



ACHC STANDARDS

PROGRAM

Home Infusion Therapy Services

SERVICES

Home Infusion Therapy Supplier

ACHC ACCREDITATION STANDARDS



FOR PROVIDERS.
BY PROVIDERS.

The following packet contains the 2022 ACHC Accreditation Standards.

Release Date: February 1, 2022

Accreditation Commission for Health Care (ACHC) has updated Home Infusion Therapy Supplier 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.

The new ACHC Home Infusion therapy Supplier Accreditation Standard is HIT4-2H. Effective dates vary by state, 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 the ACHC's annual review.

The attached accreditation packet contains:

- Preliminary Evidence Report (PER) Checklist (if applying for ACHC Accreditation for the first time)
- ACHC Accreditation Standards for Home Infusion Therapy
- Items Needed for Survey
- Glossary of Terms
- Glossary of Personnel Qualifications

PRELIMINARY EVIDENCE REPORT CHECKLIST



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

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

Required items to be submitted to the Accreditation Commission for Health Care (ACHC):

- Accreditation application
- Non-refundable deposit
- Organization's new client/patient information/admission packet
 - » It is preferred that this information be provided to ACHC in digital format
- Organizational chart by position titles
- Any current citation(s) from a federal or state agency (e.g., Board of Nursing, Board of Pharmacy, etc.)

Confirmation of the following (initial in spaces provided):

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

_____ Organization has seen a minimum of 3 clients/patients who have all received infusion services in the home by an RN according to the Medicare Conditions for Coverage (CfCs)

_____ If this is an initial HIT accreditation, I acknowledge that this organization was/is/will be in compliance with ACHC Accreditation Standards as of _____ (date).

I, having the authority to represent this organization, verify that

_____ (organization's legal name)
has met the above requirements for survey. Failure to meet any of the aforementioned requirements when the ACHC Surveyor arrives for your survey may result in a postponement of the survey or additional days of survey, which can subsequently result in additional charges to the organization. I agree that during my accreditation with ACHC that if I receive any citation(s) from a federal or state agency that I will notify ACHC within 30 calendar days.

(Name)

(Title)

(Date)

(Signature)

ACHC ACCREDITATION STANDARDS

Customized for Home Infusion Therapy Supplier

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 HIT1-1A: The organization is in compliance with federal, state and local laws.

The organization 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 clients/patients. If state or applicable local law provides for the licensure of an organization, the organization must be licensed.

The organization has a physical location and required license(s) and or permit(s) is 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 organization 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 (LLC), and 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 organization has a copy of the appropriate documentation or authorization(s) to conduct business.

Evidence: Copy of Articles of Incorporation/Bylaws and all applicable amendments

Evidence: Copy of all current applicable license(s)/permit(s) for each location

Evidence: Observation

Services applicable: HITS

Standard HIT1-2A: The organization 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 organization. The governing body/owner duties and accountabilities are clearly defined.

A governing body/owner assumes full legal authority and responsibility for the management of the organization, the provision of all services, its fiscal operations, and the continuous performance improvements that are consistent with acceptable standards of practice.

Activities of the governing body/owner include, but are not limited to:

- Decision-making
- Appointing a qualified manager/leader
- Adopting and periodically reviewing written bylaws or equivalent
- Establishing or approving written policies and procedures governing overall operations
- Human resource management
- Performance Improvement (PI)
- Oversight of the management and fiscal affairs of the organization
- 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 organization. However, oversight of the organization's program is evidenced in some manner such as in reports to the board or documented in minutes of board meetings.

The organization has a list of governing body members that includes names, addresses, and telephone numbers.

Evidence: Written Policies and Procedures

Evidence: Governing Body Meetings Minutes, if applicable

Evidence: Response to Interviews

Evidence: List of Governing Body Members, if applicable

Evidence: Observation

Services applicable: HITS

Standard HIT1-3A: Written policies and procedures are established and implemented by the organization in regard to conflicts of interest and the procedure for disclosure.

The organization's policies and procedures define conflicts of interest and the procedure for disclosure and conduct in relationships with personnel, customers, and clients/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 organization
- Personnel having an outside interest in an entity providing services to the client/patient

The individual with a conflict of interest is excluded from proceedings that require input, voting, and decisions.

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: HITS

Standard HIT1-4A: There is an individual who is designated as responsible for the overall operation and services of the organization. The manager/leader organizes and directs the organization's ongoing functions; maintains an ongoing liaison with the governing body/owner and personnel; employs qualified personnel, ensuring adequate personnel education and evaluations; ensures the accuracy of public information materials and activities; and implements an effective budgeting and accounting system.

The manager/leader is responsible for all of the organization's programs and services and is accountable to the governing body/owner. There is a job description that specifies the responsibilities and authority of this individual.

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

In the absence of the manager/leader, another individual is authorized, in writing, to act as the manager/leader. The duties this individual assumes during the absence of the manager/leader are written into the individual's job description and are included in the individual's orientation.

Evidence: Job Description

Evidence: Manager/leader Resume/Application

Evidence: Observation

Evidence: Personnel Files

Services applicable: HITS

Standard HIT1-4B: The governing body, or its designee, writes and conducts annual evaluations of the manager/leader.

The organization conducts annual reviews of the manager's/leader'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 manager/leader and documented.

This criterion does not apply to sole proprietorships or to limited liability corporations (LLCs), where the president and manager/leader is also the owner and governing body. A proprietary organization's annual outcome evaluation could serve as an evaluation of the manager's/leader's performance.

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

Evidence: Written and Dated Evaluations of the manager/leader

Evidence: Response to Interviews

Services applicable: HITS

Standard HIT1-5A: Responsibility and accountability for programs are defined. The organizational chart shows the relationship of all positions within the organization with identifiable lines of authority.

The services furnished by the organization, administrative control and lines of authority for the delegation of responsibility down to the client/patient care/service 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 organization provides.

Personnel can provide a description of the organization's chain of command that is consistent with the organizational chart.

Evidence: Organizational Chart
Evidence: Response to Interviews

Services applicable: HITS

Standard HIT1-6A: The Home Infusion Therapy supplier 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
- Professional licensure/certification
- 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 and Medicaid regulations
- Health Insurance Portability and Accountability Act (HIPAA)
- Organization policies and procedures
- Accreditation Commission for Health Care (ACHC) Accreditation Process
- Other laws and regulations as applicable to the care/service provided by the organization

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: Personnel Files
Evidence: Client/Patient Records

Services applicable: HITS

Standard HIT1-7A: The Home Infusion Therapy supplier complies with accepted professional standards and practices. (486.525(b))

National recognized standards of practice and applicable state and federal laws and regulations are utilized by the Home Infusion Therapy supplier to guide the provision of care/service.

Evidence: Observation
Evidence: Written Policies and Procedures

Services applicable: HITS

Standard HIT1-8A: The organization informs the accrediting body and other state/federal regulatory agencies, as appropriate, of negative outcomes from sanctions, regulatory inspections, and/or audits.

Negative outcomes affecting accreditation, licensure, or Medicare/Medicaid certification are reported to ACHC within 30 days. The report includes all actions 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, Medicaid regulations identified during survey by another regulatory body
- Revocation of Medicare, Medicaid or third-party provider number
- Any open investigation by any regulatory or governmental authority

Evidence: Governing Body Meeting Minutes, if applicable

Evidence: Response to Interviews

Evidence: Prior Regulatory Inspection Reports

Services applicable: HITS

Standard HIT1-9A: The organization is in compliance with disclosure of ownership and management information.

Written policies and procedures describe the required action and time frames for the disclosure of any change in authority, ownership or management to ACHC and any regulatory agencies. Notification of these changes is completed within 30 days of the change.

The organization discloses the following information to ACHC at the time of initial application and within 30 days of any change in ownership or management:

- The name and address of all persons with an ownership or control interest of 5 percent or greater
- The name and address of each person who is an officer, a director, or the site manager/leader of the organization
- The name and address of the corporation, association, or other company that is responsible for the management of the organization
- The name and address of the chief executive officer (CEO) and the chairman of the board of directors of the corporation, association, or other company responsible for management of the organization

Evidence: Observation

Evidence: Organizational Chart

Evidence: Response to Interviews

Evidence: Written Policies and Procedures

Services applicable: HITS

Standard HIT1-10A: An organization that uses outside personnel/organizations to provide care/services on behalf of the organization has a written contract/agreement for care/services that is kept on file within the organization.

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

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

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

- The care/services to be furnished
- The necessity to conform to all applicable organization policies and procedures, including personnel qualifications, orientation, competencies, and required background checks
- The responsibility for participating in developing plans of care/service
- The manner in which care/services will be controlled, coordinated, and evaluated by the organization
- The procedures for submitting progress notes, scheduling of visits, and periodic client/patient evaluation
- The procedures for payment of care/services furnished under the contract
- Duration of contract/agreement
- Overall responsibility for supervision of personnel
- Other applicable laws and regulations

In addition, the organization maintains current copies of professional liability insurance certificates for all contract personnel providing direct care/service and/or other organizations providing shared responsibility care/service.

The organization has an established process to review and renew contracts/agreements as required in the contract.

Evidence: Written Contracts/Agreements
Evidence: Professional Liability Insurance
Evidence: Observation

Services applicable: HITS

Standard HIT1-11A: Written policies and procedures are established and implemented in regard to the verification of credentials of the referring physician* or other licensed independent practitioner approved by law to prescribe medical services, treatments, and/or pharmaceuticals being conducted prior to providing care/service.

Written policies and procedures describe the process for verification of referring practitioner credentials. Periodic assessments of current physician* and other licensed independent practitioners credentials are obtained from the state and federal boards. The organization has a mechanism to ensure that orders are only accepted from currently credentialed practitioners.

****For this standard, the reference to a physician is interpreted as a physician or other licensed independent practitioner with prescriptive authority***

Evidence: Written Policies and Procedures
Evidence: Response to Interviews

Services applicable: HITS

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 HIT2-1A: Written policies and procedures are established and implemented in regard to the organization's descriptions of care/services and the distribution to personnel, clients/patients, and the community.

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

- Types of care/service available
- Care/service limitations
- Charges or client/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.

