

Achieving ACHC Home Infusion Therapy Accreditation

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Also Joining Our Training Today

- Greg Stowell Associate Director, Education & Training
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Nursing Contact Hours

- Nursing contact hours for this workshop are provided by the Virginia Nurses Association.
- The number of hours earned will depend on registration and attendance (6 hours per day).
- You must attend the full day to be eligible.
- Only registered attendees are eligible for contact hours.
- If you are not registered and would like to receive contact hours, please contact us.
- Contact hour assistance or questions:
 - Suzie Steger <u>ssteger@achcu.com</u>
 - Steve Clark <u>sclark@achcu.com</u>





Items Needed For Virtual Training

- You should have received an email with a link to the following information:
 - ACHC Standards
 - ACHC Accreditation Process
 - The presentation for today
 - The ACHC Accreditation Guide to Success
- If you have not received the email or are unable to download the information, contact <u>customerservice@ACHCU.com</u> for assistance.





Objectives

- Review the ACHC Accreditation Process.
- Learn how to prepare an organization for the ACHC Accreditation Survey.
- Establish expectations for on-site survey and strategies for survey success.
- Learn how to utilize the ACHC Accreditation Guide to Success to ensure ongoing compliance.
- Identify how to avoid condition-level deficiencies.
- Review the ACHC Accreditation Standards to understand expectations for compliance.







Understanding the Home Infusion Therapy Benefit





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Medicare Benefits

- Medicare Part A:
 - Covers inpatient hospital care, skilled nursing facility, hospice, lab tests, surgery, home health care.
- Medicare Part B:
 - Covers durable medical equipment, out-patient services, physician visits, and some preventive services.
- Medicare Part C:
 - Alternative to traditional Medicare otherwise known as Medicare Advantage Plans.
- Medicare Part D:
 - Prescription drug coverage.





Home Infusion Therapy Benefit

- Home Infusion Therapy (HIT) benefit
 - New Medicare Part B benefit effective January 1, 2021
 - Limitations to medications covered under the HIT benefit
 - Patient Part B co-pay is applicable





- Home Infusion Therapy (HIT)
 - Section 1834(u)(1) of the Social Security Act (the Act), as added by Section 5012 of the 21st Century Cures Act (Pub. L. 144-255), established a new Medicare HIT benefit under Medicare Part B. The Medicare HIT benefit is for coverage of HIT services for certain drugs and biologicals administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual, through a pump that is a DME item.
 - This benefit became effective January 1, 2021.
 - Involves the parenteral administration of drugs or biologicals in the patient's home; not in the hospital setting, clinic setting, ambulatory infusion clinics, or skilled nursing facilities.
 - This is a new payment for the professional service, training and education, and monitoring needed to administer the home infusion drug in the home.





- Who can qualify as a HIT supplier?
- A pharmacy, physician, or other provider of services or supplier licensed by the State in which the pharmacy, physician, or provider of services or supplier furnishes items or services and that:
 - Furnishes infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs;
 - Ensures the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis;
 - Is accredited by an approved organization; and
 - Meets such other requirements as the Secretary determines appropriate.





- The DME benefit covers three components: the external infusion pump, the related supplies, and the infusion drug.
 - Additionally, this benefit covers the related services required to furnish these items
 - (e.g., pharmacy services, delivery, equipment set up, maintenance of rented equipment, and training and education on the use of the covered items) by an eligible DME supplier.
- No payment is made under the HIT benefit for these DME items and services.

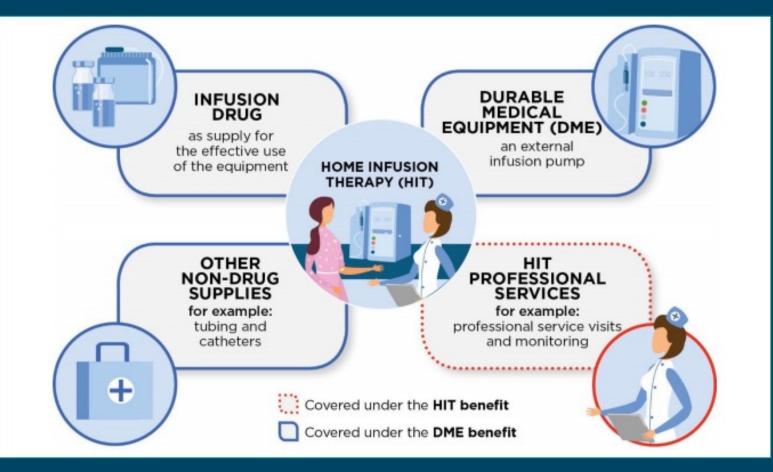




- The new HIT benefit covers the service component, meaning the professional services, training and education (not otherwise covered under the DME benefit), and monitoring furnished by a qualified HIT supplier needed to administer the home infusion drug in the patient's home.
- The service of the administration of the drug and/or biological must be provided by an RN, LPN/LVN, in accordance with state practice acts.
 - Skilled nurses may need additional training, experience, and/or competencies based on state scope of practice
 - May need additional policies or policy revisions based on changes in clinical practice







Source: https://www.cms.gov/files/document/SE19029.pdf





- The DME benefit is not changing and therefore DME providers who supply the pump, tubing, related supplies, medication, etc. do not need to obtain HIT accreditation as the HIT benefit does not cover, and will not cover, these items.
- Nursing agencies, that plan to provide the skilled nursing service, do not need to also become DME providers in order to obtain the pump, tubing, related supplies and medication; they may subcontract with a pharmacy or DME supplier for these supplies.





- The DME supplier is also responsible for delivery and set up of the equipment, as well as training and education on operation of the infusion pump.
- The DME benefit also covers pharmacy services (i.e., drug preparation and dispensing), including sterile compounding, that are associated with the furnishing of the home infusion drug.





- Qualified HIT suppliers can only bill and be paid for the HIT services furnished on the day that a professional is physically present in the patient's home and an infusion drug is being administered.
- Medicare payment for an infusion drug administration calendar day is separate from the payment for DME items and services. Therefore, a supplier could still be paid for DME items and services under the DME benefit, even if the supplier does not receive payment for home infusion therapy services under the HIT benefit.





- The HIT benefit is intended to be a separate payment from the amount paid under the DME benefit, explicitly covering the professional services that occur in the patient's home, which could include services such as:
 - Training and education on care and maintenance of vascular access devices
 - Dressing changes and site care
 - Patient assessment and evaluation
 - Medication and disease management education
 - Monitoring/remote monitoring services





Patient Qualifications for the HIT Benefit

- The patient must be receiving a parenteral drug and/or biological that is administered intravenously or subcutaneously for an administration period of 15 minutes or more; and
- Through a pump that is an item of DME covered under the Medicare Part B DME benefit; and
- The drug and/or biological is administered in the home, cannot be administered in a hospital, clinic, ambulatory infusion clinic, or skilled nursing facility; and
- Patient does not have to be homebound to qualify for HIT or have an additional skilled need.















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Who Should Seek Accreditation?







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Who Should Consider HIT Accreditation?

- A Medicare certified Home Health agency may want to consider HIT accreditation if:
 - Want to diversify and expand into home infusion services for Medicare beneficiaries
 - Plans to bill Medicare Part B for the infusion nursing services
 - Expand potential patient data base as these patients do not need to be homebound or have another skilled service





Who Does Not Need HIT Accreditation?

- A Medicare certified Home Health agency may not want to consider accreditation if:
 - Currently contracts their nursing staff to another provider that provides the infusion therapy and is HIT accredited
 - Wants to provide care provided under Part A for patients who will also receive care from a HIT accredited agency for the Part B infusion benefit
 - Provides infusion therapy to non-Medicare beneficiaries
 - Will not provide any of the approved medications that are not covered under the HIT benefit





Who Should Consider HIT Accreditation?

- A Private Duty Nursing agency, non-Medicare certified Home Health agency, may want to consider accreditation if:
 - Want to diversify and expand into home infusion services for Medicare beneficiaries
 - Plans to bill Medicare Part B for the infusion nursing services





Who Does Not Need HIT Accreditation?

