

Standards of Excellence Infusion Therapy Nursing

Copyright © 2019 by
The Community Health Accreditation Program, Inc.
1275 K Street NW, Suite 800
Washington, DC 20005

All rights reserved.

No part of this document may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, without prior written permission of the publisher.

TABLE OF CONTENTS

INTRODUCTION.....i-viii

STANDARD	DESCRIPTION	PAGE(S)
	Infusion Therapy Nursing ITNI PATIENT-CENTERED CARE	1
ITNI.1	Statement of Infusion Therapy Nursing Scope of Services	3
ITNI.2	24/7 Accessibility	3
ITNI.3	Patient Bill of Rights	5
ITNI.4	Complaints	7
ITNI.5	Infusion Care Admission and Care Coordination	9
	Infusion Therapy Nursing ITNII DELIVERY OF QUALITY PATIENT CARE	10
ITNII.1	Patient Assessment Care Planning	12
ITNII.2	Infusion Therapy Services – General	14
	Infusion Therapy Nursing ITNIII ORGANIZATIONAL PROCESSES	15
ITNIII.1	Organizational and Clinical Policy and Procedure	17
ITNIII.2	Emergency Preparedness	19
ITNIII.3	Infection Control	21
ITNIII.4	Performance Improvement	23
ITNIII.5	Patient Record	25

TABLE of CONTENTS

STANDARD	DESCRIPTION	PAGE(S)
Infusion Therapy Nursing ITNIV	GOVERNANCE AND MANAGEMENT	26
ITNIV.1	Governance and Management	28
ITNIV.2	Clinical Management and Oversight	30-32
ITNIV.3	Human Resources	34
ITNIV.4	Contracted Services	36
ITNIV.5	Alternate Site Physical Space	38

INTRODUCTION

CHAP 2019 INFUSION THERAPY NURSING STANDARDS

The Community Health Accreditation Program (CHAP) revised 2019 Infusion Therapy Nursing Standards 2019 are designed to:

- Establish standards that represent the delivery quality home and community-based Infusion therapy in a variety of settings (in-home, ambulatory infusion centers, contracted in-office services to physicians or pharmacies, etc.);
- Emphasize the rights of Infusion Therapy patients, their family and other caregivers;
- Integrate the quality standards associated with the Medicare Home Infusion benefit effective January 1, 2021; and.
- Advance the recognition of home and community-based infusion therapy as an integral component of the health care delivery system

The Infusion Therapy Nursing Standards address the scope, complexity and challenges of providing infusion therapy in a variety of community-based settings, including the patient's home.

Underlying Principles:

Six (6) key principles form the framework for the standards:

- I. Patient Centered Care
- II. Assessment, care planning and coordination
- III. Care delivery in accordance with nationally recognized practice standards;
- IV. Organization functions and process support the delivery of quality care (e.g. operational and clinical policies and procedures, infection control, quality improvement, emergency management, etc.);
- V. Qualified staff provide services under the effective oversight a clinical manager; and,
- VI. Designated staff assume responsibility for compliance with law and regulation.

Infusion Therapy Nursing

As you use these standards to evaluate your infusion services, consider the following characteristics of the CHAP Infusion Therapy Nursing Standards.

Composition of a Standard:

Each standard statement can be comprised of four (4) parts.

1. Standard: The key area of performance that represents quality in the delivery of quality home and community-based infusion services.
2. Criterion: A statement that defines the requirements of the standard
3. Element: A component of a criterion that further delineates requirements
4. Sub-element: Additional requirements that address detail of a specific standard - few standards have sub -element definition of selected elements.

Example:

Standard: TI.1 (i.e. TIII.1 Policies and procedures support the scope of the infusion services and products provided and represent current standards of practice.

Criterion: TI.1a (i.e. Clinical policies and procedures)

Element: 1) (i.e. As appropriate to therapies provided, blood component administration)

Sub element: (i) (i.e. Transporting of blood product)

Sources of Evidence in Demonstrating Compliance:

This Manual is formatted with *Evidence Guidelines* on the page opposite the standards. These evidence guidelines are not standards. The statements are intended to provide your organization guidance as to how the CHAP site visitor may determine compliance with the standards.

The capital letter preceding each statement identifies one or more of three sources of information used by the site visitor to assess compliance with the standard, criterion, element, or sub-element.

D – Documents Policies and procedures, patient record entries, etc.

I – Interview Interviews of management, staff, and/or the patient or caregiver

O – Observation Site visitor observation during a home visit or at an alternate infusion site

Infusion Therapy Nursing

Eligibility:

The Infusion Therapy Nursing service seeking accreditation must have provided care to at least five (5) patients and have at least three (3) active patients at the time of the site visit.

