limited to:

- Informing patients of their responsibilities
- Informing patient of right to refuse acceptance of investigational drugs or experimental therapies
- Informing patient of right to refuse participation in research and clinical studies
- Notifying patients that they will not be discriminated against for refusal to participate in research and clinical studies.
- Stating which personnel are administering investigational medications/treatments
- Describing personnel monitoring a patient's response to investigational medications/treatments
- Identifying the responsibility for obtaining informed consent
- Defining the use of experimental and investigational drugs and other atypical treatments and interventions

Evidence: Written Policies and Procedures

Services applicable: HHA, MSS, OT, PT, SN, ST

Appendix A: Standard Service Table for Selected Services

Standard	HHA	MSS	OT	PT	SN	ST
HH1-1A	X	X	X	X	X	X
HH1-1A.01	X	X	X	X	X	X
HH1-1B	X	X	X	X	X	X
HH1-1C	X	X	X	X	X	X
HH1-2A	X	X	X	X	X	X
HH1-2A.03	X	X	X	X	X	X
HH1-4A.01	X	X	X	X	X	X
HH1-5A	X	X	X	X	X	X
HH1-5A.01	X	X	X	X	X	X
HH1-6A	X	X	X	X	X	X
HH1-6B	X	X	X	X	X	X
HH1-6C	X	X	X	X	X	X
HH1-7A	X	X	X	X	X	X
HH1-8A	X	X	X	X	X	X
HH1-8B	X	X	X	X	X	X
HH1-9A.01	X	X	X	X	X	X
HH1-10A	X	X	X	X	X	X
HH1-11A	X	X	X	X	X	X
HH1-12A.01	X	X	X	X	X	X
HH2-1A.01	X	X	X	X	X	X
HH2-2A	X	X	X	X	X	X
HH2-2C	X	X	X	X	X	X
HH2-3A	X	X	X	X	X	X
HH2-4A	X	X	X	X	X	X
HH2-4B	X	X	X	X	X	X
HH2-5A	X	X	X	X	X	X
HH2-5C.01	X	X	X	X	X	X
HH2-6A	X	X	X	X	X	X
HH2-6B.01	X	X	X	X	X	X
HH2-6B.02	X	X	X	X	X	X
HH2-7A.01	X	X	X	X	X	X
HH2-8A	X	X	X	X	X	X
HH2-8B.01	X	X	X	X	X	X
HH2-9A.01	X	X	X	X	X	X
HH2-10A.01	X	X	X	X	X	X
HH2-11A.01	X	X	X	X	X	X
HH2-12A.01	X	X	X	X	X	X
HH3-1A	X	X	X	X	X	X
HH3-1B	X	X	X	X	X	X
HH3-1C	X	X	X	X	X	X
HH3-2A.01	X	X	X	X	X	X
HH3-3A.01	X	X	X	X	X	X
HH3-3B.02	X	X	X	X	X	X
HH3-4A.01	X	X	X	X	X	X
HH3-4C	X	X	X	X	X	X
HH3-4D.01	X	X	X	X	X	X
HH4-1A.01	X	X	X	X	X	X
HH4-1A.02	X	X	X	X	X	X
HH4-1B.01	X	X	X	X	X	X
HH4-2B.01	X	X	X	X	X	X
HH4-2C.01	X	X	X	X	X	X
HH4-2D.01	X	X	X	X	X	X
HH4-2E.01	X	X	X	X	X	X
HH4-2F.01	X	X	X	X	X	X
HH4-2H.01	X	X	X	X	X	X
HH4-2I.01	X	X	X	X	X	X
HH4-2J.01	X	X	X	X	X	X
HH4-2K	X	X	X	X	X	X
HH4-4A.01	X	X	X	X	X	X