- A Private Duty agency, non- Medicare certified Home Health agency may not want to consider accreditation if:
 - Currently serves a very small infusion therapy population and does not want to diversify into home infusion therapy
 - Wants to continue to provide infusion therapy but do not plan on billing Medicare Part B
 - Currently contracts their nursing staff to another provider that provides the infusion therapy





Who Should Consider HIT Accreditation?

- An Infusion Pharmacy with Infusion Nursing services or an Infusion Nursing agency may want to consider accreditation if:
 - They employ or contract for nursing services to administer infusion therapy services in the home and they plan to bill Medicare part B for the infusion nursing service





Who Does Not Need HIT Accreditation?

- An Infusion Pharmacy with Infusion Nursing services or an Infusion Nursing agency may not want to consider accreditation if:
 - They plan on providing infusion therapy but do not plan on billing Medicare Part B; they are billing Medicaid, private insurance or the patient





Dual Accreditation

- Home Health, Private Duty Nursing, Infusion Nursing Services can continue to provide infusion therapy services, to non-Medicare beneficiaries, and not be HIT accredited.
- Agencies may also be accredited for both programs:
 - Home Health and HIT would be two separate surveys with different qualifying criteria.
 - Home Health would need to meet the Medicare Conditions of Participation, have a skilled need and be homebound.
 - HIT would need to meet the Conditions for Coverage and do not need to be homebound nor need another skilled service.





Dual Accreditation

- Private Duty Nursing (with or without other PD services) and HIT would be two separate surveys.
 - Private Duty Nursing (with or without other PD services) would not need to meet the Conditions for Coverage.
 - HIT would need to meet the Conditions for Coverage.
- Infusion Pharmacy that provides Infusion Nursing Services would be two separate surveys.
 - Infusion Nursing patients would not need to meet the Conditions for Coverage.
 - HIT would need to meet the Conditions for Coverage.
- Agencies can also choose to only be HIT accredited and not have their other program(s) accredited.
- Must be able to demonstrate Separation of Services.







Separation Of Services







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Separation of Services

 If you do not want the Conditions for Coverage and the ACHC HIT Standards for accreditation to apply to all of your patients, then you must establish Separation of Services.





Separation of Services

- Agency Operation:
 - Separate clinical records must be kept for patients receiving Infusion Nursing (IRN) and Home Infusion Therapy Supplier (HITS) services and for patients receiving Private Duty Nursing (PDN) and Home Infusion Therapy Supplier (HITS) services.
 - Additional policies address the requirements of providing home infusion therapy services.
- Consumer Awareness:
 - Marketing materials should be reviewed to verify that the materials note the differences between the services.
 - Written materials should clearly identify the Home Infusion Therapy Supplier service as separate and distinct from the Infusion Nursing and Private Duty Nursing services.





Separation of Services

- Staff Awareness:
 - Staff should be able to identify the differences in services they provide under Home Infusion Therapy Supplier, Infusion Nursing, or Private Duty Nursing.







Survey Requirements







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Survey Requirements

- Be licensed according to applicable state and federal laws and regulations and maintain all current legal authorization to operate.
- Have established policies and procedures.
- Demonstrate ability to provide all services needed by patients served.
- Have a staff Pharmacist, Physician or Registered Nurse. (Must have an RN to administer, can be under contract).





Survey Requirements

- Be in compliance with all federal requirements, including Home Infusion Therapy Conditions for Coverage.
- Have served a minimum of three patients. If a home infusion therapy supplier is in a rural area as defined by CMS, it should have served at least two patients. ACHC does not require an active patient for survey.
 - The three patients must have been served in the home, not in an ambulatory care clinic.
 - Medication administered does not have to be a Part B reimbursable medication.
- Clearly define the services it provides directly or under contract.
- Submit all required documents and fees to ACHC within specified time frames.















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Achieving A Successful Survey Outcome

Pre-Survey Preparation







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ACHC Accreditation Guide To Success

- Essential Components
 - Each ACHC standard contains "Essential Components" that indicate what should be readily identifiable in policies and procedures, personnel records, medical records, etc.
 - Each section also contains audit tools, sample policies and procedures, templates, and helpful hints.
- Other Tools
 - Each section contains a compliance checklist and a selfassessment tool to further guide the preparation process.
- Section Index
 - Quickly locate important information for successfully completing the ACHC accreditation process.







Preparation

- Educate Key Staff:
 - Clinical staff (employees and contract)
 - Leader/manager
 - Patients
- Prepare Agency:
 - Human resources
 - IT/EMR
 - Office space:
 - Walk around your agency





Preparation

- Helpful tools in the ACHC Accreditation Guide to Success
- Mock Surveys
 - Interview Questions Survey Process
 - Observation of the Environment Survey Process
 - Items Needed for the On-Site Visit Survey Process
 - Personnel File Audits Section 4
 - Home Visits Section 4
 - Medical Chart Audits Section 5





Preliminary Evidence Report

PER

- Mandatory documents and/or criteria that must be submitted and met in order to begin the survey process
- Date of Compliance you establish on the PER
 - ACHC-only requirements
 - Survey will not be conducted prior to this date for start-up agencies
- Medicare Conditions for Coverage, state requirements
 - Acceptance of first patient
- Agency policies
 - Implementation date of policy







Items Needed For On-Site Survey

ACHC Standard

HITI-5A/HIT4-8A

HITI-4B

HITI-6A

HITI-8A

HITI-9A

HITI-10A

HITI-IIA

HIT2-1A

HIT2-2A

HIT2-3A

HIT2-5A

HIT2-5B

HIT2-6A

HIT2-6B

HIT2-7A

HIT2-8A

HIT2-8B

HIT2-9A

HIT2-10A

HIT3-1A

HIT3-3A

HIT2-4A/HIT2-4B

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location

Required Item

Organizational chart

or Medicare/Medicaid certification

liability insurance certificates

provided by the agency

and governing body/owner

resuscitative policies

discussed

On-call calendar

complaints

practitioner with prescriptive authority

Client/patient grievance/complaint log

Evidence of cultural diversity training

Evidence of a Compliance Program

Most recent annual operating budget

Annual performance review of the manager/leader

Notification of change in ownership, if applicable

All required federal and state posters are placed in a prominent

Action plans for any negative outcomes that impacted licensure

Contracts for direct care staff, including copies of professional

Verification of physician licensure or other licensed independent

Marketing materials and/or written description of care/services

Written information regarding the reporting of client/patient

Signed confidentiality statement for all personnel, contract staff,

Business Associate Agreements (BAAs) for non-covered entities

Advance Directive information provided to client/ patients

Information provided to clients/patients regarding agency's

Evidence of how ethical issues are identified, evaluated and

Evidence of communication assistance for language barriers

Client/Patient Rights and Responsibilities statement

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: III72-2A Client/Patient rights and responsibilities III72-3A investigation of abuse, neglect, and exploitation III74-4A Reporting and investigation client/patient grievances/compliants III74-2E Background checks III74-2E Ackground checks III74-2H COVID-9 Vaccination requirements III76-3A Investigation of adverse events III77-12A Pharmaceutical storage requirements	
HITI-1A	Copy of current applicable licenses or permits and copy of articles of incorporation/bylaws	
HITI-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	
HITI-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.	

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List of care/services with corresponding charges

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Located

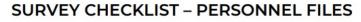
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ACHC Standard	Required Item	Located			
HIT3-4A	Evidence clients/patients are provided information on their financial liability				
HIT4-1C	Personnel records (including direct care and contract staff) contain evidence of the items listed in the standard. 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 macross				
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	Pl annual report				





Personnel File Review





HOME INFUSION THERAPY

Please gather or flag the identified items for the following personnel/contract individuals.