Application for Certification:

- ✓ The first step is to contact a CHAP representative and request an application. Go to CHAP website, www.CHAP.org.
- ✓ **Application of an infusion Therapy Nursing program that is a service of an already CHAP accredited organization:** You are requested to update information in your organization's LinQ account regarding the Infusion Therapy Nursing services and complete the infusion therapy nursing care specific application questions.

NOTE: "Off-Cycle" available for a Currently CHAP-Accredited Organization. A CHAP accredited organization may seek infusion therapy nursing accreditation 4 months or more prior to the expiration date of the hospice or home health accreditation. This is referred to as "off-cycle" and is accomplished through executing an addendum to your existing accreditation contract.

- The Accreditation Specialist currently assigned to your account will create the Addendum to the Accreditation Contract for execution.
- At the next accreditation renewal, you have the option to add Infusion Therapy Nursing for a full 36-month cycle as part of your accreditation contract.
- ✓ **Application of an Infusion Therapy Nursing Program, independent or a service of another setting:** The application process begins with creating a LinQ account – LinQ is CHAP's database that houses all your accreditation documents electronically.
 - Please note that you will need an Employer Identification Number (EIN) and a National Provider Number (NPI) for use on the application.
 - CHAP staff are available to assist in creating the LinQ account, completing the application and answering other questions you may have.

Contract for Accreditation:

- ✓ Your organization receives the CHAP Accreditation contract electronically in your LinQ account.

Infusion Therapy Nursing

Contract for Accreditation (continued)

- ✓ CHAP asks that you attach your organization's Business Associate Agreement (BAA) for CHAP's execution, or CHAP will provide you with a generic BAA for your completion, signature and return to CHAP with your executed contract.

Assessing Readiness for a Certification Site-Visit:

Upon receipt of the executed contract and initial payment, you receive a document in your LinQ account to assist your staff in assessing readiness for the on-site review. The document reviews the standards and provides your team with another source of internal evaluation of readiness for the site review.

The Site Visit:

- ✓ An Infusion Therapy Nursing program site visit is unannounced. The accreditation site visit is most often be 1-2 days in duration. The length of the visit depends on the infusion patient census, both in-home and in an alternate site, and the number of sites.
 - If your Infusion Therapy Nursing program is a service of a currently CHAP accredited home health agency or hospice, the duration of the site visit considers "equivalent" standards your organization has already met such as infection control, quality assurance, human resources, etc. These policies and procedures do not need to be duplicated for the Infusion Therapy Nursing program. The site visitor will assess how these policies and processes are applied to the Infusion Therapy Nursing Program.
- ✓ Upon the site visitor's arrival, they briefly meet with management and request an introductory meeting introducing the review process and what to expect over the coming day(s). Any staff that the Infusion Therapy Nursing program wish can be present.
- ✓ The Site Visitor proceeds with asking for a space to work in and advising of any policy and procedures they want to review and how they can access a list of current patients and their related records. They also ask for members of the staff and times for interviews.
- ✓ If in-home infusion is being delivered during the course of the site visit, they will ask the organization to obtain permission to accompany the staff to the home. Any patient selected for interview is asked permission to participate in the interview and may decline. Interviews may occur during a home visit of a patient receiving home infusion and/or by phone with patients who have completed therapy.

The Site Visit (continued):

- ✓ If infusion is provided in an alternate physical site, they will arrange to visit the site.
- ✓ The Site Visitor also conducts a summation conference at the end of each site visit day for multi-day site visits, or at the end of the single day site visit in order to summarize preliminary findings and answer any questions.
 - Please note that although you may appeal any decision at any time during the accreditation process, the best time to bring up a question is while the site visitor is there.

Initial Internal CHAP Review:

- ✓ The results of the site review are next reviewed by a Director of Accreditation (DA) assigned to your organization. The DA ensures that any citation for not meeting a standard is supported by site visitor documentation and appropriately considers the scope and severity of the non-compliance.
- ✓ The findings as approved by the Director of Accreditation are returned electronically to the Infusion Therapy Nursing program via their LinQ account within 10 business days of the last or only day of the site visit.

Plan of Correction (POC):

If there is evidence that the intent of one or more infusion therapy standard has not been met, the Director of Accreditation sends the organization a detailed report with the standard and the evidence of non-compliance. The report is available in your LinQ account within 10 business days of the last or only day of the site visit.

Your organization is requested to submit a written plan of correction noting what action you will take to address the area of non-compliance noted and how you will ensure that your compliance is sustained. Your staff may ask the Director of Accreditation assigned to your organization for more information about compliance with the standard, the citation and the Plan of Correction.

- ✓ The completed Plan of Correction is due via electronic submission within 10 calendar days of electronic receipt of the report.