HH4-5A.01	X	X	X	X	X	X
HH4-5B.01	X	X	X	X	X	X
HH4-6A.01	X	X	X	X	X	X
HH4-6C.01					X	
HH4-7C.01	X	X	X	X	X	X
HH4-8A	X					
HH4-8A.01	X	X	X	X	X	X
HH4-10A.01					X	
HH4-11H	X					
HH4-12A	X					
HH4-12B	X					
HH4-12C	X					
HH4-12F	X					
HH4-12G	X					
HH4-13A	X					
HH4-14A	X					
HH5-1A	X	X	X	X	X	X
HH5-1A.01	X	X	X	X	X	X
HH5-1B	X	X	X	X	X	X
HH5-2A.01	X	X	X	X	X	X
HH5-2B	X	X	X	X	X	X
HH5-2C	X	X	X	X	X	X
HH5-2C.01			X	X		X
HH5-2C.02		X				
HH5-2E	X	X	X	X	X	X
HH5-2F	X	X	X	X	X	X
HH5-2F.01	X	X	X	X	X	X
HH5-2F.02	X	X	X	X	X	X
HH5-3A	X	X	X	X	X	X
HH5-3B	X	X	X	X	X	X
HH5-3C	X	X	X	X	X	X
HH5-4A	X	X	X	X	X	X
HH5-5A	X	X	X	X	X	X
HH5-6A	X	X	X	X	X	X
HH5-8A	X	X	X	X	X	X
HH5-8B	X	X	X	X	X	X
HH5-10A				X		X
HH5-11A		X	X	X	X	X
HH5-11F	X					
HH5-12A.01	X	X	X	X	X	X
HH5-13A.01	X	X	X	X	X	X
HH5-14B.01	X	X	X	X	X	X
HH5-16A.01	X	X	X	X	X	X
HH6-1A	X	X	X	X	X	X
HH6-1B.01	X	X	X	X	X	X
HH6-1C	X	X	X	X	X	X
HH6-1D.01	X	X	X	X	X	X
HH6-3A.01	X	X	X	X	X	X
HH6-4A.01	X	X	X	X	X	X
HH6-4A.02	X	X	X	X	X	X
HH6-4A.04	X	X	X	X	X	X
HH6-4A.05	X	X	X	X	X	X
HH6-4A.06	X	X	X	X	X	X
HH6-4A.07	X	X	X	X	X	X
HH6-5A	X	X	X	X	X	X
HH6-6A	X	X	X	X	X	X
HH6-7A.01	X	X	X	X	X	X
HH7-1A	X	X	X	X	X	X
HH7-1D	X	X	X	X	X	X
HH7-2A.01	X	X	X	X	X	X
HH7-2B.01	X	X	X	X	X	X
HH7-3A	X	X	X	X	X	X
HH7-3B	X	X	X	X	X	X

HH7-3C	X	X	X	X	X	X
HH7-3D	X	X	X	X	X	X
HH7-3E	X	X	X	X	X	X
HH7-5A.01	X	X	X	X	X	X
HH7-6A.01	X	X	X	X	X	X
HH7-6B.01	X	X	X	X	X	X
HH7-7A.01	X	X	X	X	X	X
HH7-8A.01					X	
HH7-9A.01	X	X	X	X	X	X
HH7-10A.01	X	X	X	X	X	X

Appendix B: Reference Guide for Required Documents, Policies and Procedures

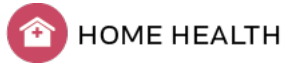
Customized for: HHA, MSS, OT, PT, SN, ST

Standard #	Documents, Policies and Procedures	Agency Notes
HH1-1A.01	Written Policies and Procedures	
HH1-1B	Written Policies and Procedures	
HH1-1C	Written Policies and Procedures	
HH1-2A	Written Policies and Procedures	
HH1-4A.01	Written Policies and Procedures	
HH1-6B	Written Policies and Procedures	
HH1-6C	Written Policies and Procedures	
HH1-8B	Written Policies and Procedures	
HH2-1A.01	Written Policies and Procedures	
HH2-2A	Written Policies and Procedures	
HH2-3A	Written Policies and Procedures	
HH2-4A	Written Policies and Procedures	
HH2-5A	Written Policies and Procedures	
HH2-6A	Written Policies and Procedures	
HH2-6B.01	Written Policies and Procedures	
HH2-6B.02	Written Policies and Procedures	
HH2-7A.01	Written Policies and Procedures	
HH2-8A	Written Policies and Procedures	
HH2-8B.01	Written Policies and Procedures	
HH2-9A.01	Written Policies and Procedures	
HH2-12A.01	Written Policies and Procedures	
HH3-1A	Written Policies and Procedures	
HH3-1B	Written Policies and Procedures	
HH3-3A.01	Written Policies and Procedures	
HH3-4A.01	Written Policies and Procedures	
HH4-1A.01	Written Policies and Procedures	
HH4-2C.01	Written Policies and Procedures	
	Personnel Files or other Confidential Employee Records	
HH4-2D.01	Written Policies and Procedures	
HH4-2H.01	Written and Procedures	
HH4-2I.01	Written Policies and Procedures and/or Employee Handbook	
HH4-2J.01	Written Policies and Procedures	
HH4-5A.01	Written Policies and Procedures	
HH4-6A.01	Written Policies and Procedures	
HH4-6C.01	Written Policies and Procedures	
HH4-7C.01	Written Policies and Procedures	
HH4-8A	Written Policies and Procedures	
HH4-8A.01	Written Policies and Procedures	
HH4-10A.01	Written Policies and Procedures	
HH4-11H	Written Policies and Procedures	
HH5-1A.01	Written Policies and Procedures	
HH5-1B	Written Policies and Procedures	
HH5-2A.01	Written Policies and Procedures	
HH5-2C	Written Policies and Procedures	
HH5-2C.01	Written Policies and Procedures	