COMPLIANCE	DATE:	1	1	1	1	, \	5
Standard	Item Required						
HITI-3A	Conflict of Interest Disclosure Form, if applicable						
HIT2-5A	Signed confidentiality statement						
HIT2-6B	Evidence of current CPR certification, if applicable						
HIT4-1B	Position application (N/A for contract staff)						
HIT4-1B	Dated and signed withholding statements (N/A for contract staff)						
HIT4-1B	I-9 Form (N/A for contract staff)						
HIT4-2A	Primary Source verification of licensure/credentials						
HIT4-2B	Evidence of initial and annual TB screening						
HIT4-2C	Evidence of Hepatitis B vaccination received or signed declination statement						
HIT4-2D	Signed job description						
HIT4-2E	Criminal background checks						

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Survey Preparation Tools



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OBSERVATION AUDIT TOOL

- Organization has appropriate Articles of Incorporation or other documents of le
- Copy of Fair Labor Standards Act is posted in a prominent location
- Evidence of an on-call process to ensure nursing services are available 24 ho week as necessary to meet client/patient needs
- Evidence of charges in writing and available upon request
- Marketing materials reflect the services provided by the organization
- Evidence of a referral log or other tool to record all referrals as well as referrals
- Evidence of an annual practice drill to evaluate the adequacy of the disaster/c
- Organization tests its emergency power system at least once per year
- Fire exits and escape routes are identified throughout the building
- Fire extinguishers are inspected/maintained per manufacturer recommendation
- Personnel have access to appropriate SDS info for hazardous chemicals used job duties
- Evidence of quality control logs used for equipment that perform waive testing
- Evidence of cleaning and maintaining of equipment used in the provision of ca
- Client education materials
- CLIA Certificate of Waiver, if applicable
- Organization has access to copies of federal, state, and local laws and regulat
- Medical records and other Protected Health Information (PHI)/Electronic Prote Information (EPHI) are located in a secure and properly maintained for require
- Current organization chart reflects current organizational structure
- Marketing materials describe the referral process, hours of operation, and con
 Evidence that the organization has completed an assessment indicating the cc
 company TB incidence and prevalence rates as recommended by CDC guidel
- Organization maintains and documents an effective infection control program
- Organization ensures adequate backup systems and processes are in place in utility failure
- Signs designating a smoke-free facility are evident

PERSONNEL CHART AUDIT TOOL

HOME





	ENT/PATIENT	RE	со	RD	A	UD	т	Ŷ
ertains	to the services provided to Auditor:				II clier			r the a
	REGUILEMENTO							
Start of	Care Date:							
2-1A	Receipt of description of services							
2-2A	Receipt of rights and responsibilities							
2-4B	Receipt of complaint process							
2-5A	Receipt of privacy notice (HIPAA)							
2-6A	Advance Directive information							
3-4A	Information on financial responsibility							
4-12A	LPN/LVN supervision							
5-1A	Identification data							
5-1A	Name of family/legal guardian/emergency contact information							
5-1A	Referral source							
5-1A	Physician responsible for care							
5-1A	Diagnosis							
5-1A	Physician's orders							
5-1A	Signed release of information							
5-1A, B	Admission/consent documents							
5-1A	Initial assessment							
5-1A	Signed, dated progress							
5-1A	Rights and responsibilities				-		-	-

Potential Organization Staff Interview Questions						
FOR PROVIDERS. BY PROVIDERS.		🌍 номі	E INF	USION	THERA	P
POTENTIAL ORGANIZATION STAFF INTERVIEW	7	overning Body	hembers Owner/CEO	/anager/Leader		
QUESTIONS Gray box indicates question is non-applicable.	Standard	Governi	Member	Manage	Nurse	
Can you describe your responsibilities as a board member?	HIT1-2A					
Whom did you receive an evaluation from? When was the last evaluation?	HIT1-4B					
Can you describe the chain of command?	HIT1-5A					
What negative outcomes must you report to ACHC? Have you had any negative outcomes?	HIT1-8A					
What type of organizational changes would you report to ACHC?	HIT1-9A					
Describe the process to ensure orders are only accepted from currently licensed physicians.	HIT1-11A					
List three to four client/patient rights.	HIT2-2A					
To whom would you report any alleged violation involving mistreatment, neglect, or abuse to a client/patient and in what time frames?	HIT2-3A					
How are clients/patients informed of their right to report a grievance or complaint?	HIT2-4A					
What training did you receive on the organization's policies and procedures on ethical issues? Give an example of an ethical issue you may encounter in your day-to-day work.	HIT2-7A					
How would you provide care/service to clients/patients/families with various cultural backgrounds, beliefs and/or religions?	HIT2-8B					
Who is your Compliance Officer?	HIT2-9A					
Who develops the budget and how often is it reviewed?	HIT3-1A					
How often do you have a performance evaluation? Is it shared with you?	HIT4-2J					
Have you received a performance evaluation?	HIT4-2G					
Did you receive a competency assessment upon hire?	HIT4-5A					
Whom do you report to within the organization when you are on-call?	HIT4-8A					
How often are you supervised? (LPN/LVN only)	HIT4-11B					

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CLIENT/PATIENT RECORD AUDIT

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Documentation Expectations

	-		_
CLINICAL DOCUMENTATION EXPECTATIONS FOR INFUSION THERAPY INFUSION THERAPY	on should include: noval. of catheter.	Patient and caregiver education documentation should include: Medication purpose, actions, side effects, dosing times. // tubing/medication setup/purp setup. e of purps/Infusion devices. ishing and care of VAD. satile VAD complications and what/how to report. turn demonstration of tasks and competency by patient/caregiver. e administration documentation should include: idication purpose, actions, side effects, dosing times. tubing imadication subje parts.	Inserted central catheter (PICC) documentation should include: ter length (only at 50C and if problems). rcumfremco to makeva entrolitation focus to assess the presence of sible deepvein thrombools (DV T) (only at SOC and if problems).
Q,		shing and care of VAD.	
PHYSICIAN ORDERS Orders for vascular access device (VAD) care/dressing change should include: Frequency of dressing change. Prequency of dressing change. Description of any patches, ontmainer, or stabilization devices [StatLock, splints, etc.]. Draders for medication administration should include: Duals of purplements articles Route of administration. Status of any provide in the splint of	moral. ed/interventions duringVAD removal. explicable. cumentation should include: y'drug. its of measure and/or concentration). tart and stop times). ers used for multi-lumen VADs. atton (Intermittent, bolus, continuous). ings. a baffore and after infusion. etts, if any. itation should include: previous dressing. If applicable. G, elohoi, and/or povidone-iodine). ing dress used [StatLock, Hubguer 4] WingGuer 0]. sor applicable [Dipath, CHG]	 yVAD complications. Itent history of any allergies to this class of medication. dars on stops to take and medication(s) to be given should an anaphylactic reaction occur. Itent is consideration of and rejection to receiving the first dose in a hospital, physicitar's office, or other medical site; Itent demonstration of tasks and competency by patient/caregiver. Intrification of locations and phone numbers for emerging support, development of an emergency support contact scedure. propriate monitoring of the client/patient fisher first-dose administration. (Nurse administration give with the cloup/patient all sets and competency after the administration. (Nurse administration give mith the client/patient after the administration of the medication system that constrained and after the administration of the medication to research bailt documentation should include: iquency, solution (NS, hepstrin), volumes, and concentrations, including when the SASH method is to be used (cannot twrite "SASH"). and replacid document: agrisolution and dosage, including unit of measure (mg or units). uant type and volume. ua of administration. 	al an 3 inches in length; inserted into superficial vain in hand or forearm. real re 3-8 inches in length; inserted in larger vains of upper arm. r inserted into larger vains of upper arm, then threaded into central lan above the heart. ter r inserted into the superior veno cava, then tunneled under the skin; acits theneok, chest, or abdomen. atheter r inserted through subcutaneous tissue directly into the subclavian, or fermoral vains. r (ports-cath) alling injection port body implanted benasti the skin, generally in the usion; attached to an Vicatheter threaded down the heart.
	sused.	int and stop dates.	Not attactive to anny catileter threaded above the heart.
Kernel Content Co	Hed (TSM, gauze, CHG-imprograted), with physician or actions taken to resolve complications, should include: ever, vacuum exastisted),	e of pump/infusion device, if applicable. if insertion, parigheral IV catheter documentation should include: te and time of insertion, number of attempts, and location. ngth and gauge (or stee) of device (need both). repreparation (CHG, alcohol, or povidone iodine). so of dressing used after interaction.	
 Functionality of device patency: resistance when flushing: presence of blood return, if flushed, and signs and symptoms of complications, if any. Site assessment redness, welling, drainage, pair, or odor. Care provided (flushes, dressing change, lab draw, medication administration, cap/connector, tubing change) and response. WD problems, issues, and/or complications, missed/delayed doses. 	ist-blood draw, including solutions, volumes, and concentrations (heparin), if applicab i blood god. site after blood draw.		AD

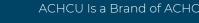
» Patient/caregiver education and response to education.