Plan of Correction (POC) continued:

- ✓ The Director of Accreditation either accepts your Plan or requests additional information within 10 business days of electronic receipt of your Plan.
- ✓ Upon the Director's acceptance of the Plan of Correction, the accreditation report and findings, as well as the Plan of Correction are submitted to the Board of Review, a Committee of the Board of Directors who make the accreditation decision.
- ✓ The accreditation awards include:
 - Accreditation without required Action
 - Accreditation with Required Action
 - Accreditation with Required Action and a Focus Visit
 - Accreditation deferred or denied

Accreditation Award:

- ✓ All awards of accreditation are for 3 three years.
- ✓ The Infusion Therapy Nursing Program is initially advised of the accreditation decision via e-mail.
- ✓ You may appeal an accreditation decision within 10 business days of notification of the decision.
- ✓ A letter verifying the decision is provided to the Organization; a Certificate; and the accreditation status is posted on the CHAP website.
 - CHAP is also available to confirm your accreditation for a health plan or a consumer/patient.

ITNI.

**THE INFUSION THERAPY NURSING ORGANIZATION
CONSISTENTLY SUPPORTS PATIENT-CENTERED CARE**

Infusion Therapy Nursing

LEGEND: *Evidence Guidelines*

D - DOCUMENTATION

I - INTERVIEW

O - OBSERVATION

ITNI.1 and ITNI.2

- D: There is a statement of the organization's scope of services and products that includes business hours and how to contact professional staff 24/7 (ITNI.1a)
- I: Staff describe the process for making the information available to the patient. (ITNI.1b)
- I & O Staff and patient interviews confirm that professional staff, including nursing, and products are accessible and available 24/7. (ITNI.2)
- I: Management and professional staff can describe the process and scope of professional services available 24/7. (ITNI.2 a1-3)
- O: During a home visit or clinic interview, the patient acknowledges how to contact the organization and professional staff 24/7. (ITNI.2 b)

ITNI.1 A written statement by the Organization identifies the scope of services and products available and accessible to patients.

ITNI.1a The organization has a statement of the scope of services, including professional services, and products accessible and available to patients.

The statement includes business hours and how to contact professional staff 24 hours-a-day, 7 days-a-week.

ITNI.1b Patients are informed of the process for accessing professional staff and products during normal business hours, after hours, weekends and holidays.

ITNI.2 Professional services, including nursing services, and products are accessible and available to patients 24 hours-a-day, 7 days -a-week.

ITNI.2a Professional staff able to provide clinical knowledge and advice, as well as education and training are accessible and available to patients, family or other caregivers 24-hours-a-day, 7 days-a -week.

Access and availability of professional staff includes:

- 1) Timely remote response and monitoring by telephone or electronically;
- 2) Timely on-site response including the provision and administration of home infusion therapy; and,
- 3) Medication, equipment and supply delivery for use.

Applicable Regulation: CMS § 486.525 (a)(1)(2)(3)
(Pending CMS Approval)

ITNI.2b The organization has a process for and evidence of accessibility to professional staff including nursing services – and products 24 hours-a-day, 7 days-a-week.

Infusion Therapy Nursing

LEGEND: *Evidence Guidelines*

D - DOCUMENTATION

I - INTERVIEW

O - OBSERVATION

ITNI.3

- D: A Patient Bill of Rights statement includes elements of ITNI.3b 1-11

- D: Policy and procedure define the process of providing the Bill of Rights to the patient or designated representative at the initiation of services. (ITNI.3a)

- D: Record review confirms that the patient Bill of Rights is provided to the home infusion patient or designated representative. (ITNI.3b)

- O: Observation in an alternate infusion site(s) validates that the Patient Bill of Rights is posted in a public area. (ITNI.3a)

- I: During home visits, or patient interviews at the alternate infusion site, the patient recalls having received the Bill of Rights, or referenced to its presence in the public area. (ITNI.3c)

ITNI.3	The Organization defines patient rights in the delivery of infusion care and supports the exercise of those rights.
---------------	--

ITNI.3a A Patient Bill of Rights statement is provided to the patient or the designated patient representative at the initiation of service per Organization policy and procedure.

In an alternate infusion site, the patient's Bill of Right is posted in a public area and referenced.

ITNI.3b The Patient Bill of Rights includes the right to:

- 1) Be informed of the services and products being provided;
- 2) Receive education and training about the products and services being provided;
- 3) Be involved in planning care;
- 4) Participate in one's own care, as appropriate;
- 5) Refuse part or all the services and products;
- 6) Receive services and products in a timely manner;
- 7) Be free from mistreatment, neglect, or verbal, mental, sexual, or physical abuse;
- 8) Receive information, both verbal and written, in an understandable manner;
- 9) A confidential record per federal and state law and regulation;
- 10) Be informed how to voice complaints to the Organization and to CHAP; and
- 11) Be informed about payment sources and any expected or known patient financial liability prior to the start of care, as well as any subsequent changes in payment liability during care.