HH5-2C.02	Written Policies and procedures	
HH5-2F.01	Written Policies and Procedures	
HH5-2F.02	Written Policies and Procedures	
HH5-4A	Written Policies and Procedures	
HH5-6A	Written Policies and Procedures	
HH5-8A	Written Policies and Procedures	
HH5-10A	Written Policies and Procedures	
HH5-11A	Observation	
HH5-12A.01	Written Policies and Procedures	
HH5-13A.01	Written Policies and Procedures	
HH5-16A.01	Written Policies and Procedures	
HH6-1A	Written Policies and Procedures	
HH6-6A	Written Policies and Procedures	
HH7-1A	Written Policies and Procedures	
HH7-2A.01	Written Policies and Procedures	
HH7-2B.01	Written Policies and Procedures	
HH7-3B	Written Policies and Procedures	
HH7-5A.01	Written Policies and Procedures	
HH7-6A.01	Written Policies and Procedures	
HH7-6B.01	Written Policies and Procedures	
HH7-7A.01	Written Policies and Procedures	
HH7-8A.01	Written Policies and Procedures	
HH7-9A.01	Written Policies and Procedures	
HH7-10A.01	Written Policies and Procedures	

ITEMS NEEDED FOR ON-SITE SURVEY

MEDICARE CERTIFICATION AND RECERTIFICATION



Below are items that will need to be reviewed by the Surveyor during your on-site survey. Please have these items available prior to your Surveyor's arrival to expedite the process. If you have any questions, please contact your Account Advisor.

- Number of unduplicated admissions per Medicare provider number during the past 12 months (or since start of operation if less than one year)
- Number of unduplicated admissions per branch location served under the parent Medicare provider number during the past 12 months (or since start of operation if less than one year)
- Current patient census, complete with start-of-care date, admitting diagnosis, and disciplines providing care
- Current schedule of patient visits
- Discharge/transfer patient census for past 12 months (or since start of operation if less than one year)
- Most recent OASIS Reports, such as Adverse Outcome, Risk Adjusted Outcome, Case Mix, Submission Statistics, and Error Summary (N/A for initial Medicare Certification surveys)
- Personnel list with title, discipline, and hire date (including direct care and contract staff)
- Any survey results from the past year
- Admission packet and education materials given to patients
- Staff meeting minutes for the past 12 months
- Any internal Plans of Correction based on identified deficiencies along with audit results

Annual requirements are not applicable to agencies in operation for less than one year. Unduplicated admissions refer to all patients admitted one time during the past 12 months regardless of payor.

ACHC Standard	Required Item	Located
HH1-1A	Copy of current applicable licenses or permits and copy of articles of incorporation/bylaws	
HH1-1A.01	Access to policies and procedures manual with the following policies flagged: <ul style="list-style-type: none"> • HH2-2A Patient rights and responsibilities policy • HH2-9A.01 Compliance Program • HH5-1B HIPAA policies • HH5-6A Transfer and discharge policies • HH5-8A Acceptance of verbal orders • HH7-3B Emergency Preparedness Plan/Policies 	
HH1-1A.01	All required federal and state posters are placed in a prominent location	
HH1-1B	Current 855A/CMS approval letter	

ACHC Standard	Required Item	Located
HH1-2A, HH1-2A.03/ HH1-9A.01/HH2-4A/ HH2-7A.01/HH3-1A/ HH3-1C/HH6-1C	Governing body meeting minutes for the past 12 months and documentation of orientation and signed confidentiality statement(s) List of governing body members	
HH1-5A	Job description for the Administrator	
HH1-5A.01	Annual evaluation of the Administrator	
HH1-6A	Organizational chart	
HH1-6B	Job description for the clinical manager(s)	
HH1-8A/HH1-8B	Previous 4 month's final OASIS Validation reports	
HH1-10A	Contracts for direct care, including copies of professional liability insurance certificates	
HH1-11A	CLIA certificate of waiver for agency or CLIA certificate for the reference laboratory	
HH1-12A.01	CMS letter of approval for branch addition (if applicable)	
HH2-1A.01	Marketing materials	
HH2-4A	Grievance/complaint log	
HH2-5C.01	Business Associate Agreements (BAAs)	
HH2-7A.01	Evidence of how ethical issues are identified, evaluated and discussed	
HH2-8A	Evidence of communication assistance for language barriers	
HH2-9A.01	Evidence of a Compliance Program	
HH2-10A.01/HH2-11A.01	On-call calendar	
HH3-1A	Most recent annual operating budget	
HH3-1B	Most recent capital expenditure plan (if applicable)	
HH3-1C	Evidence of the review of the budget	
HH3-3B.02	Recent Medicare cost report (N/A for initial Medicare certification)	
HH3-4A.01	Listing of patient care charges	
HH4-1B.01	Personnel records (including direct care and contract staff) contain evidence of the items listed in the standard. Surveyor will review personnel records at a minimum for the following disciplines: Administrator, Clinical Manager, Nurses, Aides, Social Worker, Physical Therapist, Occupational Therapist, Speech Therapist (if services are provided by the home health agency)	
HH4-2E.01	Job descriptions for identified staff	
HH4-2I.01	Employee handbook or access to personnel policies	
HH4-8A/HH4-8A.01	Evidence of ongoing education and/or written education plan	
HH4-12A/HH4-12B/HH4-12C/HH4-12F	Home Health Aide competency evaluation and/or training materials (if applicable)	
HH5-11A	Evidence of skilled services are provided by or under the supervision of qualified professionals per ACHC Glossary of Personnel Qualifications	
HH5-12A.01	Patient education materials	
HH5-13A.01	Referral log	
HH5-16A.01	Verification of physician or allowed practitioner licensure	