Clients/patients will receive information about the scope of services that the organization will provide and specific limitations on those services. The client/patient will receive this information prior to receiving care/service with evidence documented in the client/patient record.

Evidence: Written Policies and Procedures

Evidence: Marketing Materials Including Electronic Media

Evidence: Documents that include Service Descriptions

Evidence: Client/patient Records

Evidence: Response to Interviews

Evidence: Observation

Services applicable: HITS

Standard HIT2-2A: Written policies and procedures are established and implemented by the organization in regard to the creation and distribution of the Client/Patient Rights and Responsibilities statement. (Standard HIT2-2A is in regard to the creation and distribution of the statement of the Client/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 client/patient rights and responsibilities. The organization provides the client/patient a written notice of the client's/patient's rights and responsibilities in advance of furnishing care/service to the client/patient or during the initial evaluation visit before the initiation of care/service. The policies and procedures state that if a client/patient cannot read the statement of rights and responsibilities, it is read and a copy is given to the client/patient in a language the client/patient understands. For a minor or a client/patient needing assistance in understanding these rights and responsibilities, both the client/patient and the parent, legal guardian, or other responsible person are fully informed of these rights and responsibilities. If required to do so an organization will provide written information concerning Advance Directives prior to providing care/service. Documentation of receipt and understanding of the information is signed, dated, and maintained in the client/patient record.

The written Client/Patient Rights and Responsibilities statement includes, but is not limited to:

- Being informed in advance about care/service to be provided, including the disciplines that furnish care/service and the frequency of visits, as well as any modifications to the plan of care/service (HIT2-1A)
- Being informed, in advance, of care/service being provided and their financial responsibility (HIT3-4A)
- Receiving information about the scope of services that the organization will provide and specific limitations on those services (HIT2-1A)
- Participating in the development and periodic revision of the plan of care/service (HIT5-3D and F)
- Refusing care or treatment after the consequences of refusing care or treatment are fully presented (HIT2-6A)
- Being informed of client/patient rights under state law to formulate an Advanced Directive, if applicable (HIT2-6A and HIT2-6B)
- Having one's property and person treated with respect, consideration, and recognition of client/patient dignity and individuality (HIT2-2B)
- Being able to identify visiting personnel members through organization proper identification (HIT2-2B)
- Being free from mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of client/patient property (HIT2-3A)
- Voicing grievances/complaints regarding treatment or care/service, lack of respect of property or recommend changes in

- policy, personnel, or care/service without restraint, interference, coercion, discrimination, or reprisal (HIT2-4A)
- Having grievances/complaints regarding treatment or care/service that is (or fails to be) furnished, or lack of respect of property investigated (HIT2-4A)
- Having confidentiality and privacy of all information contained in the client/patient record and of Protected Health Information (PHI) (HIT2-5A)
- Being advised of the organization's policies and procedures regarding the disclosure of client/patient records (HIT2-5A)
- Choosing a healthcare provider, including a physician, if applicable (HIT2-2B)
- Receiving appropriate care/service without discrimination in accordance with physician's orders, if applicable (HIT2-2B)
- Being informed of any financial benefits when referred to an organization (HIT2-2B)
- Being fully informed of one's responsibilities (HIT2-2B)

When additional state or federal regulations exist regarding client/patient rights, the organization's Client/Patient Rights and Responsibilities statement must include those components. The client/patient has the right to be informed and exercise their rights. If the client/patient has been adjudged incompetent under state law by a court of proper jurisdiction, the rights of the client/patient are exercised by the person appointed to act on the client's/patient's behalf. If a state court has not adjudged a client/patient incompetent, any legal representative designated by the client/patient in accordance with state law may exercise the client's/patient's rights to the extent allowed by state law.

The organization protects and promotes the exercise of these rights. The organization also develops a statement of client/patient responsibilities.

Personnel are provided training during orientation and at least annually thereafter concerning the organization's policies and procedures on client's/patient's rights and responsibilities.

Evidence: Written Policies and Procedures

Evidence: Statement of Client's/Patient's Rights and Responsibilities

Evidence: Client/patient Records

Evidence: Response to Interviews

Services applicable: HITS

Standard HIT2-2B: The organization protects and promotes the exercise of the Client/Patient Rights.

Personnel honor the client/patient right to:

- Have one's property and person treated with respect, consideration, and recognition of client/patient dignity and individuality
- Be able to identify visiting personnel members through proper identification
- Choose a healthcare provider, including choosing an physician
- Receive appropriate care/service without discrimination in accordance with physician's orders
- Be informed of any financial benefits when referred to organization
- Be fully informed of one's responsibilities

Evidence: Observation

Services applicable: HITS

Standard HIT2-3A: Written policies and procedures are established and implemented by the organization 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 client/patient property by anyone furnishing services on behalf of the organization.

The client/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 client/patient property.

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

The organization immediately investigates all alleged violations involving anyone furnishing services on behalf of the organization, and 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 organization takes appropriate corrective action in accordance with state law if the alleged violation is verified by the organization's administration or an outside body having jurisdiction, such as ACHC, the state survey organization, or the local law enforcement organization. The organization ensures that verified violations are reported to ACHC as well as state, and local bodies

having jurisdiction (including to the state survey and certification organization) within five 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

Services applicable: HITS

Standard HIT2-4A: Written policies and procedures are established and implemented by the organization requiring that the client/patient be informed at the initiation of care/service how to report grievances/complaints.

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

The organization 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 client/patient
- Documentation of all activities involved with the grievance/complaint, investigation, analysis, and resolution

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

The organization maintains records of grievances/complaints and their outcomes, submitting a summary report quarterly to the governing body/owner. This information is included in the PI 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, if applicable
Evidence: Response to Interviews

Services applicable: HITS

Standard HIT2-4B: The organization provides the client/patient with written information concerning how to contact the organization, appropriate state agencies and ACHC concerning grievances/complaints at time of admission.

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

The organization advises clients/patients in writing of the telephone number for the appropriate state regulatory body's hotline, the hours of operation, and the purpose of the hotline. This may be a separate information sheet given to the client/patient or incorporated with the client/patient rights information. ACHC's telephone number must be provided. The ACHC phone number requirement is not applicable to organization if this is its first ACHC survey.

Evidence: Client/Patient Records
Evidence: Admission/New client/patient packet

Services applicable: HITS

Standard HIT2-5A: Written policies and procedures are established and implemented by the organization in regard to securing and releasing confidential and Protected Health Information (PHI) and Electronic Protected Health Information (EPHI).

The client/patient has the right to a confidential client/patient record. The organization ensures this right and follows all policies and procedures to secure client/patient information.

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

- A definition of protected health and confidential information, and 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 that warrant its release
- Persons to whom it may be released
- Signature of the client/patient or someone legally authorized to act on the client's/patient's behalf
- A description of what information the client/patient is authorizing the organization to disclose
- Securing client/patient records and identifying who has authority to review or access client/patient 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 organization has clearly established written policies and procedures that address the areas listed above and are clearly communicated to personnel.

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

The individual seeing the client/patient for the first time will provide written information and will discuss confidentiality/privacy of client/patient-specific information as included in the Client/Patient Rights and Responsibilities statement. Client/patient records contain signed release of information statements/forms when the organization bills a third-party payor or shares information with others outside the organization as required by the Health Insurance Portability and Accountability Act (HIPAA) and other applicable laws and regulations.

Evidence: Written Policies and Procedures
Evidence: Signed Confidentiality Agreements
Evidence: Observation
Evidence: Client/Patient Records

Services applicable: HITS

Standard HIT2-5B: The organization has Business Associate Agreements (BAAs) for all Business Associates that may have access to Protected Health Information (PHI) as required by HIPAA and other applicable laws and regulations.

A copy of all Business Associate Agreements (BAAs) will be on file at the organization 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 healthcare provider involves access to PHI
- An attorney whose legal services to a health plan involve access to PHI
- A consultant that has access to PHI
- An independent medical transcriptionist that provides transcription services to a physician

A BAA 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 PHI, and where any access to PHI by such persons would be incidental, if at all.

Evidence: Business Associate Agreements

Services applicable: HITS

Standard HIT2-6A: Written policies and procedures are established by the organization in regard to the client's/patient's rights to accept or refuse medical care, client/patient resuscitation, surgical treatment and the right to formulate an Advance Directive.

Clients/patients have the right to be informed under state law to formulate an Advance Directive and to refuse care or treatment after the consequences of refusing care or treatment are fully presented.

The organization's policies and procedures describe client/patient rights under law to make decisions regarding medical care, including the right to accept or refuse care/service and the right to formulate an Advance Directive.

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

- Determining the existence of an Advance Directive
- Rendering care/service in the absence or presence of an Advance Directive
- Educating personnel

Client/patient care/service is not prohibited based on whether or not the individual has an Advance Directive.

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

The organization's personnel respect the client's/patient's wishes and assist the client/patient in obtaining resources to complete an Advance Directive, if requested.

Evidence: Written Policies and Procedures

Evidence: Client/Patient Records

Evidence: Response to Interviews

Services applicable: HITS

Standard HIT2-6B: Written policies and procedures are established and implemented by the organization in regard to resuscitative guidelines and the responsibilities of personnel.

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

Evidence: Written Policies and Procedures

Evidence: Personnel Files

Services applicable: HITS

Standard HIT2-7A: Written policies and procedures are established and implemented by the organization in regard to identification, evaluation, and discussion of ethical issues.

The organization 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 organization.

Examples of forums utilized to consider and discuss ethical issues include:

- Ethics Committee
- Ethics forum
- Professional expert access
- Performance Improvement Committee

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

All personnel received training during initial orientation and annually, that 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, if applicable

Evidence: Ethic Committee Reports

Evidence: Response to Interviews

Services applicable: HITS

Standard HIT2-8A: Written policies and procedures are established and implemented by the organization in regard to the provision of care/service to clients/patients with communication or language barriers.

Personnel can communicate with the client/patient in the appropriate language or format understandable to the client/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 client/patient by using special telephone devices for the deaf or other communication aids such as picture cards or written materials in the client's/patient's language.