OR PROVIDERS



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The HOME HEALTH O HOME INFUSION THERAPY C PRIVATE DUTY S HOSPICE



Standard- And Condition-Level Deficiencies

- Standard-level deficiencies are ACHC-only deficiencies
 - Not as "severe"
 - Individual, random issue vs. a systemic issue
- Condition-level deficiencies result when multiple deficiencies are cited under a Condition for Coverage and are considered to impact patient safety





Focus Areas

- Utilize the audit tools, Compliance Checklists, and Self-Assessment to prioritize education.
- Implement an internal Plan of Correction (POC).
- Share improvements with your Surveyor during survey.









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Achieving A Successful Survey Outcome

On-Site Survey Process







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On-Site Survey

- Notification call
- Opening conference
- Tour of facility
- Personnel file review
- Patient chart review
- Patient home visit or simulation
- Interview with staff, management, and governing body
- Review of agency's implementation of policies
- Performance Improvement (PI)
- Exit conference





Opening Conference

- Begins shortly after arrival of Surveyor
- Good time to gather information needed by the Surveyor
- KEY REPORTS
 - Current census and current schedule of visits:
 - Name, diagnosis, start-of-care date
 - Discharge and transfers
 - Personnel and contracted individuals:
 - Name, start of hire, and discipline/role







Brief tour of facility

- Medical record storage
- Maintaining confidentiality of Protected Health Information (PHI)
- Supply closet
- Biohazard waste
- Required posters
- Fire extinguishers/smoke detectors/non-smoking signage
- Restrooms





Personnel File Review

- Review personnel records for key staff and contract staff
 - Application, tax forms, and I-9
 - Job descriptions and evaluations
 - Verification of qualifications
 - Orientation records, competencies, ongoing education
 - Medical information
 - Background checks

For a complete listing of items required in the personnel record, review Section 4 of the ACHC Accreditation Standards.





Medical Chart Reviews

- Three medical records will be reviewed
- Patient does not have to be receiving a Medicare Part B reimbursed medication
- Electronic Medical Record :
 - Do not print the medical record.
 - Surveyor needs access to the entire record Read-only format.
 - Agency needs to provide a laptop/desktop for the Surveyor.
 - Navigator/outline.





Home Visit

- One home visit if there is an available patient
- Agency responsibility to obtain consent from patient/family
- Prepare patient for potential home visits
- If no active patients at time of survey, can do a competency simulation





Exit Conference

- Present all corrections prior to the Exit Conference.
- Surveyor cannot provide a score.
- Invite those you want to attend.
- Preliminary Summary of Findings (SOF) as identified by Surveyor and the ACHC standard.
- Seek clarification from your Surveyor while still on site.





Corrected On Site

- ACHC only/non-CfC requirements can be corrected on site and a Plan of Correction (POC) will not be required.
- CfCs that are corrected on site will still be scored as a "No" and a POC will be required.
 - Always want to demonstrate regulatory compliance







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Achieving A Successful Survey Outcome

Post-Survey Process







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Post-Survey Process

- ACHC Accreditation Review Committee examines all the data.
- Accreditation decision is determined based primarily on compliance with the Conditions for Coverage.
- Summary of Findings is sent within 10 business days from the last day of survey.





Summary Of Findings Sample

Deficier	ncy Category - Patient/Client Records	Comments	Defi
Standard		Comments	cien
HIT5-3C	There is a written plan of care for each client/patient accepted to services. (486.520(a)), (486.520(b))	Upon patient record review, 3 of 3 (Patient #1, 2, 3) did not have evidence of a written plan of care for each client/patient accepted to services that includes all required elements of this standard. Patient #1: The heparin flush order read, 'Flush CVAD with heparin 100u/ml. 5ml flush post hydration or Venofer infusion, and daily when not in use and prn." There was not evidence of a reason for the prn flush. Patient #2: The heparin flush order read, 'Heparin 100u/ml. 5ml flush IV daily and prn." There was not evidence of a reason for the prn flush. In addition there were several other medications that did not include a reason for the prn administration. The medications included Ondansetron 4mg po 1 po q8h prn, Metamucil 1 po q8h prn (also no unit of measurement for '1'), Hydromorphone-acetaminophen 5-325 po q4h prn, and NTG 0.4mg SL 1 q5 x3. Patient #3: The flush order read, 'Flush PICC with 10ml NS pre and post infusion, prn and daily when no infusion followed by a final flush of 5ml heparin, 10u/ ml.' There was not evidence of a reason for the prn flush.	×
		Corrective Action: The agency will need to ensure there is evidence of a written plan of care for each client/patient accepted to services that includes all required elements of this standard. Educate staff on requirement. Conduct chart audits to ensure compliance.	
HIT5-3D	The organization shows evidence of the client/patient participation in the plan of care.	Upon patient record review, 1 of 3 records (Patient #2) did not have evidence that the client/patient agrees to the plan of care prior to the beginning of services and as subsequent changes occur.	x
		Corrective Action: The agency will need to ensure that the client/patient agrees to the plan of care prior to the beginning of services and as subsequent changes occur. Educate staff on requirement. Conduct chart audits to ensure compliance.	





Patient Record And Personnel File Review



1 HOME INFUSION THERAPY

PATIENT RECORD AND

PERSONNEL FILE REVIEW

Patient Record Reviews: First & Last Name	Personnel File Reviews: First & Last Name
#1	#1
#2	#2
#3	#3
#4	#4
#5	#5
#6	#6
#7	#7

Patient home visits are identified by HV after name.

Effective: 08/30/2019 [907] Patient Record and Personnel File Review – Home Infusion Therapy Page1of1l achc.org





Standard- And Condition-Level Deficiencies

- Standard-level deficiencies are ACHC-only deficiencies
 - Not as "severe"
 - Individual, random issue vs. a systemic issue
 - Only require a Plan of Correction
- Condition-level deficiencies result when either a Condition for Coverage is out of compliance
 - Requires another on-site survey





Accreditation Decision Definitions



ACCREDITED

Provider meets all requirements for full accreditation status. Accreditation is granted but Plan of Correction (POC) may still be required.*



ACCREDITATION PENDING

Provider meets basic accreditation requirements but accredited status is granted upon submission of an approved POC.



DEPENDENT

Provider has significant deficiencies to achieve accreditation. An additional on-site visit will be necessary to be eligible for accreditation.



DENIED

Accreditation is denied. Provider must start process from the beginning once deficiencies are addressed.





Plan Of Correction

PLAN OF CORRECTION (POC)

Organization: < <organization name="">></organization>		Company ID: < <comp< th=""><th>anyID>></th><th>Application ID: <<applicationid>></applicationid></th></comp<>	anyID>>	Application ID: < <applicationid>></applicationid>
Address: < <address>></address>				Date Generated: < <date>></date>
Services Reviewed: < <services reviewed="">></services>	Date of Surv	/ey < <survey date="">></survey>	Surveyor	r: < <surveyor>></surveyor>

FOR PROVIDERS. BY PROVIDERS.

ACHC.

INSTRUCTIONS:

- The standards to be addressed are already listed in the first column; the rest should be filled out accordingly. Please see the sample below.
- For Home infusion Therapy Suppliers, date of compliance for Conditions for Coverage (CfC) standard-level and ACHC deficiencies must be within 30 calendar days from receipt of Summary of
 Findings (SOF) and date of compliance for condition-level deficiencies must be within 10 calendar days from receipt of the SOF.
- For corrective action measures that require chart audits, please be sure to include the percentage of charts to be audited, frequency of the audit, and target threshold. Ten records or 10% of daily
 census (whichever is greater) on at least a monthly basis is required until threshold is met. Include actions for continued compliance once threshold is met.
- . Do not send any Protected Health Information (PHI) or other confidential information with the POC or when submitting evidence to your Account Advisor.
- If you need any assistance, contact your Account Advisor.