ACHC Standard	Required Item	Located
HH6-1A	Quality Assessment and Performance Improvement (QAPI) Program	
HH6-1B.01	Job description for individual responsible for the QAPI Program	
HH6-1C	Governing body meeting minutes demonstrate involvement of the governing body in QAPI	
HH6-1D.01	Evidence of personnel involvement in QAPI	
HH6-3A.01	QAPI annual report	
HH6-4A.02	Evidence of monitoring processes that involve risks, including infections and communicable diseases	
HH6-4A.04	Evidence of monitoring of an aspect related to administrative function of the agency	
HH6-4A.05	Satisfaction surveys utilized in QAPI	
HH6-4A.06	Evidence of monitoring of patient grievances/complaints and actions needed to resolve problems	
HH6-4A.07	Evidence of quarterly record reviews and results are utilized in QAPI	
HH6-5A	Evidence QAPI activities focus on high risk, high volume, or problem prone areas	
HH6-6A	Evidence of the monitoring of all patient related variances	
HH6-7A.01	OASIS reports (most recent OBQM, OBQI, Patient/Agency Characteristics Report, Submission Statistics by Agency Report, and Error Summary Report) and evidence of ongoing monitoring of reports	
HH7-1A	Evidence of an Infection Control Program, Annual Agency TB Assessment, TB Exposure Control Plan, and OSHA Bloodborne Pathogen Plan	
HH7-1D	Infection control logs for patients and personnel and evidence infection control data is monitored and incorporated into QAPI as appropriate	
HH7-3A	Emergency Preparedness Plan that includes the all-hazards risk assessment	
HH7-3C	Communication Plan	
HH7-3D	Evidence of emergency preparedness training for all existing and new staff, including staff that provide services under arrangement	
HH7-3D	<p>Evidence of a minimum of one test/drill completed annually</p> <ul style="list-style-type: none"> • One is a community-based or facility-based exercise functional exercise, and opposite the year of the full-scale exercise <ul style="list-style-type: none"> • A community-based or a facility-based functional exercise, or a mock disaster drill or a tabletop exercise or workshop, that is led by a facilitator. The tabletop exercise or workshop must include a group discussion using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan 	

ACHC Standard	Required Item	Located
HH7-3E	Emergency plan for integrated healthcare systems can demonstrate that the agency's needs and circumstances, patient population, and services offered were included in all aspects of the emergency preparedness requirements (if applicable)	
HH7-5A.01	Report of annual fire drill and results of testing of emergency power systems	
HH7-6B.01	Access to Safety Data Sheets (SDS)	
HH7-7A.01	OSHA forms 300, 300A, and/or 301 (if applicable)	
HH7-8A.01/HH 7-9A.01	Quality control logs of any equipment used in the provision of care	



All-Hazards Approach: An all-hazards approach is an integrated approach to emergency preparedness that focuses on identifying hazards and developing emergency preparedness capacities and capabilities that can address those as well as a wide spectrum of emergencies or disasters. This approach includes preparedness for natural, man-made, and or facility emergencies that may include but is not limited to: care-related emergencies; equipment and power failures; interruptions in communications, including cyber-attacks; loss of a portion or all of a facility; and, interruptions in the normal supply of essentials, such as water and food. Planning for using an all-hazards approach should also include emerging infectious disease (EID) threats. Examples of EIDs include Influenza, Ebola, Zika Virus and others. All facilities must develop an all-hazards emergency preparedness program and plan.

Bereavement Counseling: Emotional, psychosocial, and spiritual support and services provided before and after the death of the patient to assist with issues related to grief, loss, and adjustment.