All personnel are knowledgeable regarding the written policies and procedures for the provision of care/service to clients/patients with communication barriers.

Evidence: Written Policies and Procedures

Evidence: Observation

Services applicable: HITS

Standard HIT2-8B: Written policies and procedures are established and implemented for the provision of care/service to clients/patients from various cultural backgrounds, beliefs and religions.

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

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

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

Evidence: Written Policies and Procedures

Evidence: Observation

Evidence: Response to Interviews

Services applicable: HITS

Standard HIT2-9A: Written policies and procedures are established and implemented by the organization in regard to a Compliance Program aimed at preventing fraud and abuse.

The organization 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 organization 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 organization personnel for receiving complaints and protecting callers from retaliation
- Performing internal audits to monitor compliance
- Establishing and publicizing disciplinary guidelines for failing to comply with policies and procedures, applicable statutes, and regulations
- Promptly responding to detected offenses through corrective action

Evidence: Written Policies and Procedures

Evidence: Performance Improvement Activities

Evidence: Response to Interviews

Services applicable: HITS

Standard HIT2-10A: Home Infusion Therapy services are provided according to the client's/patient's plan of care with access to professional services available 24 hours a day, 7 days per week. (486.525), (486.525(a)), (486.525(a)(1))

The organization provides home infusion therapy services 24 hours a day, 7 days a week as necessary to ensure services associated with the administration of infusion drugs in a patient home is provided in accordance with the plan of care. The organization provides on-call professional services which includes nursing.

Evidence: On Call Schedule

Evidence: Observation

Services applicable: HITS

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 HIT3-1A: The organization's annual budget is developed in collaboration with management and personnel and under the direction of the governing body/owner.

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

The organization's leaders and the individuals in charge of the day-to-day program operations are involved in developing the budget and in planning and review of periodic comparisons of actual and projected expenses and revenues for care/service.

The budget is reviewed and updated at least annually by the organization's governing body/owner and leadership personnel.

Evidence: Current Annual Budget

Evidence: Governing Body Meeting Minutes, if applicable

Evidence: Responses to Interviews

Services applicable: HITS

Standard HIT3-2A: The organization 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 clients/patients and third-party payors
- Notification to the client/patient of changes in reimbursement from third-party payors
- Collection of accounts
- Reconciliation of accounts
- Extension of credit, if applicable
- Financial hardship, if applicable
- Defining consequences of non-payment; if applicable
- Assignment of revenue to the appropriate program
- Retention of financial records per applicable laws and regulations

Evidence: Observation

Services applicable: HITS

Standard HIT3-3A: The organization develops care/service rates and has methods for conveying charges to the client/patient, public, and referral sources.

Current charges for care/services are available in writing for reference by personnel when conveying information to the client/patient, public, and referral sources.

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

Evidence: List of Care/Services with Corresponding Charges

Services applicable: HITS

Standard HIT3-4A: The client/patient is advised of their financial responsibility for the equipment/services being provided at, or prior to the receipt of the equipment/services. The client/patient also has the right to be informed of changes in payment information, as soon as possible but no later than 30 days after the organization becomes aware of the change.

The client/patient record contains documentation of the communication to the client/patient in regard to their financial responsibility

and any insurance verification completed by the organization which may include deductibles, copayments, and coverage criteria.

Evidence: Client/Patient Records
Evidence: Response to Interviews

Services applicable: HITS

Standard HIT3-5A: There is verification that the care/service(s) billed for reconciles with the care/service(s) provided by the organization.

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

Evidence: Observation

Services applicable: HITS

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 HIT4-1A: 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 files
- 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 organization has personnel records for all organization employees that are available for inspection by federal, state regulatory, and accreditation agencies.

Evidence: Written Policies and Procedures

Evidence: Personnel File

Evidence: Observation

Services applicable: HITS

Standard HIT4-1B: 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 that confirms citizenship or legal authorization to work in the United States)

Evidence: Personnel Files

Services applicable: HITS

Standard HIT4-1C: 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	HIT4-1B
Dated and signed Withholding Statements	HIT4-1B
Form I-9 (employee eligibility verification that confirms citizenship or legal authorization to work in the United States)	HIT4-1B
Personnel credentialing/verification of qualifications	HIT4-2A
TB screening	HIT4-2B
Hepatitis B vaccination	HIT4-2C
Job description	HIT4-2D
Criminal background check	HIT4-2E
National sex offender registry	HIT4-2E
Office of Inspector General (OIG's) exclusion list	HIT4-2E
Personnel policies review or employee handbook	HIT4-2F
Annual performance	HIT4-2G
Orientation	HIT4-3A
Confidentiality agreement	HIT2-5A
Competency assessments	HIT4-5A,
Annual evaluation of job duties	HIT4-7A

- 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 statements, 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 client/patient care - care of a client/patient provided personally by a staff member or contracted individual/ organization in a client's/patient's residence or healthcare facility. Direct client/patient care may involve any aspects of the health care of a client/patient, including treatments, counseling, self-care, client/patient education, and administration of medication.

Evidence: None required/Informational Standard

Services applicable: HITS

Standard HIT4-2A: Personnel are qualified for the positions they hold by meeting the education, training, and experience requirements defined by the organization. Personnel credentialing activities are conducted at the time of hire and upon renewal to verify qualifications of all personnel.

Personnel hired for specific positions within the organization meet the minimum qualifications for those positions in accordance with applicable laws or regulations and the organization's policies and procedures and 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.

All professionals who furnish services directly, under an individual contract, or under arrangements with an organization, must be legally authorized (licensed, certified, or registered) in accordance with applicable federal, state, and local laws, and must act only within the scope their state license, certification, or registration. All personnel qualifications must be kept current at all times.

The personnel file or other personnel records contain validation that credentialing information is obtained at the time of hire, upon renewal, and in accordance with specific state practice act requirements. Credentialing information includes a procedure for the review of professional occupational licensure, certification, registration, or other training as required by state boards and/or professional associations for continued credentialing.

Credentials are verified through the appropriate licensing or credentialing organizations.

Evidence: Personnel Files (Primary Source Verification)

Services applicable: HITS

Standard HIT4-2B: 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: HITS

Standard HIT4-2C: 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.

The 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 exempt 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: Personnel Files or other Confidential Employee Records

Evidence: Written Policies and Procedures

Services applicable: HITS

Standard HIT4-2D: There is a job description for each position within the organization 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 organization'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 the time of orientation and whenever the job description changes (e.g., signed job description, orientation checklist, and electronic verification).

Evidence: Job Descriptions

Evidence: Organizational Chart

Evidence: Personnel Files

Services applicable: HITS

Standard HIT4-2E: Written policies and procedures are established and implemented in regard to background checks being completed on personnel that have direct client/patient care and/or access to client/patient records. Background checks include: Office of Inspector General (OIG) exclusion list, criminal background record and national sex offender registry.

The organization obtains a criminal background check, OIG exclusion list check, and national sex offender registry check on all organization employees who have direct client/patient care. Organization contracts requires that all contracted entities obtain a criminal background check, OIG exclusion list check, and national sex offender registry check on contracted employees who have direct client/patient contact.

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

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

The organization 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 Policies and Procedures

Evidence: Personnel Files

Services applicable: HITS

Standard HIT4-2F: 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 the employee handbook include, but are not limited to:

- Wages
- Benefits
- Complaints and grievances
- 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 the employee handbook are reviewed at least annually and updated as needed, and are in accordance with applicable laws 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. Agencies that 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/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 organization has written policies and procedures on its recruitment, hiring, and retention of personnel that demonstrate non-discriminatory practices.

Disciplinary Action and Termination of Employment

Policies and Procedures on disciplinary action and termination of employment define time frames for probationary actions, conditions warranting termination, steps in the termination process, and the 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 and 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: HITS

Standard HIT4-2G: 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

Evidence: Response to Interviews

Services applicable: HITS

Standard HIT4-2H: Written policies and procedures are developed and implemented in regard to the requirement of all personnel to receive the COVID-19 vaccine. 486.525(c)(1-3)

The organization 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 personnel, who provide any care, treatment, or other services for the organization and/or its patients:

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

The policies and procedures of 42 CFR 486.525(c) do not apply to the following organizational personnel:

- Personnel who exclusively provide telehealth or telemedicine services outside of the settings where home infusion therapy 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 486.525(c)(1); and
- Personnel who provide support services for the organization that are performed exclusively outside of the settings where home infusion therapy 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 486.525(c)(1).

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

- A process for ensuring all personnel specified in 42 CFR 486.525(c)(1) (except for those personnel who have pending requests for, or who have been granted, exemptions to the vaccination requirements of 42 CFR 486.525(c), 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 organization and/or its patients.
- A process for ensuring that all personnel specified in 42 CFR 486.525(c)(1) are fully vaccinated, except for those personnel who have been granted exemptions to the vaccination requirements of 42 CFR 486.525(c), 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 486.525(c)(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 organization 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 HIT's COVID-19 vaccination requirements for personnel 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
Evidence: Observation

Services applicable: HITS

Standard HIT4-3A: Written policies and procedures are established and implemented that describe the orientation process. Documentation reflects that all personnel have received an orientation.

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

- Review of the individual's job description, duties performed, and his or her role in the organization
- Organizational chart
- Record-keeping and reporting
- Confidentiality and privacy of Protected Health Information (PHI)
- Client's/patient's rights
- Advance Directives, if applicable to the service(s) provided
- Conflict of interest
- Written policies and procedures
- Emergency plan
- Training specific to job requirements
 - Infusion site management
 - Infusion pump management
- Additional training for special populations, if applicable (e.g., pediatrics, disease processes with specialized care and, developmentally disabled individuals)
- Cultural diversity
- Communication barriers
- Ethical issues
- Professional boundaries
- Performance Improvement (PI) Plan
- Compliance Program
- Conveying of charges for care/service
- OSHA requirements, safety, and infection control
- Orientation to equipment, if applicable
- Incident/variance reporting
- Handling of client/patient complaints/grievances
- Accreditation Commission for Health Care Home Infusion Therapy Accreditation Standards

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

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

Services applicable: HITS

Standard HIT4-4A: The organization designates an individual who is responsible for conducting orientation activities.