SAMPLE: Below is a sample on how to correctly fill out your POC.

Standard	Plan of Correction (Specific action taken to bring standard into compliance)	Date of Compliance (Date correction to be completed)	Title (Individual responsible for correction)	Process to Prevent Recurrence (Describe monitoring of corrective actions to ensure they effectively prevent recurrence)	POC Compliant (ACHC internal use only)	Evidence Required (ACHC internal use only)	Evidence Approved (ACHC internal use only)	Comments (ACHC interna use only)
HIT5-3C (486-520(a))	There is evidence in the client/patient record that the patient receiving home infusion therapy is under the care of an applicable provider.	.MM/DD/YY	Clinical Manager	Audii 10% of all active clients/patients to ensure the plan of care is indivivialized, complete and addresses the care and served in escary to meet the needs of the clarification of the server is the server of the server of the clarification of the server is a lot of SSW. Check threshold is not, will out here to a lot 10% of all interplatement not do ename.				
HIT4-2B	There is evidence in the personnel file that upon inter tuberculosis testing in performed on all direct care personnel. The testing could be a skin or blood test. The amual nsis assessment is used to determine the need, type, and frequency of screen ng/testing for direct care personnel.	MATONY	Manager/Leader	100% of newly hired, direct-care personnel records will be audited within 30 days of hire for evidence that an initial baseline. TB screen using TST or BAMT was completed. Threshold is 100% compliance. Once threshold is met, 50% of direct care personnel records will be audited annually.			NAL USE (
) HOME II Page 1	NFUSION THERAPY			1913	POC Templa	te-HIT Effe	ective: 10/	04/2019





Plan Of Correction Requirements

- Due in 10 calendar days to ACHC
- Deficiencies are autofilled
- Plan of Correction:
 - Specific action step to correct the deficiency
- Date of compliance of the action step:
 - 10 calendar days for condition-level
 - 30 calendar days for standard-level
- Title of individual responsible
- Process to prevent recurrence (two-step process):
 - Percentage and frequency
 - Target threshold
 - Maintaining compliance







Evidence

- Evidence is required to support compliance.
- Once POC is approved, POC identifies which deficiencies will require evidence.
- All evidence to the Account Advisor within 60 days.
- No PHI or other confidential information of patients or employees.
- Accreditation can be terminated if evidence is not submitted.

Additional evidence may be required based on the decision of the ACHC Review Committee.





Submission Of Evidence





Company Name:

Date:

As you compile evidence to support your approved Plan of Correction (POC), please complete the following:

- In the Client/Patient Record/Personnel File Audit Summary chart, summarize the results of your client/patient record and/or personnel file audits.
- In the Observation Deficiencies chart, note observation deficiencies from your POC and provide documents to support evidence of continued compliance. Examples of documents that may need to be submitted are: governing body meeting minutes, revised contracts, annual program evaluations, PI activities, or administrator qualifications.

For the week/month of:

All evidence supporting the implementation of the POC must be submitted at one time to your Account Advisor within 60 days following the survey decision letter.

Do not submit evidence until your POC has been approved.

Do not submit any Protected Health Information (PHI) or confidential employee information.

CLIENT/PATIENT RECORD/PERSONNEL FILE AUDIT SUMMARY

ACHC Standard	Brief Summary of Audit Findings Specific to the Deficiency	Number of Correct Charts (Audits)/Number of Total Charts (Audits) Completed	Percentage of Compliance
Example: HIT5-3E	Audited charts to determine care was provided in accordance with the plan of care	9/10	90%

Revised: 02/03/2020 [931] Evidence Chart - HIT Page 1 of 3 l achc.org















Questions









Achieving A Successful Survey Outcome

Understanding The Standards



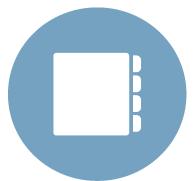




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Review The Standards

- Identifier
 - HIT: Home Infusion Therapy
- Standard
 - Provides a broad statement of the expectation in order to be in compliance with ACHC standards
 - Gives you more detailed information and specific direction on how to meet ACHC standards
- Evidence
 - Items that will be reviewed to determine if the standard is met
- Services applicable







Most Stringent Regulation

 Must be in compliance with the most stringent regulation in order to be determined compliant with ACHC Accreditation Standards.







Section 1

ORGANIZATION AND ADMINISTRATION

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





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

If state or local law provides for licensing of the agency, the agency must be licensed.

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

The organization has a copy of the appropriate documentation or authorization(s) to conduct business.



Standard HITI-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.

The organization has a list of governing body members that includes name, address and telephone number.



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

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 patient

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

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



Standard HITI-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 ongoing liaison among the governing body/owner and the 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 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.



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

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 (LLC), where the president and manager/leader is also the owner and governing body.

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



Standard HITI-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.



Standard HITI-6A: The Home Infusion Therapy supplier is in compliance with all applicable federal, state, and local laws and regulations.

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



5 Standard HITI-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.



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

Negative outcomes affecting accreditation, licensure, or Medicare/Medicaid certification are reported to ACHC within 30 days.

The report includes all action taken and plans of correction.



Standard HITI-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.



Standard HITI-10A: An organization that uses outside personnel to provide care/services on behalf of the organization has a written contract/agreement for care furnished. The contract/agreement contains all requirements and is kept on file within the organization.

Arranged care/services are supported by written agreements.

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.



Standard HITI-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



Workbook Tools

- Compliance Checklist
- Self-Audit
- Governing Body Meeting Agenda Template
- Hourly Contract Staff Audit Tool
- Organizational Chart
- Conflict of Interest Disclosure Statement
- Acknowledgement of Confidentiality statement
- Governing Body Orientation















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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, protected health information, cultural diversity, and compliance with fraud and abuse prevention laws.





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

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

Patients will receive information about the services covered under the organization benefit and the scope of services that the organization will provide and specific limitations on those services.

The client/patient and/or family will receive this information prior to receiving care/service with evidence documented in the patient record.



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.

Patient Rights and Responsibilities statement contains the required components.

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

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



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

Personnel honor the patient right to:

Have his or her 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 an attending physician Receive appropriate care without discrimination in accordance with physician orders

Be informed of any financial benefits when referred to an organization

Be fully informed of one's responsibilities



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 patient property by anyone furnishing services on behalf of the organization.

Any organization staff must report these findings immediately to the organization and other appropriate authorities in accordance with state law.

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

The organization ensures that verified violations are reported to ACHC, state and local bodies having jurisdiction within five working days of becoming aware of the verified violation.



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 organization must investigate complaints made by a client/patient or client's/patient's representative.

The organization must document both the existence of the complaint and the resolution of the complaint.

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 Performance Improvement annual report.



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 agency advises clients/patients in writing of the appropriate state regulatory body's hotline, the hours of operation, and the purpose of the hotline.

The ACHC phone number requirement is not applicable to organization if this is its first ACHC survey.



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

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

There is a signed confidentiality statement for all personnel and governing body/owner.

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.



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

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

A Business Associate Agreement is not required with persons or organizations (e.g., janitorial service or electrician) whose functions or services do not involve the use or disclosure of protected health information.



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

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

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.



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 policies and procedures identify which personnel perform resuscitative measures, respond to medical emergencies, and utilization of 911 services (EMS) for emergencies.

Successful completion of appropriate training, such as a CPR certification course is defined in the policies and procedures.

Online CPR certification is accepted with in-person verification of competency.

Clients/patients are provided information about the organization's policies and procedures for resuscitation, medical emergencies, and accessing 911 services.



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

Written policies and procedures address the mechanisms utilized to identify, address, and evaluate ethical issues in the organization.

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

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



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 form understandable to the patient.

Mechanisms are in place to assist with language and communication barriers.

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



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 for clients/patients of different cultural backgrounds, beliefs and religions.

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



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.