Branch Office (Medicare-Certified Home Health Agency): An approved location or site from which an HHA provides services within a portion of the total geographic area served by the parent agency. The parent home health agency must provide supervision and administrative control of any branch office. It is unnecessary for the branch office to independently meet the Conditions of Participation as a home health agency.

Bylaws: A set of rules adopted by an HHA for governing the agency's operation.

Clinical Note (Medicare-Certified Home Health Agency): A notation of a contact with a patient that is written timed and which describes signs and symptoms, treatment, drugs administered and the patient's reaction or response and any changes in physical or emotional condition during a given period of time .

Comprehensive Assessment: A thorough evaluation of the patient's physical, psychosocial, emotional and spiritual status related to the diagnosis and related conditions. This includes a thorough evaluation of the caregiver's and family's willingness and capability to care for the patient.

Disaster: A hazard impact causing adverse physical, social, psychological, economic or political effects that challenges the ability to respond rapidly and effectively. Despite a stepped-up capacity and capability (call-back procedures, mutual aid, etc.) and change from routine management methods to an incident command/management process, the outcome is lower than expected compared with a smaller scale or lower magnitude impact (see "emergency" for important contrast between the two terms). Reference: Assistant Secretary for Preparedness and Response (ASPR) 2017-2022 Health Care Preparedness and Response Capabilities Document (ICDRM/GWU Emergency Management Glossary of Terms) (November 2016).

Emergency/Disaster: An event that can affect the facility internally as well as the overall target population or the community at large or community or a geographic area.

Emergency: A hazard impact causing adverse physical, social, psychological, economic or political effects that challenges the ability to respond rapidly and effectively. It requires a stepped-up capacity and capability (call-back procedures, mutual aid, etc.) to meet the expected outcome, and commonly requires change from routine management methods to an incident command process to achieve the expected outcome (see "disaster" for important contrast between the two terms). Reference: Assistant Secretary for Preparedness and Response (ASPR) 2017-2022 Health Care Preparedness and Response Capabilities Document (ICDRM/GWU Emergency Management Glossary of Terms) (November 2016).

Emergency Plan: An emergency plan provides the framework for the emergency preparedness program. The emergency plan is developed based on facility- and community-based risk assessments that assist a facility in anticipating and addressing facility, patient, staff and community needs and support continuity of business operations.

Emergency Preparedness Program: The Emergency Preparedness Program describes a facility's comprehensive approach to meeting the health, safety and security needs of the facility, its staff, their patient population and community prior to, during and after an emergency or disaster. The program encompasses four core elements: an Emergency Plan that is based on a Risk Assessment and incorporates an all hazards approach; Policies and Procedures; Communication Plan; and the Training and Testing Program.

Facility-Based: We consider the term "facility-based" to mean the emergency preparedness program is specific to the facility. It includes but is not limited to hazards specific to a facility based on its geographic location; dependent patient/resident/client and community population; facility type and potential surrounding community assets, i.e. rural area versus a large metropolitan area.

Full-Scale Exercise: A full-scale exercise is an operations-based exercise that typically involves multiple agencies, jurisdictions, and disciplines performing functional (for example, joint field office, emergency operation centers, etc.) and integration of operational elements involved in the response to a disaster event, i.e. "boots on the ground" response activities (for example, hospital staff treating mock patients).

Functional exercises: Functional exercises focus on exercising plans, policies, procedures, and staff members involved in management, direction, command, and control functions. In comparison to a full-scale exercise, a functional exercise involves fewer participants and the movement of personnel and equipment is simulated.

HHA Employee (Medicare-Certified Home Health Agency): An HHA is considered to provide a service "directly" when the person providing the service is an HHA employee. An individual who works for the HHA on an hourly or per-visit basis may be considered an agency employee if the HHA is required to issue a W-2 form on their behalf.

HHA: Home health agency.

Hospice Care: A comprehensive set of services described in Section 1861(dd)(1) of the Social Security Act, identified and coordinated by an Interdisciplinary Group (IDG)/ Interdisciplinary Team (IDT) to provide for the physical, psychosocial, spiritual, and emotional needs of a terminally ill patient and/or family members, as delineated in a specific patient plan of care.

In Advance: "In advance" means that home health agency staff must complete the task prior to performing any hands-on care or any patient education.

Interdisciplinary Group/ Interdisciplinary Team: A group of individuals who work together to meet the physical, medical, psychosocial, emotional, and spiritual needs of palliative care patients and families facing serious illness and bereavement.

Mock disaster drill: A mock disaster drill is the practice of how to save lives in a real time situation. The drill addresses any kind of disaster that occurs with no advance notice, or very little time to implement.

Nonprofit Agency: An agency exempt from federal income taxation under section 501 of the Internal Revenue Code of 1954.