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

Evidence: Orientation Schedule

Services applicable: HITS

Standard HIT4-5A: Written policies and procedures are established and implemented requiring the organization to design a competency assessment program on the care/service provided for all direct care personnel.

The organization designs and implements a competency assessment program based on the care/service provided for all direct care personnel. Competency assessment is an ongoing process and focuses on the primary care/service, and/or therapies being provided. Competency assessment is 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 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 like disciplines is acceptable if defined by the organization. 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/Competency Assessments

Evidence: Response to Interviews

Services applicable: HITS

Standard HIT4-6A: A written education plan is developed and implemented which defines the content, frequency of evaluations and amount of ongoing in-service training for each classification of personnel.

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

The ongoing in-service 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.

The organization has an ongoing education plan that annually addresses, but is not limited to:

- Emergency/disaster training
- How to handle grievances/complaints
- Infection control training
- Cultural diversity
- Communication barriers
- Ethics training
- Workplace (OSHA), client/patient safety and components of HIT7-2A
- Client/patient rights and responsibilities
- Compliance Program

There is written documentation confirming attendance at ongoing education programs.

Evidence: Written Policies and Procedures

Evidence: Response to Interviews

Evidence: Personnel Files

Evidence: Observation

Services applicable: HITS

Standard HIT4-7A: Written policies and procedures are established and implemented in regard to the observation and evaluation of direct care/service 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 direct care/service 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 at least once annually to assess that quality care/service 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: HITS

Standard HIT4-8A: Supervision is available during all hours that care/service is provided.

There is administrative (and clinical, when applicable) supervision provided in all areas during the hours that care/service is furnished. Supervision is consistent with state laws and regulations.

Evidence: Observation
Evidence: On-Call Schedules
Evidence: Response to Interviews

Services applicable: HITS

Standard HIT4-9A: There is a qualified Registered Nurse (RN), Pharmacist or licensed skilled professional responsible for supervision of all services.

All Home Infusion Therapy services must be provided under the direction of an RN, Pharmacist or licensed skilled professional with sufficient education and experience in the scope of services offered. A minimum of two years of Home Infusion Therapy experience is required and one-year supervisory experience is required.

Evidence: Personnel Files
Evidence: Observation

Services applicable: HITS

Standard HIT4-10A: Written policies and procedures are established and implemented relating to special education, experience or certification requirements for Home Infusion Therapy 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.

Evidence: Written Policies and Procedures
Evidence: Personnel Files

Services applicable: HITS

Standard HIT4-11A: Written policies and procedures are established and implemented in regard to Home Infusion Therapy services being provided by a Nurse in the home in accordance with the state's regulations and and/or job descriptions.

Nurses function in accordance with professional standards, state regulations, and according to the organization's policies and procedures and/or job descriptions.

Current copies of applicable rules/regulations are available to personnel.

Evidence: Written Policies and Procedure
Evidence: Observation

Services applicable: HITS

Standard HIT4-12A: Written policies and procedures are established and implemented in regard to Licensed Practical Nurses/Licensed Vocational Nurses (LPN/LVN) being supervised by a Registered Nurse (RN).

Written policies and procedures outline the supervision of care/service provided by LPN/LVN personnel. The procedure outlines the process for assessing LPN/LVN practice and a method for ensuring that client/patient care needs are met.

Supervision includes:

- Client/patient record reviews
- Case conferences
- A visit to the client's/patient's home by the RN, with or without the LPN/LVN present, at least every 60 days, unless state laws requires more frequently

Evidence: Written Policies and Procedures
Evidence: Client/Patient Records

Evidence: Response to Interviews

Services applicable: HITS

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 HIT5-1A: Written policies and procedures are established and implemented relating to the required content of the client/patient record. An accurate record is maintained for each client/patient.

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

- Identification data
- Names of family/legal guardian/emergency contact
- Name of primary caregiver(s)
- Source of referral
- Name of physician responsible for care
- Diagnosis
- Physician's orders that include medications, dietary, treatment and activity orders, (as appropriate to the level of care/service the client/patient is receiving)
- Signed release of information and other documents for Protected Health Information (PHI)
- Admission and informed consent documents
- Initial assessments
- Signed and dated clinical and progress notes
- Signed notice of receipt of Client/Patient Rights and Responsibilities statement
- Initial plan of care
- Updated plan of care
- Evidence of coordination of care/service provided by the organization with others who may be providing care/service, if applicable
- Ongoing assessments, if applicable
- Assessment of the home, if applicable
- Copies of summary reports sent to physicians, if applicable
- Client/patient response to care/service provided
- A discharge summary, if applicable
- Advance Directives, if applicable
- Admission and discharge dates from a hospital or other institution, if applicable

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

Evidence: Written Policies and Procedures

Evidence: Client/Patient Record

Services applicable: HITS

Standard HIT5-1B: Client/patient records contain documentation of all care/services provided. All entries are legible, clear, complete, appropriately authenticated and dated in accordance with policies and procedures and currently accepted standards of practice.

The client/patient record contains documentation of all care/service provided, directly or by contract, and has entries dated and signed by the appropriate personnel. Each home visit, treatment, or care/service is documented in the client/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 organization is following appropriate safeguards to prevent unauthorized access to the client/patient records.

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

****For this standard, the reference to a physician is interpreted as a physician or other licensed independent practitioner with prescriptive authority***

Evidence: Client/Patient Records

Services applicable: HITS

Standard HIT5-2A: Written policies and procedures are established and implemented that address access, storage, removal, and retention of client/patient records and information.

Written policies and procedures are consistent with Health Insurance Portability and Accountability Act (HIPAA) standards, which include, but are not limited to:

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

All active client/patient records are kept in a secure location. Current electronic client/patient records are stored in an appropriate secure manner to maintain the integrity of the client/patient data through routine backups on- or off-site. Client/patient record information is safeguarded against loss or unauthorized use. An organization has written consent from the client/patient to release information not authorized by law.

All client/patient records are retained for a minimum of seven years from the date of the most recent discharge or the death of the client/patient, or per state law (whichever is the greater). Records of minor clients/patients are retained until at least seven years following the client's/patient's 18th birthday, or according to state laws and regulations. The organization's policies and procedures provide for retention even if the organization discontinues operations.

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

The client/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: Observation

Services applicable: HITS

Standard HIT5-3A: Written policies and procedures are established that describe the process for assessment and the plan of care. (486.520)

Written policies and procedures describe the process for a client/patient assessment, the development of the plan of care, and the frequency and process for the plan of care review.

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

A Registered Nurse (RN), Pharmacist or licensed skilled professional, per state licensure rules or regulations, conducts an assessment to determine eligibility, care, and support needs of the client/patient. The plan of care should be appropriate for the type of care/service that is needed. Care planning is directed toward driving positive client/patient outcomes.

Evidence: Written Policies and Procedures

Services applicable: HITS

Standard HIT5-3B: The assessment must be completed in a timely manner, consistent with client's/patient's immediate needs prior to initiation of Home Infusion Therapy services.

The assessment is performed on clients/patients referred for Home Infusion Therapy services and documented in the client's/patient's record. The assessment is based on client/patient need or perceived need and addresses physical status. The assessment is conducted and documented whether services continue or not. The assessment is appropriate to the client/patient age and diagnosis (e.g., infant, older adult, prenatal, or postpartum client/patient).

The assessment includes, but is not limited to:

Client/patient information:

- Client/patient demographics

The physical health component:

- Appropriateness of In-Home Infusion Therapy
- Identification of health problems
- Principle diagnosis and other pertinent diagnoses
- Review of medications:
 - Dosing
 - Frequency
 - Method
- Allergies
- Special dietary requirements
- Equipment and supply needs
- Other needed information that could impact the level of services required to meet the client/patient needs

The mental component:

- Orientation/memory
- Reasoning/judgment

The social component:

- Identification of the responsible party
- Identification of an emergency contact

The environmental component:

- Identification of safety and health hazards
- Presence of adequate living arrangements (e.g., heat, electricity, and water)
- Home environmental assessments, which include the potential for safety and security hazards, if applicable (e.g., water, heat, cooling, refrigeration, throw rugs, furniture layout, bathroom safety, cluttered stairways and blocked exits, unsecured doors, lack of smoke detectors, and fire risks)

The economic component:

- A review of the financial resources available to pay for the care/service provided

Functional limitations:

- Documentation of all functional limitations

A Registered Nurse (RN), Pharmacist, or licensed skilled professional conduct assessments. Specialized populations such as infants and children are assessed by a RN, Pharmacist or licensed skilled professional with appropriate training and experience.

Evidence: Client/Patient Records

Evidence: Observation

Services applicable: HITS

Standard HIT5-3C: There is a written plan of care for each client/patient accepted to services. (486.520(a)), (486.520(b))

All clients/patients have a plan of care established by a physician that prescribes the type, amount, and duration of the home infusion therapy services that are to be furnished. The initial plan of care includes, but is not limited to:

- Start of care date
- Client/patient demographics
- Principle diagnoses and other pertinent diagnoses
- Medications: dose/frequency/route
- Allergies
- Orders for specific clinical services, treatments, procedures (specify amount/frequency/duration)
- Equipment and supply needs
- Expected client/patient outcomes/goals
- Interventions
- Monitoring
- Functional limitations, if applicable
- Diet and nutritional needs, if applicable
- Safety measures, if applicable

Physician orders are required prior to the initiation of Home Infusion Therapy and the patient receiving home infusion therapy is under the care of an applicable provider.

Verbal orders are documented and signed with the name and credentials of the personnel receiving the order and signed by the physician within the time frame established in the organization's policies and procedures and/or state requirement.

Evidence: Client/Patient Records

Services applicable: HITS

Standard HIT5-3D: The organization shows evidence of the client/patient participation in the plan of care.

The client/patient has a right to be involved in the development of the plan of care and any changes in that plan. The degree of involvement may vary depending on the status of the client/patient. At a minimum, the client/patient agrees to the plan of care prior to the beginning of services and as subsequent changes occur.