ITNI.3c There is evidence that the home infusion patient has received the Patient Bill of Rights or is referred to the public posting if receiving infusion in an alternate site.

LEGEND: *Evidence Guidelines*

D - DOCUMENTATION

I - INTERVIEW

O - OBSERVATION

TINI.4

D: Documentation validates that the complaint process includes elements 1-5. (ITNI.4a)

D: Review of organizational documentation indicates that complaints have been responded to consistent with the organization's process. (ITNI.4a)

I: Staff and patient verbalize knowledge of the complaint process. (ITNI.4a)

ITNI.4 Complaints are responded to and resolved in a timely manner.

ITNI.4a There is a documented complaint process that includes:

- 1) Designation of the individual(s) responsible for responding to the complaint;
- 2) Procedures and timeframe for responding to complaints;
- 3) Documentation of corrective action taken, as appropriate;
- 4) Resolution of the complaint, as indicated; and
- 5) Defined follow-up with the complainant.

LEGEND: *Evidence Guidelines*

D - DOCUMENTATION

I - INTERVIEW

O - OBSERVATION

ITNI.5

- D: Written policy procedure defines home infusion admission criteria, including advising the referral source if the patient's needs cannot be met. (ITNI.5a, 2)

- D: Patient records and policy and procedure confirm that patients are seen within 48 hours of referral or the physician's ordered start date. (ITNI.5a,1)

- D: Patient records confirm that each patient admitted is under the care of a physician, a nurse practitioner or physician assistant. (ITNI.5b)

- D: Policies and procedures define the responsibilities and processes for service coordination. (ITNI.5c 1-6, ITNI.5d)

- D: Patient records confirm care coordination activities. (ITNI.5d and e)

- e) D: Infusion nurse and pharmacist review is documented. (ITNI.5e, 1-3)

- I: Procedures for coordinating delivery of medication, equipment, and supplies in a timely manner for medication administration are described by staff and confirmed in patient interviews. (ITNI.5f)

ITNI. 5 The Organization admits infusion patients whose care needs can be reasonably met and ensures coordination of services with others involved in patient care.

ITNI.5a Patients are admitted and continued service based on the reasonable expectation that their needs can adequately and safely be met.

- 1) Home infusion patients are visited within 48 hours of referral unless otherwise indicated by the physician; and,
- 2) If a patient cannot be admitted, the referral source is advised.

ITNI.5b Each patient admitted for infusion therapy is currently under the care of a physician, a nurse practitioner or a physician assistant.

Applicable Regulation: CMS 486.50(a)

ITNI.5c Policy and procedure defines the coordination process with other professionals involved in patient care, including in the following activities:

- 1) Developing the plan of care;
- 2) Establishing expected outcomes;
- 3) Implementing the care plan;
- 4) Ongoing monitoring and evaluation of patient status;
- 5) Periodic update and communication; and,
- 6) Planning for discharge from infusion services.

ITNI.5d There is evidence that infusion therapy nursing staff coordinate infusion care with other health care professionals also involved in patient care.

ITNI.5e Infusion therapy nursing staff and pharmacy staff review the ordered medication regimen, equipment and supplies:

- 1) Prior to initiation of therapy;
- 2) When a change in therapy occurs; and
- 3) As appropriate to the patient's therapy and response.

ITNI.5f The delivery of medications, equipment, and supplies is coordinated with other providers involved in the care of the patient to ensure availability when needed for medication administration

ITNII.

**THE INFUSION THERAPY ORGANIZATION
CONSISTENTLY PROVIDES QUALITY PATIENT CARE**

Infusion Therapy Nursing

LEGEND: *Evidence Guidelines*

D – DOCUMENTATION

I - INTERVIEW

O – OBSERVATION

ITNII.1

- D: Patient assessment policies and record review validate the inclusion of specified items. (ITNII.1a)

- D: Record review confirms that written plans of care are signed by the physician, upon update to the plan or at least every 30 days. (ITNII.1b, ITNII.1d)

- D: Record review confirms care plans for each patient and include elements 1-10. (ITNII.1c)

- I: Staff describe mechanisms for involving the patient and the physician in care plan development and update. (ITNII.1c)

- D: Record review confirms that drugs and treatments are administered according to physician orders. (ITNII.1c, 2 and 3)

- D: Patient records confirm that the care plan is reviewed and revised as appropriate to the care of the patient, as often as deemed necessary by the physician or at least every 30 days. (ITNII.1d)

ITNII.1 The Organization defines the plan of care process, including initial and ongoing assessment, care plan development and update, and physician oversight.