Palliative Care: Patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care throughout the continuum of illness involves addressing physical, intellectual, emotional, social and spiritual needs and facilitating patient autonomy, access to information and choice. ACHC Palliative Care Standards are based on the National Consensus Project Clinical Practice Guidelines for Quality Palliative Care.

Parent Home Health Agency (Medicare-Certified Home Health Agency): An agency that provides direct support and administrative controls of branch.

Primary Home Health Agency (Medicare-Certified Home Health Agency): The home health agency which accepts the initial referral of a patient, and which provides services directly to the patient or via another health care provider under arrangements (as applicable).

Progress Note: 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: A private, for-profit agency.

Pseudo-patient: A Pseudo-patient is a person trained to participate in a role-play situation, or a computer-based mannequin device. A pseudo-patient must be capable of responding to and interacting with the home health aide trainee, and must demonstrate the general characteristics of the primary patient population served by the HHA in key areas such as age, frailty, functional status, and cognitive status.

Public Agency: An agency operated by a state or local government.

Quality Indicator: A specific, valid, and reliable measure of access, care outcomes, or satisfaction, or a measure of a process of care.

Representative: The patient's legal representative, such as a guardian, who makes healthcare decisions on the patient's behalf, or a patient-selected representative who participates in making decisions related to the patient's care or well-being, including but not limited to, a family member or an advocate for the patient. The patient determines the role of the representative, to the extent possible.

Risk Assessment: The term risk assessment describes a process facilities use to assess and document potential hazards that are likely to impact their geographical region, community, facility and patient population and identify gaps and challenges that should be considered and addressed in developing the emergency preparedness program. The term risk assessment is meant to be comprehensive, and may include a variety of methods to assess and document potential hazards and their impacts. The healthcare industry has also referred to risk assessments as a Hazard Vulnerability Assessments or Analysis (HVA) as a type of risk assessment commonly used in the healthcare industry.

Simulation: A simulation is a training and assessment technique that mimics the reality of the homecare environment, including environmental distractions and constraints that evoke or replicate substantial aspects of the real work in a fully interactive fashion, in order to teach and assess proficiency in performing skills, and to promote decision making and critical thinking.

Staff: The term "staff" refers to all individuals that are employed directly by a facility. The phrase "individuals providing services under arrangement" means services furnished under arrangement that are subject to a written contract conforming with the requirements specified in section 1861(w) of the Act.

Subdivision (Medicare-Certified Home Health Agency): 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 branch offices is considered a parent agency.

Summary Report: The compilation of the pertinent factors of a patient's clinical notes and progress notes that is submitted to the patient's physician, physician assistant, nurse practitioner, or clinical nurse specialist.

Supervised Practical Training: Training in a practicum laboratory or other setting in which the trainee demonstrates knowledge while providing covered services to an individual under the direct supervision of either a registered nurse or a licensed practical nurse who is under the supervision of a registered nurse.

Tabletop Exercise (TTX): A tabletop exercise involves key personnel discussing simulated scenarios in an informal setting. TTXs can be used to assess plans, policies, and procedures. A tabletop exercise is a discussion-based exercise that involves senior staff, elected or appointed officials, and other key decision making personnel in a group discussion centered on a hypothetical scenario. TTXs can be used to assess plans, policies, and procedures without deploying resources.

Verbal Order: A verbal order mean a physician, physician assistant, nurse practitioner, or clinical nurse specialist order that is spoken to appropriate personnel and later put in writing for the purposes of documenting as well as establishing or revising the patient's plan of care.

GLOSSARY OF PERSONNEL QUALIFICATIONS



FOR PROVIDERS.
BY PROVIDERS.



HOME HEALTH

Administrator (Medicare-Certified Home Health Agency):

- For individuals that began employment with the HHA prior to January 13, 2018, a person who:
 - » Is a licensed physician; or
 - » Is a Registered Nurse; or
 - » Has training and experience in health service administration and at least one year of supervisory or administrative experience in home health care or related health programs.
- For individuals that begin employment with an HHA on or after January 13, 2018, a person who:
 - » Is a licensed physician, a registered nurse, or holds an undergraduate degree; and
 - » Has experience in health service administration, with at least 1 year of supervisory or administrative experience in home health care or a related health care program.

Allowed Practitioner (Medicare-Certified Home Health Agency):

An allowed practitioner means a physician assistant, nurse practitioner, or clinical nurse specialist as defined in 42 CFR 484.2.

Audiologist (Medicare-Certified Home Health Agency):

A person who:

- Meets the education and experience requirements for a Certificate of Clinical Competence in audiology granted by the American Speech-Language-Hearing Association; or
- Meets the educational requirements for certification and is in the process of accumulating the supervised experience required for certification.