The methods by which the organization documents participation include, but are not limited to:

- The plan of care is signed by the client/patient
- A notation is made in the client/patient record that the client/patient participated in the development of the plan of care
- There is documentation in the client/patient record that the plan of care was reviewed and accepted by the client/patient

Evidence: Response to Interviews

Evidence: Client/Patient Records

Services applicable: HITS

Standard HIT5-3E: Care/services are delivered in accordance with the written plan of care.

The client/patient record reflects that the care is delivered in accordance with the plan of care and is directed at achieving established goals. The documentation also shows effective communication and coordination between all personnel involved in the client's/patient's care.

Evidence: Client/Patient Records

Services applicable: HITS

Standard HIT5-3F: There is evidence that the plan of care for Home Infusion Therapy services is reviewed periodically by the client's/patient's physician and revised based on reassessment data by a Registered Nurse (RN), Pharmacist or licensed skilled professional. (486.520(c))

There is documentation in the client/patient record that reflects the plan of care is reviewed periodically by the client's/patient's physician for:

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

The organization follows program policies and procedures and any applicable laws and rules for the frequency of the plan of care review. Review of the plan of care can occur more frequently if indicated by the client's/patient's needs.

The plan of care should be reviewed by an RN, Pharmacist, or licensed skilled professional:

- At a minimum of every refill request
- When there are changes in client's/patient's response to infusion therapy
- When orders change
- At the request of client/patient
- As defined in the organization's policies and procedures

Included in this review is a discussion with the client/patient to determine the level of satisfaction with the care/services being provided. Notation of a review may be made in the client/patient record and in meeting minutes (team meetings or case conferences).

Evidence: Client/Patient Records

Evidence: Response to Interviews

Services applicable: HITS

Standard HIT5-3G: Home Infusion providers use monitoring and remote monitoring technology and/or techniques to monitor the patient's compliance with the plan of care. (486.525(a)(3))

Monitoring and remote monitoring is provided to review the overall compliance of the client/patient. Monitoring the client's/patient's infusion history assists with the ongoing assessment of the client's/patient's plan of care.

The Home Infusion provider monitors the following:

- Treatment response
- Drug complications
- Adverse reactions
- Infusion rates
- Hours of therapy
- If client/patient regularly under or over infuses

Evidence: Observation

Evidence: Client/Patient Records

Evidence: Response to Interviews

Services applicable: HITS

Standard HIT5-3H: The Home Infusion Therapy (HIT) supplier is responsible for coordinating care effectively with pharmacy, nurse and any licensed professional involved in the clients/patients care.

All HIT suppliers furnishing services maintain a liaison with other health care professionals and/or organizations to ensure that their efforts are coordinated effectively and support the objectives outlined in the plan of care.

The Hit supplier coordinates care by:

- Ensuring communication with the physician involved in the plan of care
- Integrating services, whether services are provided directly or under arrangement, to assure the identification of patient needs and factors that could affect client/patient safety and treatment effectiveness and the coordination of care provided by all disciplines
- Coordinating care delivery to meet the client's/patient's needs, and involve the client/patient, representative (if any), and caregiver(s), as appropriate, in the coordination of care activities
- Ensuring that each client/patient, and his or her caregiver(s) where applicable, receives ongoing education and training provided by a licensed health care professional, as appropriate, regarding the care and services identified in the plan of care.

The client/patient record documents the effective interchange, reporting, and coordination of client/patient care.

Evidence: Client/Patient Records

Evidence: Response to Interviews

Services applicable: HITS

Standard HIT5-4A: Written policies and procedures are established and implemented for addressing client/patient needs which cannot be met by the organization at time of referral. The organization coordinates planning and care/service delivery efforts with other community agencies. Clients/patients are referred to other agencies when appropriate.

Care/service needs that cannot be met by the organization are addressed by referring the client/patient to other organizations when appropriate.

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

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

Evidence: Written Policies and Procedures

Evidence: Referral Log/Tool

Evidence: Response to Interviews

Services applicable: HITS

Standard HIT5-5A: Written policies and procedures are established and implemented that describe the client/patient referral and acceptance process.

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

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

Evidence: Written Policies and Procedures

Evidence: Client/Patient Records

Services applicable: HITS

Standard HIT5-6A: Written policies and procedures are established and implemented that describe the process for client/patient education. (486.525(a)(2))

Written policies and procedures describe client/patient education. The policies/procedures and practices include, but are not limited to:

- Disease management as appropriate to the care/service provided
- Proper use, safety hazards, and infection control issues related to the use and maintenance of any equipment that is provided
- Plan of care
- Site management
- How to notify the organization of problems, concerns and complaints
- Emergency preparedness information

Client/patient training and education includes components that are not otherwise paid for as durable medical equipment services as described in 42 CFR 424.57(c)(12).

Evidence: Written Policies and Procedures

Evidence: Client/Patient Records

Services applicable: HITS

Standard HIT5-6B: Client/patient education focuses on goal and outcome achievement as established in the plan of care.

Client/patient education is an integral part of care/services provided. Assessment of the client's/patient's knowledge deficits and learning abilities are evaluated during the initiation of care/services.

Client/patient education/instruction proceeds in accordance with the client's/patient's willingness and condition to learn.

Education is coordinated with the client/patient and the healthcare team, and that focuses on goals and outcome achievement as established in the plan of care. Elements of client/patient education include, but are not be limited to:

- Ongoing assessment of client's/patient's learning needs
- Communication of needs to other healthcare team members
- Incorporating client/patient needs into the plan of care

The client/patient record must indicate educating the client/patient about appropriate actions to take if a medication or treatment reaction occurs when a healthcare professional is not present.

The client/patient record includes documentation of all teaching, client's/patient's response to teaching, and the client's/patient's level of progress/achievement of goals/outcomes. Written instructions are provided to the client/patient.

If medical supplies are provided, written instructions must be provided to clients/patients regarding the safe and appropriate use and care of the supplies.

Evidence: Client/Patient Records

Evidence: Response to Interviews

Services applicable: HITS

Standard HIT5-7A: Written policies and procedures are established and implemented that describe the process for discharge/transfer of a client/patient.

The client/patient record should reflect discharge/transfer planning activities, the client's/patient's response and understanding to these activities, client/patient care instructions, and a reasonable notice prior to discharge/transfer, whenever possible.

There is a discharge/transfer summary report, a notation in the progress notes, or a software section dedicated to discharge/transfer that includes:

- A summary of the services provided
- Client's/patient's response to therapy (e.g., progress toward clinical goals)
- The date and reason for the discharge/transfer
- A brief description of ongoing needs that could not be met
- Any instructions or referral information given to the client/patient

A copy of the discharge/transfer summary is made available to the physician and a copy is placed in the client/patient record.

Evidence: Written Policies and Procedures

Evidence: Client/Patient Records

Services applicable: HITS

Standard HIT5-8A: Written policies and procedures are established and implemented in regard to the requirements for organization staff administering the first dose of a medication in the home setting.

The organization 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 organization 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* 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 client/patient at least a half hour after the administration of the medication to ensure the client/patient has tolerated the medication well
- The appropriate monitoring of the client/patient after the first dose is administered

*** For this standard, the reference to a physician is interpreted as a physician or other licensed independent practitioner with prescriptive authority**

Evidence: Written Policies and Procedures

Evidence: Client/Patient Records

Services applicable: HITS

Standard HIT5-8B: A Registered Nurse (RN), Pharmacist or a licensed skilled professional reviews all client/patient medications, both prescription and non-prescription, on an ongoing basis as part of the care/services to a client/patient.

An RN, Pharmacist or licensed skilled professional reviews and documents all prescription and non-prescription medications that a client/patient is taking.

A medication profile includes, but is not limited to:

- All current client/patient medications
- Date prescribed or taken
- Name of medication
- Dose
- Route
- Frequency

- Date discontinued
- Drug and/or food allergies

The RN, Pharmacist or licensed skilled professional is specifically accountable for recognizing the following:

- Side effects
- Toxic effects
- Allergic reactions
- Immediate desired effects
- Unusual and unexpected effects
- Changes in the client's/patient's condition that contraindicates continued administration of the medication

In addition, the RN, Pharmacist or licensed skilled professional is able to anticipate those effects that may rapidly endanger a client's/patient's life or well-being, and instruct the client/patient as necessary in following the prescribed regimen.

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

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

****For this standard, the reference to a physician is interpreted as a physician or other licensed independent practitioner with prescriptive authority***

Evidence: Client/Patient Records

Evidence: Observation

Services applicable: HITS

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 HIT6-1A: The organization develops, implements, and maintains an effective, ongoing, organization wide Performance Improvement (PI) program. The organization measures, analyzes, and tracks quality indicators, including adverse client/patient events, and other aspects of performance that enable the organization to assess processes of care, services, and operations. Organizational-wide performance improvement efforts address priorities for improved quality of care/service and client/patient safety, and that all improvement actions are evaluated for effectiveness.

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

- Current documentation (e.g., review of client/patient records, incident reports, complaints, and client/patient satisfaction surveys)
- Client/patient care/services
- Direct observation in care/service setting
- Operating systems
- Interviews with clients/patients and/or personnel

The information gathered by the organization is based on criteria and/or measures generated by personnel. This data reflects best practice patterns, personnel performance, and client/patient outcomes.

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 following elements are considered within the plan:

- Program objectives
- All disciplines
- Description of how the program will be administered and coordinated
- Methodology for monitoring and evaluating the quality of care/service
- Priorities for resolution of problems
- Monitoring to determine effectiveness of the action
- Oversight and responsibility for reports to the governing body/owner

Evidence: Written Policies and Procedures/PI Plan

Evidence: PI reports and/or documents

Evidence: Observation

Services applicable: HITS

Standard HIT6-1B: The organization ensures the implementation of an organization wide Performance Improvement (PI) plan by the designation of a person responsible for coordinating PI activities.

Duties and responsibilities relative to PI coordination include:

- Assisting with the overall development and implementation of the PI plan
- Assisting in the identification of goals and related client/patient outcomes
- Coordinating, participating in and reporting of activities and outcomes

The position responsible for coordinating PI 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: HITS

Standard HIT6-1C: There is evidence of involvement of the governing body/owner and organizational leaders in the Performance Improvement (PI) process.