ITNII.1a Initial, and as appropriate, ongoing patient assessments are conducted in the location where the patient receives infusion therapy.

The assessment includes the patient's:

- 1) Medical status;
- 2) Self-care capability;
- 3) The home physical environment including safety, adequate refrigeration, storage and cleanliness; and,
- 4) Family or other caregiver support.

ITNII.1b Infusion care is provided under the oversight of a physician and follows a documented and signed plan of care.

- 1) Infusion therapy is terminated per physician order.

ITNII.1c A plan of care is developed for each patient in consultation with the patient and the physician, and includes:

- 1) The patient's medical and psychosocial status;
- 2) Scope and frequency of services, including the professional responsible;
- 3) Supplies and equipment being used;
- 4) Drug or biological route, dosage, rate, duration and administration frequency;
- 5) Any patient functional limitations;
- 6) Nutritional requirements;
- 7) Patient and family education and training, including in self-administration;
- 8) Expected outcomes;
- 9) Any safety measures; and,
- 10) Precautions, contraindications, and laboratory procedures.

Applicable Regulation: CMS §486.520 (b) (Pending CMS Approval)

ITNII.1d The patient care plan is reviewed and revised as appropriate to the care of the patient, as often as deemed necessary by the physician or at least every 30 days.

Applicable Regulation: CMS §486.520(c) (Pending CMS Approval)

LEGEND: *Evidence Guidelines*

D - DOCUMENTATION

I - INTERVIEW

O - OBSERVATION

ITNII.2

- D, I, O: Interview, observation and patient record review confirm that nursing visit frequency corresponds to items listed in 1-6. (ITNII.2a)
- D, O: Patient record review and observation of staff validate that drugs, biologicals and nutritional therapies are administered in accordance with physician orders and professional standards of practice. (ITNII.2b)
- D: Patient records document that first dose infused medications are administered per physician order in the setting appropriate to the patient and medication. (ITNII.2d)
- D&I: Standing Orders/protocols are available for emergency kits. Interviews confirm that staff are familiar with the emergency kit process and provide examples of appropriate use (ITNII.2c)
- D & I: Patient record review and interview confirm the administration and disposal of controlled substances meets regulatory requirements. (ITNII.2e)

ITNII.2 Infusion Therapy Nursing Services are provided in accordance with organizational policies and procedures and professional standards of practice.

ITNII.2a Nursing visits to patients, remotely or in-home, are made as frequently as necessary to:

- 1) Assess and evaluate the patient's status;
- 2) Assess the physical environment, including safety, refrigeration, storage and cleanliness;
- 3) Administer therapy according to the plan of care;
- 4) Train and educate the patient, family or other caregiver in the care and maintenance of vascular devices, and as appropriate, self-administration;
- 5) Assess patient's and family's or other caregiver's ability to manage when staff are not present; and,
- 6) Monitor the patient's status with consideration of the complexity of treatment, patient response, and plan of care.

ITNII.2b Infusion services are provided in accordance with nationally recognized standards of practice and in compliance with state and federal law and regulation.

Applicable Regulation: CMS §486.525(b)

ITNII.2c There are physician standing orders and procedures to obtain emergency kits with appropriate medications for use in the patient's home or alternate infusion site.

ITNII.2d The first dose of any infusion medication is given in a setting appropriate to the patient, the medication, and physician orders as well as in accordance with organizational policy and procedure.

ITNII.2e Staff administration and disposal of controlled substances is documented and complies with state and federal law and regulation.

ITNIII.

**THE INFUSION THERAPY NURSING ORGANIZATION'S
PROCESSES CONSISTENTLY SUPPORT
THE SAFE DELIVERY OF QUALITY PATIENT CARE**

Infusion Therapy Nursing

LEGEND: *Evidence Guidelines*

D - DOCUMENTATION

I - INTERVIEW

O - OBSERVATION

ITNIII.1

- D: Organization policies and procedures reflect standards of professional practice. (ITNIII.1a)

- D: Operational policies and procedures at a minimum address items 1– 6 (ITNIII.1b)

- D: Clinical policies and procedures at a minimum address items 1 –11c. (ITNIII.1c)

ITNIII.1 Policies and procedures support the scope of the infusion services and products provided and represent current standards of practice.

ITNIII.1a Organization operational and clinical policies and procedures reflect professional standards of practice.

ITNIII.1b Operational policies and procedures address the scope of services and products provided and include:

- 1) Storage of infusion medications and solutions;
- 2) Criteria and requirements of first dose administration;
- 3) Acquisition, storage and dispensing of emergency kits;
- 4) Patient, family or other caregiver training and education;
- 5) Timely delivery of care and products;
- 6) Maintenance and use of infusion control devices for therapy administration.