There is a designated Compliance Officer and Compliance Committee.



Programs and Services

Standard HIT2-11A: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.



Workbook Tools

- Compliance Checklist
- Self-Audit
- Patient Rights and Responsibilities Audit Tool
- Hints for an Effective Compliance Program/Plan
- Sample Ethical Issues/Concerns Reporting Form
- Sample Patient Complaint/Concern Form















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FISCAL MANAGEMENT

The standards in this section apply to the financial operations of the company. These standards will 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 budget is reviewed and updated at least annually by the organization's governing body/owner and leadership personnel.



Standard HIT3-2A: The organization implements financial management practices that ensure accurate accounting and billing.

The organization ensures sound financial management practices.



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.



Standard HIT3-4C: 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.



Standard HIT3-4D: There is verification that the care/service(s) billed for reconciles with the care/service(s) provided by the organization.

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



Workbook Tools

- Compliance Checklist
- Self-Audit
- Home Health Financial Disclosure Statement















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

Personnel files are kept in a confidential manner.



Standard HIT4-1B: Prior to or at the time of hire all personnel complete appropriate documentation.

Personnel files contain:

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



Standard HIT4-1C: All personnel files at a minimum contain or verify the following items. (Informational Standard Only)

Personnel includes, but is not limited to: support personnel, licensed clinical personnel, unlicensed clinical personnel, administrative and/or supervisory personnel, contract personnel, and volunteers.

For contract staff the organization must have access to all of the above items, except position application, withholding statement, I-9, and personnel handbook. The remainder of items must be available for review during survey but do not need to be kept on site.

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



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.

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.



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.





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.

Personnel sign a declination statement for the Hepatitis B vaccination within 10 working days of employment if they choose not to become vaccinated.



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
- Reviewed at hire and whenever the job description changes.



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

The organization obtains a criminal background check, Office of Inspector General (OIG) exclusion list check and national sex offender registry check on all employees who have direct client/patient contact.

The organization contracts require that all contracted entities obtain criminal background check, Office of Inspector General exclusion list check and national sex offender registry check on contracted employees who have direct patient contact.



Standard HIT4-2E continued:

The organization obtains a criminal background check and OIG exclusion list check on all organization employees who have access to client/patient records.

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

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



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 an Employee Handbook include, but are not limited to:

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



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.

Policies and procedures describe how performance evaluations are conducted, who conducts them, and when they are to be conducted.

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



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.

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.



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



5 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.



Standard HIT4-5A: Written policies and procedures are established and implemented requiring the organization to design a competency assessment program based on the care/services 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 assessments are conducted initially during orientation, prior to providing a new task and annually thereafter.

Competency assessment may be accomplished through clinical observation, skills lab review, supervisory visits, knowledge-based tests, situational analysis/case studies, and self-assessment. All competency assessments and training are documented. A self-assessment tool alone is not acceptable.



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

The education plan includes training provided during orientation as well as ongoing in-service education. 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.



Standard HIT4-6A continued

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), patient safety and components of HIT7-2A
- Client/patient Rights and Responsibilities
- Compliance Program



Standard HIT4-7A: Written policies and procedures are established and implemented in regard to the observation and evaluation of direct care personnel performing their job duties by qualified personnel prior to providing care independently and at least annually and/or in accordance with state or federal regulations.

Qualified personnel observe and evaluate each direct care personnel performing their job duties prior to providing care independently and at frequencies required by state or federal regulations.

This activity may be performed as part of a supervisory visit and is included as part of the personnel record.



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.



5 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.



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.

Personnel files contain documentation of completion of all special education, experience, or licensure/certification requirements.

Qualifications may vary based upon Board of Nursing requirements for Licensed Practical Nurses and Registered Nurses.



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.



Human Resource Management

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



Workbook Tools

- Compliance Checklist
- Self-Audit
- Job Description Template
- Physical Demands Documentation Checkoff List
- Sample Employee Educational Record
- Sample Annual Observation/Evaluation Visit form
- Personnel Record Audit Tool
- Hints for Developing an Educational Plan
- Sample Hepatitis B Declination Statement
- Tuberculosis Screening Tool
- Sample In-Service Attendance form















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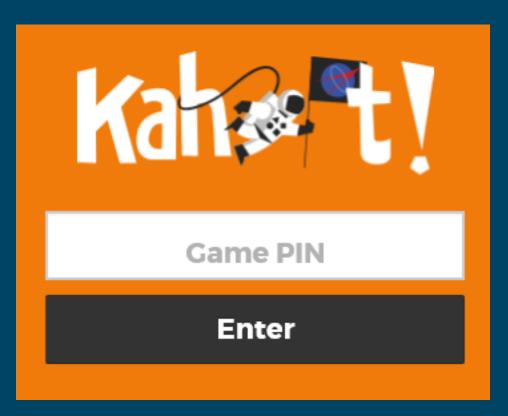






TEACHING TOOL: Kahoot!

- Cellphone or laptop
- Go to Kahoot.it
- Enter Game PIN
- Enter your nickname
 See "You're in"
- You're ready!









PROVISION OF CARE AND RECORD MANAGEMENT

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

ACHC client/patient record content requirements.



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.



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

Access, storage, removal and retention of medical records and patient information.

All client/records are retained for a minimum of seven years after the discharge of the patient, unless state law stipulates a longer period of time.

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.



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

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

A Registered Nurse (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.



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.



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.

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.



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

- Start of care date
- Client/patient demographics
- Principal 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



5 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 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



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.



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))

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).





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



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



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.



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.



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).





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

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

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.



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.

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



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.



Standard HIT5-8B:A Registered Nurse (RN), Pharmacist or a licensed skilled professional reviews all client/patient medications, both prescription and nonprescription, 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.

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.



Workbook Tools

- Compliance Checklist
- Self-Audit
- Referral Log
- Patient Record Audit
- Sample Medication Profile















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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.

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.



Standard HIT6-1B: The organization ensures the implementation of an organization wide Performance Improvement (PI) Program 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 program
- Assisting in the identification of goals and related patient outcomes
- Coordinating, participating and reporting of activities and outcomes



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 are ultimately responsible for all actions and activities of the organization PI program.

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.



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

Personnel receive training related to PI activities and their involvement.

Training includes, but is not limited to:

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



Standard HIT6-3A: 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.



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

Each performance improvement activity/study includes the following items:

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



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

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



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).



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

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



Standard HIT6-2F: The Performance Improvement (PI) program includes a review 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.



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

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



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



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.



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.

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.

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.



Section 6

Workbook Tools

- Compliance Checklist
- Self-Audit
- Annual QAPI Evaluation Template
- QAPI Activity/Audit Descriptions
- Sample QAPI Plan















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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 must maintain and document an infection control program which has as its goal the prevention and control of infections and communicable diseases.

Written policies and procedures detail OSHA Blood Borne Pathogen and TB Exposure Control Plan.

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.





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

The organization must maintain a coordinated agency-wide program for the surveillance, identification, prevention, control, and investigation of infectious and communicable diseases that is an integral part of the organization's Performance Improvement (PI) 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.

Data is utilized to assess the effectiveness of the infection control program.



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.



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

Written policies and procedures address patient safety in the home.



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 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.



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



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

Providing emergency power

Testing of emergency power systems (at least annually)

A no-smoking policy and how it will be communicated

Fire drills conducted at least annually

Maintenance of:

- Smoke detectors
- Fire alarms
- Fire extinguishers



Standard HIT7-5A: Written policies and procedures are established and implemented for the acceptance, transportation, pickup, and/or disposal of hazardous chemicals and/or contaminated materials used in the provision of patient care.

Written policies and procedures include safe methods of handling, labeling, storage, transportation, disposal and pick-up of hazardous wastes, hazardous chemicals and/or contaminated materials used in the home/organization. The organization follows local, state and federal guidelines.



Standard HIT7-6A: Written policies and procedures are established and implemented for following OSHA's Hazard Communication Standard that describe appropriate labeling of hazardous chemicals and/or materials, instructions for use, and storage and disposal requirements.