The governing body/owner and managers/leaders are ultimately responsible for all actions and activities of the organization; therefore, their role in the evaluation process and the responsibilities delegated to personnel are documented.

There is evidence that the results of PI activities are communicated to the governing body/owner and organizational managers/leaders.

The organization's managers/leaders allocate resources for implementation of the PI program. Resources include, but are not limited to:

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

Evidence: Governing Body Meeting Minutes, if applicable

Evidence: Response to Interviews

Services applicable: HITS

Standard HIT6-1D: There is evidence of personnel involvement in the Performance Improvement (PI) process.

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

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

Personnel are involved in the evaluation process through carrying out PI 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: HITS

Standard HIT6-2A: There is an annual Performance Improvement (PI) report written.

There is a comprehensive, written annual report that describes the PI 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, client/patient questionnaires, feedback from referral sources, and outside survey reports).

Evidence: Performance Improvement Annual Report

Services applicable: HITS

Standard HIT6-2B: Each Performance Improvement (PI) activity or study contains the required items.

Each PI 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/threshold
- 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 PI activity.

Evidence: Performance Improvement Activities/Studies

Services applicable: HITS

Standard HIT6-2C: Performance Improvement (PI) activities include ongoing monitoring of processes that involve risks, including infections and communicable diseases.

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

Evidence: Performance Improvement Reports

Evidence: Incident/Variance Reports

Services applicable: HITS

Standard HIT6-2D: Performance Improvement activities include ongoing monitoring of at least one important aspect related to the care/service provided.

The organization monitors at least one important aspect of the care/service provided by the organization. An important aspect of care/service reflects a dimension of activity that may be high-volume (occurs frequently or affects a large number of clients/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 clients/patients in the past).

Evidence: Performance Improvement Reports

Services applicable: HITS

Standard HIT6-2E: Performance Improvement (PI) activities include satisfaction surveys.

The PI plan identifies the process for conducting client/patient and personnel satisfaction surveys.

Evidence: Performance Improvement Reports

Services applicable: HITS

Standard HIT6-2F: The Performance Improvement (PI) plan includes ongoing monitoring of the client/patient record.

The client/patient record review is conducted by all disciplines or members of the client/patient care/service team. An adequate sampling of open and closed records is selected to determine the completeness of documentation.

Evidence: Performance Improvement Reports

Services applicable: HITS

Standard HIT6-2G: Performance Improvement (PI) activities include the ongoing monitoring of client/patient grievances/complaints.

PI activities include ongoing monitoring of client/patient grievances/complaints and the action(s) needed to resolve grievances/complaints and improve client/patient care/service.

Evidence: Performance Improvement Reports

Services applicable: HITS

Standard HIT6-2H: The organization monitors all care/service provided under contract/agreements to ensure that care/services are delivered in accordance with the terms of the contract/agreement.

The organization has implemented a process for monitoring all care/service provided under a contract/agreement. Processes include, but are not limited to:

- Satisfaction surveys

- Record reviews
- On-site observations and visits
- Client/patient comments and other performance improvement (PI) activities

Data and outcomes from monitoring activities are reported to the organization leadership to ensure the overall quality of the care/service provided to the client/patient.

Evidence: Performance Improvement Activities

Evidence: Board Minutes or Leadership Meeting Documentation

Services applicable: HITS

Standard HIT6-2I: Performance Improvement (PI) activities include ongoing monitoring of billing and coding errors.

The organization tracks the number of billing inconsistencies found through client/patient record reviews as well as errors found through Medicare and third-party payor claim denials.

Evidence: Performance Improvement Reports

Services applicable: HITS

Standard HIT6-3A: Written policies and procedures are established and implemented by the Organization to identify, monitor, report, investigate and document all adverse events, incidents, accidents, variances, or unusual occurrences that involve client/patient care/service.

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*, if applicable
- Follow-up reporting to the administration/board/owner

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

The organization investigates all adverse events, incidents, accidents, variances or unusual occurrences that involve client/patient services, and develops a plan to prevent the same or a similar event from occurring again. Events include, but are not limited to:

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

There are written policies and procedures for the organization 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 organization used to report incidents.

This data is included in the Performance Improvement (PI) plan. The organization assesses and utilizes the data for reducing further safety risks.

****For this standard, the reference to a physician is interpreted as a physician or other licensed independent practitioner with prescriptive authority***

Evidence: Written Policies and Procedures

Evidence: Incident/Variance Reports

Evidence: Performance Improvement Reports

Services applicable: HITS

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 HIT7-1A: 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.

The organization maintains and documents an effective infection control program that protects clients/patients and personnel by preventing and controlling infections and communicable diseases.

The organization'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 and clients/patients 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 include accepted standards of practice to prevent the transmission of infections and communicable diseases, including the use of standard precautions.

Accepted standards of practice for healthcare 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 organization 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])

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

The organization has written policies and procedures that detail Occupational Safety and Health Administration (OSHA) Blood Borne Pathogen and Tuberculosis (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 TB 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 are responsible for implementation of the infection control activities and personnel education.

The organization provides infection control education to employees, contracted providers, clients/patients, and family members 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 clients/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: Response to Interviews
Evidence: Client/Patient Records
Evidence: Home Visit/Mock Demonstration

Services applicable: HITS

Standard HIT7-1B: The organization reviews and evaluates the effectiveness of the infection control program.

The organization monitors infection statistics of both clients/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.

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

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

Data is utilized to assess the effectiveness of the infection control program. Corrective action plans and steps for improvement are to be implemented as needed. Data and action plans must be included in the performance improvement (PI) reports and communicated to leadership and personnel.

The organization 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: Performance Improvement Reports

Services applicable: HITS

Standard HIT7-2A: 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
Evidence: Response to Interviews
Evidence: Observation

Services applicable: HITS

Standard HIT7-2B: Written policies and procedures are established and implemented that address client/patient safety in the home.

Written policies and procedures address client/patient safety in the home. The safety training activities include, but are not limited to:

- Compliance monitoring measures relating to the client's/patient's medication, if applicable
- Client/patient medical equipment safety, if applicable
- Basic home safety measures (e.g., household chemicals, throw rugs, furniture layout, cluttered stairways, blocked exits,

bathroom safety, and electrical safety)

Evidence: Written Policies and Procedures

Evidence: Response to Interviews

Services applicable: HITS

Standard HIT7-3A: Written policies and procedures are established and implemented that outline the process for meeting client/patient needs in a disaster or crisis situation.

Written policies and procedures describe a process to organize and mobilize personnel adequate to secure resources needed to meet client/patient needs in the event of a disaster or crisis. The process includes:

- A system to identify alternative methods for contacting personnel
- Mobilizing resources to meet critical needs
- Alternative methods, resources, and travel options for the provision of care/service
- Safety of personnel
- Identified time frames for initiation of the plan
- Specific measures for anticipated emergencies typical or appropriate for the geographical area served (e.g., hurricanes, tornadoes, floods, earthquakes, chemical spills, and inclement weather)
- Clients/patients identified and prioritized based upon their need so that care/service is ensured for clients/patients whose health and safety might be at risk

The organization educates all personnel about the process to meet patient needs in a disaster or crisis situation.

The organization has, at a minimum, an annual practice drill to evaluate the adequacy of its plan.

The emergency plan also describes access to 911 Emergency Medical Services (EMS) in the event of needed emergency care/ services for clients/patients and personnel.

Evidence: Written Policies and Procedures

Evidence: Disaster Drill Log

Evidence: Observation

Evidence: Client/Patient Records

Evidence: Response to Interviews

Services applicable: HITS

Standard HIT7-3B: The organization provides education to the client/patient regarding emergency preparedness.

This education includes information on planning for emergencies/disasters such as:

- Evacuation plans
- Medications
- Food/water
- Important documents
- Care for pets, if applicable

Evidence: Client/Patient Education Material

Evidence: Client/Patient Records

Services applicable: HITS

Standard HIT7-4A: Written policies and procedures are established and implemented that address the organization's fire safety and emergency power systems.

Written policies and procedures or a fire safety plan addresses fire safety and management for all office and worksite environments and includes:

- Providing emergency power to critical areas, such as:
 - Alarm systems, if applicable
 - Illumination of exits
 - 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:
 - Conducted at least annually
 - 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: HITS

Standard HIT7-5A: 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 client/patient care/ service.

Written policies and procedures include the safe method of acceptance, transportation, and pickup and/or disposal of hazardous wastes, chemicals and/or contaminated materials used in the home/organization. The organization follows local, state, and federal guidelines.

Evidence: Written Policies and Procedures

Evidence: Observation

Services applicable: HITS

Standard HIT7-6A: Written policies and procedures are established and implemented in regard to 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 follow OSHA's Hazard Communication Standard, detailing:

- The labeling of hazardous chemical containers and/or materials with the identity of the material and the appropriate hazard warnings
- Current Safety Data Sheets (SDSs) 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)

Products that require an SDS sheet include:

- Hand Sanitizer
- Product cleaner

Written policies and procedures address how personnel handle exposure to a hazardous product while in the home environment.

Evidence: Written Policies and Procedures

Evidence: Observation

Services applicable: HITS

Standard HIT7-7A: 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 recording work-related injuries and

illnesses that are diagnosed by a physician* or licensed healthcare 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 organization.

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 organization business
- Environmental safety hazards
- Equipment safety hazards, malfunctions, or failures
- Unusual occurrences

There is a standardized form developed by the organization to report incidents. The organization 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 laws and regulations. This data is included in the Performance Improvement (PI) program. The organization assesses and utilizes the data for reducing further safety risks.

The organization educates all personnel on its policies and procedures for documenting and reporting incidents/variances.

****For this standard, the reference to a physician is interpreted as a physician or other licensed independent practitioner with prescriptive authority.***

Evidence: Written Policies and Procedures

Evidence: Incident Reports

Evidence: OSHA 300, 300A and 301 Forms, if applicable

Evidence: Performance Improvement Reports

Evidence: Response to Interviews

Services applicable: HITS

Standard HIT7-8A: 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 client/patient care for screening, treatment, or diagnostic purposes.