ITNIII.1c Clinical policies and procedures include the following:

- 1) Patient identification;
- 2) Patient, family or other caregiver therapy training and education;
- 3) Acceptable routes of administration;
- 4) Vascular access device (VAD) related site care, flushing and locking, and VAD removal;
- 5) Accessing implanted pumps or ports;
- 6) VAD stabilization and securement;
- 7) VAD repair;
- 8) Drawing laboratory blood samples;
- 9) Identification and management of VAD and infusion related complications (e.g. infection, thrombotic occlusion, phlebitis);
- 10) Appropriate administration of the ordered infusion therapy;
- 11) As appropriate to therapies provided, blood component administration including:
 - i) Initial patient assessment
 - ii) Transporting of blood product, and
 - iii) Crossmatching procedure.

LEGEND: Evidence Guidelines

D - DOCUMENTATION

I - INTERVIEW

O - OBSERVATION

ITNIII.2

- D & I: There is documentation of the emergency information provided to patients and families. Staff interviews confirm the process for providing the information and when it is provided to the patient and family. Patient interviews confirm receipt of this information. (ITNIII.2a)

- D: Review of the management protocols for emergencies confirms management responsibilities to ensure staff safety prior to and during an emergency event, including coordination with others involved in patient care. (ITNIII.2b)

- I: Staff interviews confirm their understanding of emergency event protocols and their responsibilities. (ITNIII.2c)

ITNIII.2A geographic specific plan defines protocols for prioritizing care and services to patients and safety of the staff during disasters, emergencies or environmental situations.

- ITNIII.2a Written instructions are given to patients and families or other caregivers to ensure an appropriate and timely response in the event of a natural disaster, inclement weather, and/or other emergency event that might cause an interruption in the provision of infusion services and products.
- ITNIII.2b Written protocols define management responsibilities in ensuring the safety of staff prior to and during an emergent event, including coordination with other organizations involved in patient care.
- ITNIII.3b Staff are knowledgeable of the practices and procedures relating to emergency preparedness, and their responsibilities.

Infusion Therapy Nursing

LEGEND: Evidence Guidelines

D - DOCUMENTATION

I - INTERVIEW

O - OBSERVATION

ITNIII.3

- D: Written policies exist and include items 1-6. (ITNIII.3a)

- O: Observation of staff performing care confirms that staff adhere to infection control and safety policies and procedures. (ITNIII.3a)

- D: Patient instructions regarding preparation of sterile solutions, storage methods, and stability and expiration of the solution are documented. (ITNIII.3b 1-3)

- I: Patients preparing sterile solutions at home can describe appropriate preparation and storage precautions. (ITNIII.3b 1-3)

- D: Record review confirms that the home environment evaluation was conducted, any safety hazards identified, as well as any related precautionary instructions provided to the patient. (ITNIII.3c)

- I & O: Interviews with staff and observation confirm that equipment/supplies are inspected. (ITNIII.3d)

ITNIII.3 The health and safety of patients and staff are promoted and maintained through implementation of current infection control policies and safety measures.

ITNIII.3a Infection control and safety measures are established by the organization and implemented as a part of each infusion procedure.

Infection control and safety measures include:

- 1) Use of standard precautions;
- 2) Isolation precautions in accordance with CDC guidelines;
- 3) Cleaning and storage of reusable equipment between usage;
- 4) Inspection of equipment prior to delivery and use;
- 5) Appropriate needle disposal; and,
- 6) Proper disposal of hazardous waste products generated during staff administration of drugs or biologicals.

ITNIII.3b When patients, family or other caregivers prepare sterile preparations in the home, they are instructed verbally and in writing regarding safeguards against microbial contamination, including, but not limited to the following:

- 1) Instructions regarding the preparation of the sterile solution;
- 2) Storage methods; and,
- 3) Stability and expiration of the prepared solution.

ITNIII.3c The patient's home is evaluated for potential safety hazards, and the patient, family, or other caregiver instructed about safety precautions. The evaluation and patient teaching are documented in the patient's record.

ITNIII.3d Prior to, during, and after use, staff inspect all intravenous equipment and supplies for product integrity and expiration date.

- 1) If the patient, family or other caregiver is self-administering a medication, a written checklist is provided.

LEGEND: Evidence Guidelines

D - DOCUMENTATION

I - INTERVIEW

O - OBSERVATION

ITNIII.4

- D: The performance improvement program includes items specified in (ITNIII.4a)

- D: There is evidence that performance expectations are set for outcomes and at-risk activities, as well as data collected, and action taken in response to findings. (ITNIII.4a)

- I: Clinical management staff confirm monitoring efforts to improve care and results of the most current evaluation activities and any related action. (ITNIII.4b)

ITNIII.4	The appropriateness, effectiveness and outcomes of infusion services and products provided are routinely assessed, opportunities for improvement identified and action taken.
-----------------	--

ITNIII.4a There is a quality improvement process designed to improve the quality of Infusion services and products, including:

- 1) Establishing performance expectations regarding desired outcomes and identified at-risk activities;
- 2) Monitoring performance;
- 3) Acting in response to findings; and
- 4) Evaluating the effectiveness of action taken

ITNIII.4b The Organization has a process for informing clinical management and staff of:

- 1) Desired outcomes and at-risk activities being monitored; and
- 2) The results of monitoring and any corrective action taken.