Clinical Manager (Medicare Certified Home Health Agency):

A person who is a licensed physician, physical therapist, speech-language pathologist, occupational therapist, audiologist, social worker, or a registered nurse.

Clinical Nurse Specialist:

A clinical nurse specialist means an individual as defined at 42 CFR 410.76(a) and (b) of this chapter, and who is working in collaboration with the physician as defined at 42 CFR 410.76(c)(3) of this chapter.

Home Health Aide (Medicare-Certified Home Health Agency):

A person who meets the qualifications for home health aides specified in section 1861(a)(3) of the Act and implemented at 42 CFR 484.80.

Home Respiratory Care Practitioner:

A licensed Respiratory Care Practitioner (RCP) with documented training and experience in the delivery of home respiratory care. In states without RCP licensure the therapist must be credentialed by the National Board for Respiratory Care (NBRC) as a Certified Respiratory Therapist (CRT) or Registered Respiratory Therapist (RRT). Healthcare professionals such as LPNs, RNs, and PTs may be utilized to deliver respiratory care services, within their scope of practice, provided there is adequate documentation to support supplemental training and experience in providing home respiratory care.

Licensed Practical/Vocational Nurse (LPN/LVN):

A person who has completed a practical (vocational) nursing program, is licensed in the state where practicing, and who furnishes services under the supervision of a qualified registered nurse.

Nurse Practitioner:

A nurse practitioner means an individual as defined in 42 CFR 410.75(a) and (b) of this chapter, and who is working in collaboration with the physician as defined in 42 CFR 410.75(c)(3) of this chapter.

Occupational Therapist (OT):

- A person who:
 - » Is licensed or otherwise regulated, if applicable, as an Occupational Therapist by the state in which practicing, unless licensure does not apply;
 - » 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
 - » 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).
- **On or before December 31, 2009:**
 - » Is licensed or otherwise regulated, if applicable, as an Occupational Therapist by the state in which practicing; or
 - » When licensure or other regulation does not apply:
 - ⑩ 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
 - ⑩ 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).
- **On or before January 1, 2008:**
 - » 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
 - » Is eligible for the National Registration Examination of the American Occupational Therapy Association or the National Board for Certification in Occupational Therapy.
- **On or before December 31, 1977:**
 - » Had two years of appropriate experience as an Occupational Therapist; and
 - » Achieved a satisfactory grade on an Occupational Therapist proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.
- **If educated outside the United States, must meet all of the following:**
 - » Graduated after successful completion of an occupational Therapist education program accredited as substantially equivalent to occupational Therapist entry-level education in the United States by one of the following:
 - ⑩ The Accreditation Council for Occupational Therapy Education (ACOTE)
 - ⑩ Successor organizations of ACOTE
 - ⑩ The World Federation of Occupational Therapists
 - ⑩ A credentialing body approved by the American Occupational Therapy Association
 - » Successfully completed the entry-level certification examination for Occupational Therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

- » **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 (COTA):

A person who:

- **Meets all of the following:**
 - » Is licensed, or otherwise regulated, if applicable, as an Occupational Therapy Assistant by the state in which practicing, unless licensure does not apply.
 - » 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.
 - » 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).
- **On or before December 31, 2009:**
 - » 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
 - » Must meet both of the following:
 - ⑩ Completed certification requirements to practice as an Occupational Therapy Assistant established by a credentialing organization approved by the American Occupational Therapy Association
 - ⑩ After January 1, 2010, meets the requirements in paragraph (f)(1) of this section
- **After December 31, 1977, and on or before December 31, 2007:**
 - » Completed certification requirements to practice as an Occupational Therapy Assistant established by a credentialing organization approved by the American Occupational Therapy Association; or
 - » Completed the requirements to practice as an Occupational Therapy Assistant applicable in the state in which practicing.
- **On or before December 31, 1977:**
 - » Had two years of appropriate experience as an Occupational Therapy Assistant; and
 - » Achieved a satisfactory grade on an Occupational Therapy Assistant proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.
- **If educated outside the United States, on or after January 1, 2008:**
 - » 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 one of the following:
 - ⑩ The Accreditation Council for Occupational Therapy Education (ACOTE)
 - ⑩ Its successor organizations
 - ⑩ The World Federation of Occupational Therapists
 - ⑩ By a credentialing body approved by the American Occupational Therapy Association; and
 - » 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 (PT):

A person who is licensed, if applicable, by the state in which practicing, unless licensure does not apply and who meets one of the following requirements:

- Graduated after successful completion of a Physical Therapist education program approved by one of the following:
 - » The Commission on Accreditation in Physical Therapy Education (CAPTE)