Policies and procedures for the use of equipment in 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

Evidence: In-service Logs

Services applicable: HITS

Standard HIT7-9A: Written policies and procedures are established and implemented for the use of equipment/supplies in the provision of care/service to the client/patient.

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 the organization personnel
- Calibration per manufacturer's guidelines, if applicable
- Requirements for dispensing of any disposable supply used in the provision of care/service
- Manufacturer's recalls

Personnel implement the policies and procedures for the use of the organization's equipment/supplies in the provision of care/service to the client/patient. The cleaning and maintenance of equipment used in the provision of care is documented. Supplies used

in the provision of care/service are also documented.

Evidence: Written Policies and Procedures

Evidence: Observation

Evidence: Maintenance Logs

Evidence: Response to Interviews

Services applicable: HITS

Standard HIT7-10A: Written policies and procedures are established and implemented for participating in clinical research/experimental therapies and/or administering investigational drugs.

This criterion is applicable to organization's that are participating in clinical research/experimental therapies, or administering investigational drugs.

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

- Informing clients/patients of their responsibilities
- Informing clients/patients of their right to refuse investigational drugs or experimental therapies
- Informing clients/patients of their right to refuse to participate in research and clinical studies
- Notifying clients/patients that they will not be discriminated against for refusal to participate in research and clinical studies
- Stating which personnel can administer investigational medications/treatments
- Describing personnel's role in monitoring a client's/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: HITS

Standard HIT7-11A: Written policies and procedures are established and implemented for medication and product recall.

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

- Tracking medications and products
- External and internal reporting of medication or product defects
- Safe disposition of recalled medications or products

Records are maintained to identify each client/patient who has received recalled medications or products.

Documentation includes, but is not limited to:

- The manufacturer of each client's/patient's medication
- Lot numbers
- Expiration dates
- Serial numbers used to track equipment

There is evidence of external reporting of medication or product defects. Client's/patient's physicians* are notified when medications are recalled.

****For this standard, the reference to a physician is interpreted as a physician or other licensed independent practitioner with prescriptive authority.***

Evidence: Written Policies and Procedures

Evidence: Client/Patient Records

Evidence: Response to Interviews

Evidence: Dispensing/Recall Records

Services applicable: HITS

Standard HIT7-12A: Written policies and procedures are established and implemented relating to pharmaceutical storage.

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

- Storage of pharmaceuticals (separated from food items or other sources of contamination)
- Monitoring of storage room, refrigerator, and freezer temperatures

- Accessibility of legend drugs
- Storage during delivery
- Cleaning and disinfecting of any reusable containers (e.g., delivery coolers)
- Pharmaceutical labeling as to the appropriate storage

Pharmaceuticals are stored in accordance with manufacturer's or USP requirements. Temperatures are monitored wherever pharmaceuticals are stored to ensure that the requirements are met. Prescription and legend drugs are stored in the licensed pharmacy, which is accessible only under the supervision of a licensed pharmacist(s).

Evidence: Written Policies and Procedures

Evidence: Observation

Evidence: Temperature/Cleaning Logs

Evidence: Response to Interviews

Services applicable: HITS

Standard HIT7-12B: The organization uses delivery containers that ensure pharmaceuticals are maintained under appropriate conditions of sanitation, light and temperature in the course of deliveries.

The organization ensures pharmaceuticals are maintained under appropriate conditions of sanitation, light, and temperatures in the course of deliveries. Where appropriate, the organization uses delivery containers such as coolers and ice packs to maintain the storage conditions in accordance with manufacturer's and USP <797> requirements.

Shipping methods are tested periodically to ensure that containers stay within specified temperature requirements.

Evidence: Observation

Evidence: Shipping Records

Evidence: Response to Interviews

Services applicable: HITS

Standard HIT7-12C: The organization ensures that pharmaceuticals are stored under appropriate condition of sanitation, light and temperature in the client's/patient's home.

Pharmaceuticals dispensed to the client/patient are clearly labeled with the appropriate storage conditions requirements.

The organization educates the client/patient on the appropriate conditions for the storage of pharmaceuticals in the home environment. When necessary, the Pharmacist intervenes, to ensure that appropriate conditions are achieved or maintained.

Evidence: Client/Patient Records

Evidence: Response to Interviews

Services applicable: HITS

Standard HIT7-13A: Personnel implement the organization's policies and procedures for the cleaning, storage, safe transportation, delivery and setup of equipment used in the provision of care/service. Implementation includes a home environmental and electrical safety assessment. (Only applies if nursing organization provides infusion equipment.)

The organization practices its policies and procedures for:

- Cleaning, storage, and transportation of client/patient-ready equipment/supplies
- Separation of dirty and clean equipment
- Equipment being returned to the organization for processing
- Warehousing and tagging of equipment
- Environmental assessments, set-up, and demonstration of safe and proper use of all home medical equipment according to manufacturer's guidelines
- Separation and removal/disposal of expired products
- Rotation of stock
- Equipment calibration according to manufacturer's guidelines and documented
- Routine maintenance, preventative maintenance, and repairs are performed according to manufacturer's guidelines and documented
- Cleaning and disinfecting of equipment in compliance with standard precautions and organization's policies and procedures

The organization practices safe procedures in the delivery of equipment:

- Vehicle has appropriate tie-down straps for equipment
- Vehicle is neat and clean
- Vehicle has the ability to separate clean and dirty equipment
- SDS sheets are accessible/available, if applicable
- Vehicles used for product delivery comply with all applicable laws and regulations

At time of delivery, the home assessment includes, but is not limited to:

- Safety and adequacy of electrical outlets
- Safe use of extension cords and outlet adapters
- Location and function of all equipment controls and equipment circuit breakers

Training on equipment is provided and documented in the client/patient record.

Evidence: Observation

Evidence: Response to Interviews

Services applicable: HITS

Standard HIT7-13B: Personnel implement the organization's policies and procedures relating to backup equipment for use during power failures in the client/patient home. (Only applies if Home Infusion Therapy organization provides infusion equipment.)

Client/patient home medical equipment backup systems comply with the organization's policies and procedures and state law, as applicable.

Evidence: Client/Patient Records

Evidence: Response to Interviews

Services applicable: HITS

Standard HIT7-14A: The organization follows procedures for waived tests under the Clinical Laboratory Improvement Amendment (CLIA) and state regulations when personnel perform waived tests. The organization obtains and maintains a current certificate of waiver from the Department of Health and Human Services. The organization also ensures that referral laboratories are certified.

Organizations that conduct waived tests under CLIA will obtain and maintain a current certificate of waiver from the Department of Health and Human Services. Examples of waived tests are blood glucose monitoring, fecal occult blood testing and dipstick urinalysis. If an organization refers specimens for lab testing to an outside laboratory, the referral lab is CLIA certified. The organization has a copy of the CLIA certificate for the lab it utilizes for specimen testing.

Evidence: Current Certificate of Waiver

Services applicable: HITS

Standard HIT7-15A: Written policies and procedures are established and implemented to ensure that the appropriate care/services are provided to the correct client/patient.

There is a process to verify the identity of the client/patient and the treatment the client/patient is to receive.

Evidence: Written Policies and Procedures

Evidence: Client/Patient Records

Evidence: Response to Interviews

Services applicable: HITS

Appendix A: Reference Guide for Required Documents, Policies and Procedures

Customized for: HITS

Standard #	Documents, Policies and Procedures	Agency Notes
HIT1-2A	Written Policies and Procedures	
HIT1-3A	Written Policies and Procedures	
HIT1-6A	Written Policies and Procedures	
	Observation	
HIT1-7A	Written Policies and Procedures	
HIT1-9A	Written Policies and Procedures	
HIT1-11A	Written Policies and Procedures	
HIT2-1A	Written Policies and Procedures	
HIT2-2A	Written Policies and Procedures	
HIT2-3A	Written Policies and Procedures	
HIT2-4A	Written Policies and Procedures	
HIT2-5A	Written Policies and Procedures	
HIT2-6A	Written Policies and Procedures	
HIT2-6B	Written Policies and Procedures	
HIT2-7A	Written Policies and Procedures	
HIT2-8A	Written Policies and Procedures	
HIT2-8B	Written Policies and Procedures	
HIT2-9A	Written Policies and Procedures	
HIT4-1A	Written Policies and Procedures	
HIT4-2B	Written Policies and Procedures	
HIT4-2C	Written Policies and Procedures	
HIT4-2E	Written Policies and Procedures	
HIT4-2F	Written Policies and Procedures and/or Employee Handbook	
	Observation	
HIT4-2G	Written Policies and Procedures	
HIT4-3A	Written Policies and Procedures	
HIT4-5A	Written Policies and Procedures	
HIT4-6A	Written Policies and Procedures	
HIT4-7A	Written Policies and Procedures	
HIT4-10A	Written Policies and Procedures	
HIT4-11A	Written Policies and Procedure	
HIT4-12A	Written Policies and Procedures	
HIT5-1A	Written Policies and Procedures	
HIT5-2A	Written Policies and Procedures	
HIT5-3A	Written Policies and Procedures	
HIT5-4A	Written Policies and Procedures	
HIT5-5A	Written Policies and Procedures	
HIT5-6A	Written Policies and Procedures	
HIT5-7A	Written Policies and Procedures	
HIT5-8A	Written Policies and Procedures	
HIT6-1A	Written Policies and Procedures/PI Plan	
HIT6-3A	Written Policies and Procedures	
HIT7-1A	Written Policies and Procedures	
HIT7-2A	Written Policies and Procedures	
HIT7-2B	Written Policies and Procedures	

HIT7-3A	Written Policies and Procedures	
HIT7-4A	Written Policies and Procedures	
HIT7-5A	Written Policies and Procedures	
HIT7-6A	Written Policies and Procedures	
	Observation	
HIT7-7A	Written Policies and Procedures	
HIT7-8A	Written Policies and Procedures	
HIT7-9A	Written Policies and Procedures	
HIT7-10A	Written Policies and Procedures	
HIT7-11A	Written Policies and Procedures	
HIT7-12A	Written Policies and Procedures	
HIT7-15A	Written Policies and Procedures	

ITEMS NEEDED FOR ON-SITE SURVEY



HOME INFUSION THERAPY

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.