Infusion Therapy Nursing

LEGEND: Evidence Guidelines

D - DOCUMENTATION

I - INTERVIEW

O - OBSERVATION

ITNIII.5

- D: The organization's policies and procedures for management of patient records reflect current standards of practice as well as comply with state and federal law and regulation. (ITNIII.5a)

- D: Patient record documentation reflects services and products provided, refused or not provided, as well as the patient's current status. (ITNIII.5b)

- D: Patient record entries reflect current standards of practice and follow organization policy and procedure. (ITNIII.5c)

- D: Record documentation reflects items 1-13. (ITNIII.5.d)

ITNIII.5	Records are maintained for each infusion patient and represent the services and products provided in accordance with the plan of care and current standards of professional practice.
-----------------	--

ITNIII.5a The organization has policies and procedures addressing the management of patient records in accordance with state and federal law and regulation and current standards of practice.

ITNIII.5b Record documentation provides patient information specific to services and products provided, not provided, or refused as well the patient's current status.

ITNIII.5c Entries in the record are clear, specific statements of fact, signed and dated by the staff and are consistent with organization patient record policies and procedures.

ITNIII.5d Records of patients receiving infusion therapy include:

- 1) Initial and subsequent assessments;
- 2) A plan of care and any changes;
- 3) Authenticated medical orders (verbal and written);
- 4) A medication profile including current medications including OTC; drugs, herbal remedies, vitamins and minerals;
- 5) Infusion administration record;
- 6) Patient and family or other caregiver training and education;
- 7) Nursing and other professional interventions;
- 8) Patient response to therapy, including complications and adverse reactions;
- 9) Evaluation of patient's progress to expected outcomes of care;
- 10) Laboratory results;
- 11) Pharmacy reviews;
- 12) Progress notes, dated and signed by the individual providing the service and entered per policy and procedure; and
- 13) Discontinuation of therapy, and any subsequent discharge from infusion care.

ITNIV.

**THE INFUSION THERAPY ORGANIZATION
IS EFFECTIVELY ORGANIZED, GOVERNED AND MANAGED TO
DELIVERY QUALITY PATIENT CARE**

LEGEND: *Evidence Guidelines*

D - DOCUMENTATION

I - INTERVIEW

O - OBSERVATION

ITNIV.1 and ITNIV.2:

- D: An individual or group has legal authority and accountability for the organization. (ITNIV.1a)

- I: The qualified manager or administrator confirms during interview their understanding of the scope of their responsibility including compliance with law and regulation. (ITNIV.1b)

- D: A current organizational chart is available and delineates the lines of authority and accountability for all positions to the level of patient care. (ITNIV.2a)

- I: Staff members articulate their individual lines of authority and accountability. (ITNIV.2b)

- I: Staff members articulate who will act in the day-to-day management in the absence of the manager. (ITNIV.2c)

ITNIV.1 The Organization has the legal authority to operate and in compliance with local, state and federal law and regulation.

ITNIV.1a An identified individual or group assumes full legal authority, responsibility, and accountability for organizational performance, adequate financial resources, and compliance with local, state and federal law and regulation.

ITNIV.1b A qualified administrator is appointed to manage day-to-day operations, including organization compliance with applicable law and regulation.

ITNIV.1c The organization has a budget that represents the scope of services and products provided directly or by contract.

ITNIV.2 Intra-organizational relationships are defined in writing.

ITNIV.2a Organizational relationships are clearly defined in writing.

ITNIV.2b A current organizational chart illustrates the lines of authority and accountability from administration to patient care.

ITNIV. 2cAn individual is designated to act in the absence of the day-to-day manager or administrator.

Infusion Therapy Nursing

LEGEND: *Evidence Guidelines*

D - DOCUMENTATION

I - INTERVIEW

O - OBSERVATION

ITNIV.3

- D: There is an Infusion Therapy Nursing Program Director who meets the requirements of the standard. (ITNIV.3a)

- D: The Infusion Therapy Nursing Program Director's job description and/or policies address the Director's direct and/or delegated organizational responsibilities as specified in elements 1-4B. (ITNIV.3b)

- I: Interviews of nursing staff and supervisors confirm supervisor availability during all hours of service. (ITNIV.3b 4Cii)

- I: Interview of the Nursing Program Director and nursing staff confirm their understanding of their scope of oversight. (ITNIV.3b 1-4Cii)

- D: The assignment of responsibilities in the absence of the Infusion Therapy Nursing Program Director is stated in writing. (ITNIV.3c)

- I: Staff members know who is responsible in the Director's absence. (ITNIV.3c)

ITNIV.3 Authority and responsibility is defined for the day-to-day clinical management of the Infusion therapy services.