OSHA's Hazard Communication Standard detailing:

- The labeling of containers of hazardous chemicals and/or materials with the identity of the material and the appropriate hazard warnings
- Current Safety Data Sheet (SDS) must be accessible to personnel
- The proper use, storage, and disposal of hazardous chemicals and/or materials
- The use of appropriate personal protective equipment (PPE)



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.

Process for reporting, monitoring, investigating and documenting a variance.

There is a standardized form developed by the organization used 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 law and regulation.

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



Standard HIT7-8A: Written policies and procedures are established and implemented for the use of equipment in the performance of conducting waived tests.

Policies and procedures for the use of equipment in the performance of conducting waived tests include:

- Instructions for using the equipment
- The frequency of conducting equipment calibration, cleaning, testing and maintenance
- Quality control procedures



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

Personnel implement the policies and procedures for the use of the organization's equipment/supplies in the provision of care to the patient.

The cleaning and maintenance of equipment used in the provision of care is documented.

Supplies used in the provision of care are also documented.



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

Informing patients of their responsibilities.

Informing patient of right to refuse acceptance of investigational drugs or experimental therapies.

Informing patient of right to refuse participation in research and clinical studies.

Notifying patients that they will not be discriminated against for refusal to participate in research and clinical studies.

Stating which personnel are administering investigational medications/treatments.

Describing personnel monitoring a patient's response to investigational medications/treatments.

Identifying the responsibility for obtaining informed consent.

Defining the use of experimental and investigational drugs and other atypical treatments and interventions.





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

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



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



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.



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.



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.)

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



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.



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.



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.



Workbook Tools

- Compliance Checklist
- Self-Audit
- Hints for Developing an Emergency Preparedness Plan
- Hints for an Infection Control Plan
- Infection Control Tracking Form
- Safety Tracking Log
- Report of Employee Accident Investigation
- Quality Maintenance Log





Resources

- On Customer Central cc.achc.org
 - Items Needed for Survey
 - HIT Desk Review Reference Guide
 - Crosswalk-Infusion Nursing to HIT
 - Crosswalk- Private Duty Nursing to HIT
 - HIT Survey Checklist-Personnel Files
 - HIT Preliminary Evidence Report
 - Separation of Services
 - Evidence Chart-HIT
 - Clinical Documentation Expectations for Infusion Therapy
- "Did You Know?" Newsletter
 - Sign up at <u>https://www.achc.org/e-news-signup/</u>















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Payment Considerations







ACHCU IS A BRAND OF ACCREDITATION COMMISSION for HEALTH CARE

Home Infusion Therapy Benefit vs. Home Health Benefit

- A patient is not required to be homebound to be eligible for the home infusion therapy benefit.
- A patient can be homebound and under a Home Health (HH) plan of care, and require home infusion therapy services. In this case, the patient can receive both HH services as well as HIT.
- In addition, the home health agency (HHA) and the home infusion therapy supplier may be the same entity in cases where the HHA is approved as a home infusion therapy supplier.





Home Infusion Therapy Benefit vs. Home Health Benefit

- If a patient receiving home infusion therapy is also under a HH POC and received a visit that is unrelated to home infusion therapy, payment would be covered by the home health benefit and billed on the HH claim.
- If the HHA is the qualified home infusion therapy supplier and conducts a home visit solely for services related to the administration of the home infusion drug, the HHA would submit a home infusion therapy services claim under the home infusion therapy benefit.
- If a home visit includes provision of both HH and home infusion therapy services (i.e., separate services), the HHA would submit claims under the home health benefit and the home infusion therapy benefits. However, in this case, the HHA must separate the time spent providing the HH and home infusion therapy services.





- Home infusion will be a separate payment for professional services rendered.
- Payment will be made for each infusion drug administration calendar day.
 - Bundled payment for home infusion therapy services only made when a skilled professional is in the home on the day of the drug administration.
- Based on 3 home infusion payment categories, with the associated J-codes (which describe the drugs covered under the benefit).
- Part B billing begins January 1, 2021 for applicable G-code for HIT services





- Category 1: Anti-Infective, Cardiovascular, pain management, chelation, pulmonary hypertension, other.
- Category 2: Subcutaneous immunotherapy and other certain subcutaneous infusion drugs.
- Category 3: Chemotherapy and other highly complex intravenous drugs (considered the highest paying group).
- Users of multiple categories are grouped with the higher category.





CPT Code	Description	Units	
Category 1			
96365	Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (excludes chemotherapy & other highly complex drug or highly complex biologic agent administration) – up to one hour	1	
96366	Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (excludes chemotherapy & other highly complex drug or highly complex biologic agent administration) – each additional hour	4	
Category 2			
96369	Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (excludes chemotherapy & other highly complex drug or highly complex biologic agent administration) – up to one hour	1	
96370	Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (excludes chemotherapy & other highly complex drug or highly complex biologic agent administration) – each additional hour		
Category 3			
96413	Injection and Intravenous Infusion Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration – up to one hour	1	
96415	Injection and Intravenous Infusion Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration – each additional hour	4	

*Payment Categories – CPT Codes





- The 3 payments categories are further broken down into a higher payment for the initial visit and lower payments for the subsequent visits.
- For a patient visit to be considered new again a gap of at least 60 days is required for another "first visit" to be billed (i.e., the patient must have been discharged from home infusion therapy for at least 60 days).
- Each category payment amount will be in accordance with the six CPT infusion codes described under the Physician Fee Schedule and equal to five hours of infusion.





TABLE 16: 5-HOUR PAYMENT AMOUNTS REFLECTING PAYMENT RATES FORFIRST AND SUBSEQUENT VISITS

Description	Proposed 2021 PFS Amount	5-hour Payment - First Visit	5-hour Payment - Subsequent Visits
		\$188.85	\$156.83
Ther, Proph, Diag IV/IN infusion 1 hr	\$72.26	(category 1)	(category 1)
Ther, Proph, Diag IV/IN infusion add hr	\$21.61		
		\$256.83	\$213.27
Sub Q Ther Inf 1 hr	\$156.46	(category 2)	(category 2)
Sub Q Ther Inf add hr	\$14.84		
		\$319.80	\$265.57
Chemo Inf 1 hr	\$146.14	(category 3)	(category 3)
Chemo Inf add hr	\$30.65		
	Ther, Proph, Diag IV/IN infusion 1 hr Ther, Proph, Diag IV/IN infusion add hr Sub Q Ther Inf 1 hr Sub Q Ther Inf add hr Chemo Inf 1 hr	DescriptionPFS AmountTher, Proph, Diag IV/IN infusion 1 hr\$72.26Ther, Proph, Diag IV/IN infusion add hr\$21.61Sub Q Ther Inf 1 hr\$156.46Sub Q Ther Inf add hr\$14.84Chemo Inf 1 hr\$146.14	DescriptionPFS Amount- First VisitTher, Proph, Diag IV/IN infusion 1 hr\$72.26(category 1)Ther, Proph, Diag IV/IN infusion add hr\$21.61\$256.83Sub Q Ther Inf 1 hr\$156.46(category 2)Sub Q Ther Inf add hr\$14.84\$319.80Chemo Inf 1 hr\$146.14(category 3)

Note: Rates are calculated using proposed CY 2021 PFS rates.