- Current patient census, complete with start-of-care date, and admitting diagnosis
- Current schedule of patient visits
- Discharge/transfer patient census for past 12 months (or since start of operation, if less than one year)
- Personnel list with title, discipline, and hire date (including direct care contract staff)
- Any previous survey results from the past year
- Admission packet or education materials given to patients
- Staff meeting minutes for the past 12 months
- Any internal Plan of Correction based on identified deficiencies along with audit results

Annual requirements are not applicable to agencies in operation for less than one year.

ACHC Standard	Required Item	Located
Required policies to be reviewed during survey	Access to policy and procedure manual with the following policies flagged: <ul style="list-style-type: none"> ■ HIT2-2A Client/Patient rights and responsibilities ■ HIT2-3A Investigation of abuse, neglect, and exploitation ■ HIT2-4A Reporting and investigation client/patient grievances/complaints ■ HIT4-2E Background checks ■ HIT4-2H COVID-19 vaccination requirements ■ HIT6-3A Investigation of adverse events ■ HIT7-11A Medication and product recall requirements ■ HIT7-12A Pharmaceutical storage requirements 	
HIT1-1A	Copy of current applicable licenses or permits and copy of articles of incorporation/bylaws	
HIT1-2A	Governing body meeting minutes for the past 12 months and documentation of orientation	
HIT 1-3A	Written disclosure of identified conflicts of interest, if applicable	
HIT1-4 A	The job description for the manager/leader meets any applicable state and federal laws as well as agency requirements. The job description for the individual to act in the absence of the manager/leader.	

ACCREDITATION COMMISSION *for* HEALTH CARE

ACHC Standard	Required Item	Located
HIT1-4B	Annual performance review of the manager/leader	
HIT1-5A/HIT4-8A	Organizational chart	
HIT1-6A	All required federal and state posters are placed in a prominent location	
HIT1-8A	Action plans for any negative outcomes that impacted licensure or Medicare/Medicaid certification	
HIT1-9A	Notification of change in ownership, if applicable	
HIT1-10A	Contracts for direct care staff, including copies of professional liability insurance certificates	
HIT1-11A	Verification of physician licensure or other licensed independent practitioner with prescriptive authority	
HIT2-1A	Marketing materials and/or written description of care/services provided by the agency	
HIT2-2A	Client/Patient Rights and Responsibilities statement	
HIT2-3A	Client/patient grievance/complaint log	
HIT2-4A/HIT2-4B	Written information regarding the reporting of client/patient complaints	
HIT2-5A	Signed confidentiality statement for all personnel, contract staff, and governing body/owner	
HIT2-5B	Business Associate Agreements (BAAs) for non-covered entities	
HIT2-6A	Advance Directive information provided to client/ patients	
HIT2-6B	Information provided to clients/patients regarding agency's resuscitative policies	
HIT2-7A	Evidence of how ethical issues are identified, evaluated and discussed	
HIT2-8A	Evidence of communication assistance for language barriers	
HIT2-8B	Evidence of cultural diversity training	
HIT2-9A	Evidence of a Compliance Program	
HIT2-10A	On-call calendar	
HIT3-1A	Most recent annual operating budget	
HIT3-3A	List of care/services with corresponding charges	

ACCREDITATION COMMISSION *for* HEALTH CARE

ACHC Standard	Required Item	Located
HIT3-4A	Evidence clients/patients are provided information on their financial liability	
HIT4-1C	Personnel records (including direct care and contract staff) contain evidence of the items listed in the standard. Surveyor will review personnel records based on the services provided by the agency.	
HIT4-2F	Evidence of access to Employee Handbook or access to personnel policies	
HIT4-2H	Evidence of a tracking process utilized to log the COVID-19 vaccination status of personnel and the contingency plans for personnel who are not fully vaccinated to mitigate the spread of COVID-19 infections.	
HIT4-4A	Evidence of individual designated as being responsible for orientation	
HIT4-6A	Evidence of ongoing education and/or written education plan	
HIT4-10A/HIT4-11A	Nursing Board Scope of Practice	
HIT5-1A	Client/patient records contain all required information as stated in standard	
HIT5-2A	Evidence agency maintains client/patient information in a confidential manner	
HIT5-3B	Client/patient assessment contains all items listed in the standard	
HIT5-3C	Client/patient plan of care contains all items listed in the standard	
HIT5-3G	Evidence of monitoring and remote monitoring to ensure overall compliance with the plan of care	
HIT5-4A	Referral log or other tool to record referrals	
HIT5-6A	Client/patient education materials	
HIT6-1A	Performance Improvement (PI) Program	
HIT6-1B	Job description for individual responsible for the PI Program	
HIT6-1C	Governing body meeting minutes demonstrate involvement of the governing body in PI	
HIT6-1D	Evidence of personnel involvement in PI	
HIT6-2A	PI annual report	

ACCREDITATION COMMISSION *for* HEALTH CARE

ACHC Standard	Required Item	Located
HIT6-2C	Evidence of monitoring processes that involve risks, including infections and communicable diseases, including the monitoring staff incidents, accidents, complaints and worker compensation claims	
HIT6-2D	Evidence of monitoring of an aspect related to patient care (high risk, high volume, problem prone)	
HIT6-2E	Satisfaction surveys utilized in PI	
HIT6-2F	Evidence of ongoing chart audits and that results are utilized in PI	
HIT6-2G	Evidence of monitoring of client/patient complaints and actions needed to resolve issues	
HIT6-2H	Evidence of monitoring of care provided under contract/agreement	
HIT6-2I	Evidence of monitoring billing and coding errors	
HIT6-3A	Evidence of proper documentation, investigation, and resolution of all adverse events involving clients/patients	
HIT7-1A	Evidence of an Injection Control Program, Annual TB Agency Assessment, TB exposure control plan and OSHA Blood Borne Pathogens plan	
HIT7-1B	Infection control logs for clients/patients and personnel and evidence infection control data is monitored and incorporated into PI as appropriate	
HIT7-2A	Evidence of safety education provided to personnel	
HIT7-3A	Emergency disaster plan and results of an annual emergency disaster drill	
HIT7-3B	Emergency preparedness information provided to clients/patients	
HIT7-4A	Report of annual fire drill and results of testing of emergency power systems	
HIT7-6A	Access to Safety Data Sheets (SDS) and evidence staff are provided personal protective equipment (PPE)	
HIT7-7A	Evidence of proper reporting of personnel incidents, accidents, variance or unusual occurrences. OSHA forms 300, 300A, and/or 301 (if applicable)	
HIT7-8A/HIT7-9A	Maintenance logs of any equipment used in the provision of care	
HIT7-11A	Medication dispensing and recall logs	

GLOSSARY OF TERMS

HOME INFUSION THERAPY

Applicable Provider: Means a physician, a nurse provider, and a physician assistant.

Assessment: A thorough evaluation of the patient's physical, psychosocial, emotional and spiritual status related to the terminal illness and related conditions. This includes a thorough evaluation of the caregiver's and family's willingness and capability to care for the patient.

Fully Vaccinated for COVID-19: Personnel are considered fully vaccinated if it has been two weeks or more since they completed a primary vaccination series for COVID-19. The completion of a primary vaccination series for COVID-19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

Home: Means a place of residence used as the home of an individual, including an institution that is used as a home. An institution that is used as a home may not be a hospital, critical access hospital (CAH), or a skilled nursing facility (SNF) as defined in section 1861(e)(1), 1861(mm)(1), 1819 (a)(1) of the Social Security Act, respectively.

Home Infusion Drug: Means a parenteral drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of durable medical equipment. The term does not include insulin pump systems or a self-administered drug or biological on a self-administered drug exclusion list. Infusion drug administration calendar day means the day on which home infusion therapy services are furnished by skilled professionals in the individual's home on the day of infusion drug administration. The skilled services provided on such day must be so inherently complex that they can only be safely and effectively performed by, or under the supervision of, professional or technical personnel.

Home Infusion Therapy: Home Infusion Therapy includes the provision of care to patients with acute or chronic conditions generally pertaining to parenteral administration of drugs, biologics and nutritional formulas administered through catheters and/or needles to individuals in their homes. Extensive professional pharmacy services, care coordination, infusion nursing services, supplies and equipment are provided to optimize efficacy, compliance and patient safety.

Infusion Drug Administration Calendar Day: The day on which [home](#) infusion therapy services are furnished by skilled professionals in the individual's [home](#) on the day of infusion drug administration. The skilled services provided on such day must be so inherently complex that they can only be safely and effectively performed by, or under the supervision of, professional or technical personnel.

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.

Qualified Home Infusion Therapy Supplier: A supplier of home infusion therapy that meets all of the following criteria which are set forth at section 1861(iii)(3)(D)(i) of the Act:

- (1) Furnishes infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs.
- (2) Ensures the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis.
- (3) Is accredited by an organization designated by the Secretary in accordance with section 1834(u)(5) of the Act.
- (4) Meets such other requirements as the Secretary determines appropriate.

GLOSSARY OF PERSONNEL QUALIFICATIONS



HOME INFUSION THERAPY



FOR PROVIDERS.
BY PROVIDERS.

Experienced Professional: A professional with at least one year of work experience.

Health Professional: A licensed health care provider authorized to supervise other personnel as defined in applicable occupational licensure laws and regulations.

Infusion Nurse: Is a licensed nurse, as allowed by state regulations with special education, training and expertise in home or other alternate-site administration of drugs and biologics via infusion. Services they typically provide include evaluation and assessment, education and training for the patient or caregiver, inspection and consultation of aseptic home environment, catheter insertion, and patient assessment.

Licensed Practical/Vocational Nurse (LPN/LVN): A person who is licensed as a Practical/Vocational Nurse by the state in which practicing.

Licensed Professional: A person licensed to provide patient care services by the state in which services are delivered.

Pharmacist: A licensed registered pharmacist with experience in home infusion therapy.

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 Staff: An individual that has had appropriate training and experience for the position held with evidence of education and training in accordance with applicable laws or regulations.