- » Successor organizations of CAPTE
- » 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; and
- Passed an examination for Physical Therapists approved by the state in which physical therapy services are provided.
- **On or before December 31, 2009:**
 - » Graduated after successful completion of a physical therapy curriculum approved by the Commission on Accreditation in Physical Therapy Education (CAPTE); or
 - » Must meet both of the following:
 - ⑩ 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
 - ⑩ Passed an examination for Physical Therapists approved by the State in which physical therapy services are provided
- **Before January 1, 2008:**
 - » Graduated from a physical therapy curriculum approved by one of the following:
 - ⑩ The American Physical Therapy Association
 - ⑩ The Committee on Allied Health Education and Accreditation of the American Medical Association
 - ⑩ The Council on Medical Education of the American Medical Association and the American Physical Therapy Association
- **On or before December 31, 1977** was licensed or qualified as a Physical Therapist and meets both of the following:
 - » Has two years of appropriate experience as a Physical Therapist
 - » Achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service
- **Before January 1, 1966:**
 - » Was admitted to membership by the American Physical Therapy Association; or
 - » Was admitted to registration by the American Registry of Physical Therapists; or
 - » Has graduated from a physical therapy curriculum in a four-year college or university approved by a state department of education
- **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.
- **If trained outside the United States before January 1, 2008**, meets the following requirements:
 - » 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
 - » Meets the requirements for membership in a member organization of the World Confederation for Physical Therapy

Physical Therapist Assistant (PTA):

A person who is licensed, registered, or certified as a Physical Therapist Assistant, if applicable, by the state in which practicing, unless licensure does not apply and meets one of the following requirements:

- 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

- Passed a national examination for Physical Therapist Assistants.
- **On or before December 31, 2009**, meets one of the following:
 - » Is licensed, or otherwise regulated in the state in which practicing
 - » In states where licensure or other regulations do not apply, graduated on or before December 31, 2009, from a two-year college-level program approved by the American Physical Therapy Association and, effective January 1, 2010, meets the requirements of paragraph (h)(1) of this section
- **Before January 1, 2008**, where licensure or other regulation does not apply, graduated from a two-year college-level program approved by the American Physical Therapy Association.
- **On or before December 31, 1977**, was licensed or qualified as a Physical Therapist Assistant and achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

Paraprofessional:

A trained Aide who assists a professional person (i.e. Home Care Aide, Nursing Assistant).

Physician for a Medicare-Certified Home Health Agency:

A physician is a Doctor of Medicine, osteopathy, or podiatric medicine, and who is not precluded from performing this function under paragraph (d) of this section. (A doctor of podiatric medicine may perform only plan of treatment functions that are consistent with the functions he or she is authorized to perform under state law.)

Physician Assistant:

A physician assistant means an individual as defined in 42 CFR 410.74(a) and (c) of this chapter.

Psychiatric Nurse:

A Psychiatric Nurse is a Registered Nurse (RN) who has received specialized behavioral health training and/or has behavioral health care experience that exceeds that which is required for one to become a Registered Nurse. Determination of whether a Registered Nurse meets the criteria for a Psychiatric Nurse is made by the organization through its written policies and procedures, job descriptions, and/or the CMS Regional Home Health Intermediary, and/or state requirements.

Public Health Nurse for a Medicare:

Certified Home Health Agency: 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.

Qualified Supervisor:

An individual employed directly or through contract who possesses:

- Evidence of verification of education and training requirements in accordance with applicable laws or regulations, and the organization's policy; and
- Evidence that clinical and supervisory knowledge and experience are appropriate to his/her assigned supervision responsibilities.

Social Work Assistant (Medicare-Certified Home Health Agency):

A person who provides services under the supervision of a qualified social worker and:

- 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
- Has two 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 (MSW) (Medicare-Certified Home Health Agency):

A person who has a master's degree or doctoral 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 (SLP) (Medicare-Certified Home Health Agency):

A qualified SLP is: A person who has a master's or doctoral degree in speech-language pathology, and who meets either of the following:

- Is licensed as a speech-language pathologist by the state in which the individual furnishes such services; or
- In the case of an individual who furnishes services in a state which does not license speech-language pathologist:
 - » Has successfully complete 350 clock hours of supervised clinical practicum (or be in the process of accumulating such supervised clinical experience).
 - » Perform not less than nine months of supervised full-time speech-language pathology services after obtaining a master's or doctoral degree in speech-language pathology or a related field.
 - » Successfully complete a national examination in speech-language pathology approved by the Secretary of Health and Human Services.

Spiritual Care Professional:

Spiritual care is provided by qualified individuals in accordance with professional standards and according to the job description. Individuals providing spiritual care understand and are knowledgeable of the spiritual needs related to palliative care, end-of-life care, loss, and bereavement. Spiritual care may be provided by chaplains, local clergy, volunteers, and other specifically trained personnel.