*Note rates are adjusted by geographic area





Table 3.1 – Category 1			
J-Code	Description		
J0133	Injection, acyclovir, 5 mg		
J0285	Injection, amphotericin b, 50 mg		
J0287	Injection, amphotericin b lipid complex, 10 mg		
J0288	Injection, amphotericin b cholesteryl sulfate complex, 10 mg		
J0289	Injection, amphotericin b liposome, 10 mg		
J0895	Injection, deferoxamine mesylate, 500 mg		
J1170	Injection, hydromorphone, up to 4 mg		
J1250	Injection, dobutamine hydrochloride, per 250 mg		
J1265	Injection, dopamine hcl, 40 mg		
J1325	Injection, epoprostenol, 0.5 mg		
J1455	Injection, foscarnet sodium, per 1000 mg		
J1457	Injection, gallium nitrate, 1 mg		
J1570	Injection, ganciclovir sodium, 500 mg		
J2175	Injection, meperidine hydrochloride, per 100 mg		
J2260	Injection, milrinone lactate, 5 mg		
J2270	Injection, morphine sulfate, up to 10 mg		
J3010	Injection, fentanyl citrate, 0.1 mg		
J3285	Injection, Treprostinil, 1 mg		

*Infusion Drug J-Codes- Cat 1 – MM11880 https://www.cms.gov/files/document/mm11880.pdf





	Table 3.2 – Category 2			
J-Code	Description			
J1555 JB	Injection, immune globulin (cuvitru), 100 mg			
J1558 JB	Injection, immune globulin (xembify), 100mg			
J1559 JB	Injection, immune globulin (hizentra), 100mg			
J1561 JB	Injection, immune globulin, (gamunex-c/gammaked), non-lyophilized (e.g. liquid), 500 mg			
J1562 JB	Injection, immune globulin (vivaglobin), 100 mg			
J1569 JB	Injection, immune globulin, (gammagard liquid), non-lyophilized, (e.g., liquid), 500 mg			
J1575 JB	Injection, immune globulin/hyaluronidase, (hyqvia), 100 mg immune globulin			
J7799 JB	This NOC code may be used to identify the subcutaneous immune globulin (cutaquig)			

Table 3.3 – Category 3

J-Code	Description		
J9000	Injection, doxorubicin hydrochloride, 10 mg		
J9039	Injection, blinatumomab, 1 microgram		
J9040	Injection, bleomycin sulfate, 15 units		
J9065	Injection, cladribine, per 1 mg		
J9100	Injection, cytarabine, 100 mg		
J9190	Injection, fluorouracil, 500 mg		
J9360	Injection, vinblastine sulfate, 1 mg		
J9370	Injection, vincristine sulfate, 1 mg		



*Infusion Drug J-Codes- Cat 2 & 3



Payment for HIT Services

- The single payment amount is limited so that it cannot reflect more than 5 hours of infusion for a particular therapy per calendar day.
- In the case that two (or more) home infusion drugs or biologicals from two different payment categories are administered to an individual concurrently on a single infusion drug administration calendar day, one payment for the highest payment category will be made.
- In the event that multiple visits occur on the same date of service, suppliers must only bill for one visit and should report the highest paying visit with the applicable drug. Claims reporting multiple visits on the same line item date of service will be returned as unprocessable.





- Providers will submit a single HCPCS G-code associated with the payment categories for the professional services furnished in the patient's home and on an infusion drug administration calendar day.
- The CPT codes in Table 32 were used by CMS to determine the payment amounts for the home infusion therapy services.
- The claim will include a G-code, in line item detail, for each infusion drug administration calendar day, and the claim should include the length of time, in 15-minute increments, for which the professional services were furnished.





- Visit length in 15-minute increments
 - 15 minutes = One (1) = number of service
 - Regardless of actual visit length
 - Single Payment = five hours infusion therapy per day
- Payment fixed "per day rate" Regardless of line units
- Bill total line units
 - Do not/will not multiply by rate
- Do not increase billing by line units or expect increased allowable





- Home infusion therapy services payment is contingent upon a home infusion drug J-code being billed by the DME.
- Suppliers must ensure the appropriate drug associated with the visit was billed with the visit no more than 30 days prior to the visit.
- DME bills drugs from categories
- HIT Supplier Bills Part B for appropriate HCPCS (G codes)





G-codes Descriptions:

 G0068: Professional services for the administration of anti-infective, pain management, chelation, pulmonary hypertension, and/or inotropic infusion drug(s) for each infusion drug administration calendar day in the individual's home, each

15 minutes (Short descriptor: Adm of IV Infusion in home)

- G0069: Professional services for the administration of subcutaneous immunotherapy for each infusion drug administration calendar day in the individual's home, each 15 minutes (Short descriptor: Adm of SQ Infusion drug in home)
- G0070: Professional services for the administration of chemotherapy for each infusion drug administration calendar day in the individual's home, each 15 minutes (Short descriptor: (Adm of IV chemo drug in home)





	Category 1	Category 2	Category 3
Description G-	Intravenous anti-infective, pain management, chelation, pulmonary hypertension, inotropic, and other certain	Subcutaneous immunotherapy and other certain Subcutaneous infusion	Chemotherapy and other certain highly complex
Code	intravenous infusion drugs	drugs	intravenous drugs
Initial Visit	G0088	G0089	G0090
Payment Amount	\$197.37	\$266.67	\$331.75
Subsequent Visit	G0068	G0069	G0070
Payment Amount	\$162.28	\$219.27	\$272.78





Approximate allowables: (Daily = Five hours)

HCPCS	Description	CY 2021 National Unadjusted Payment Rates	GAF Standardization Factor	CPI-U Reduced by Productivity Adjustment	Final 2022 HIT Payment Amount
G0068	Adm iv infusion drug in home	\$154.39	X 1.0001	X 1.0510	\$162.28
G0069	Adm sq infusion drug in home	\$208.61	X 1.0001	X 1.0510	\$219.27
G0070	Adm of chemo drug in home	\$259.52	X 1.0001	X 1.0510	\$272.78
G0088	Adm iv drug 1st home visit	\$187.77	X 1.0001	X 1.0510	\$197.37
G0089	Adm subq drug 1st home visit	\$253.70	X 1.0001	X 1.0510	\$266.67
G0090	Adm iv chemo 1st home visit	\$315.62	X 1.0001	X 1.0510	\$331.75

SERVICES 5-HOUR PAYMENT AMOUNTS

TABLE 36: FINAL CY 2022 NATIONAL HOME INFUSION THERAPY

Source: The unadjusted CY 2021 PFS rates are calculated based on the updated CY 2021 RVUs which were recalculated after the removal of code G2211 and the unadjusted PFS Conversion Factor which is calculated by removing the 3.75 percent increase in PFS payments for CY 2021.





Billing Example:

- First visit billable after patient discharged or 60 days GAP= Initial Visit
- Cat 1 Drug (J0133) and Cat 3 (J9000)= Multiple Infusion= Highest payment Cat= G0090
- G0090 initial infusion visit (104minutes) = seven (7) units (15 min increments)
- Billing \$420 = single payment





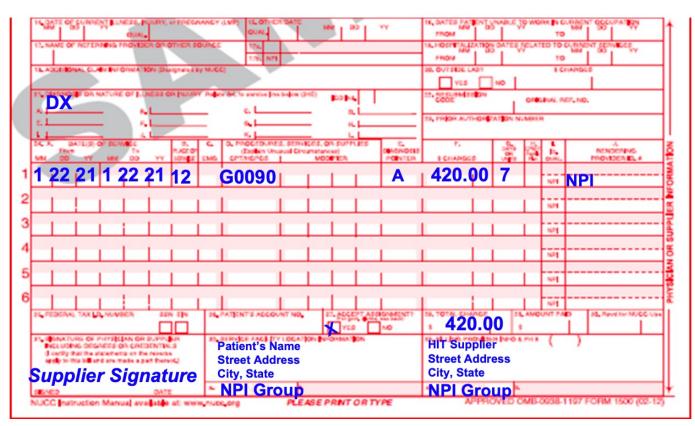
Billing process for qualified home infusion therapy suppliers including for home health agencies:

- HIT claims are submitted on the 837p/CMS-1500 professional to the A/B Medicare Administrative Contractors (MACs).
- DME suppliers, also enrolled as qualified HIT suppliers, would need to submit one claim for the DME, supplies, and drug on the 837p/CMS-1500 professional to the DME MAC and a separate 837p/CMS-1500 for the home infusion therapy professional services to the A/B MAC.





Billing done on CMS 1500- Part B







HIT Part B Enrollment

- HIT supplier MUST enroll with Part B contractor through online Provider Enrollment Chain and Ownership System (PECOS) or paper CMS-855B
- CMS states they are considering creating a "home infusion therapy supplier" type on the 855B enrollment form, but in the meantime, providers can enroll using the "other" option on the 855 add in Home Infusion Therapy
- A supplier group may submit the enrollment applications starting November 1, 2020. The earliest billing is January 1, 2021.







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