ITNIV.3a There is an Infusion Therapy Nursing clinical manager who is a currently licensed Registered Nurse (RN) with at least two year's infusion nursing experience and who is responsible for the clinical management of the infusion therapy services.

ITNIV.3b The Infusion Therapy clinical manager is responsible for the following areas either directly or by delegation to other staff:

- 1) Evaluation of the infusion therapy services and of staff competency;
- 2) Ensuring adequate and appropriate staffing;
- 3) Ensuring that services meet currently accepted standards of professional practice;
- 4) Ensuring that policies and procedures are implemented, in particular:
 - A) staff orientation;
 - B) staff competency assessment;
 - C) staff supervision, including:
 - i) oversight of the provision of services to the patient, and,
 - ii) availability to staff during all hours of service.

ITNIV.3c A qualified individual is designated in writing to act in the absence of the Infusion Therapy Nursing Program Director.

LEGEND: *Evidence Guidelines*

D - DOCUMENTATION

I - INTERVIEW

O - OBSERVATION

ITNIV.3 (continued)

- I: Policies, or contract language and staff interviews confirm how clinical services, pharmaceuticals, supplies and equipment are provided. (ITNIV.3d)

- I: Interview of the staff responsible for medication administration confirm that the delivery process identified in items 1-3 occurs. (ITNIV.3e)

- I: Interviews of staff and of patients confirm timely availability of drugs, equipment and supplies when not provided by the organization. (ITNIV.3e and f)

ITNIV.3 Authority and responsibility is defined for the day-to-day clinical management of the Infusion therapy services.

ITNIV.3d Pharmacy services are provided directly or by arrangement including provision of clinical services, pharmaceuticals, equipment and supplies.

ITNIV.3e Delivery services are provided directly or by arrangement and include:

- 1) Safe and clean transport of pharmaceuticals, equipment and supplies;
- 2) Delivery of pharmaceuticals, supplies and equipment occurs prior to administration; and,
- 3) Setting-up equipment in patient homes and alternate sites, as applicable.

ITNIV.3f The organization ensures the availability of drug and supplies in patient homes or at alternate sites when not available from the organization.

LEGEND: *Evidence Guidelines*

D - DOCUMENTATION

I - INTERVIEW

O - OBSERVATION

ITNIV.4

D: Policies and procedures confirm elements 1-7. (ITNIV.4a)

D: Personnel files include evidence of items 1-4 as appropriate to their job responsibilities. (ITNIV.4b)

I: Mechanisms for assessing and updating competencies/skills are described and evident, as well as conform to organizational policy and procedure.
(ITNIV.4b.4)

ITNIV.4 The Organization has adequate and qualified human resources to meet patient caseload and workload demand.

ITNIV.4a The Organization has defined Human Resource Management policies and procedures that include:

- 1) Job descriptions delineating position scope, responsibilities and qualifications;
- 2) Conditions of employment;
- 3) Non-discrimination information;
- 4) Employee orientation;
- 5) Initial and ongoing assessing of competencies related to job responsibilities;
- 6) Health reports, background checks and other information as required state law and regulation; and,
- 7) Employee record confidentiality and retention.

ITNIV.4b Qualified personnel provide infusion services.

- 1) Professional staff are graduates of schools approved or accredited by their respective professional entities;
- 2) Professional staff, including nursing staff, have experience and certification per organization policy and state law and regulation;
- 3) Professional staff maintain current licensure and/or certification per state law and regulation;
- 4) There is evidence that the skills and competencies of professional and technical staff is assessed and updated per organizational policy.

LEGEND: *Evidence Guidelines*

D - DOCUMENTATION

I - INTERVIEW

O - OBSERVATION

ITNIV.5

- D: Contracts for infusion therapy nursing services contain elements ITNIV.5a

- D: Contracts for pharmacy services contain elements of ITNIV.5b

- D: Contracts for delivery of equipment and supplies contain elements of ITNIV.5c

ITNIV.5 Contracts are executed with organizations and/or individuals for the provision of infusion therapy services to infusion patients and define specific responsibilities of the parties involved.

- ITNIV.5a Contracts with other organizations and/or individuals for provision of infusion therapy nursing services include the following:
- 1) The contracting organization accepts and terminates patient services, as well as develops and updates the plan of care;
 - 2) Staff meet the qualifications and demonstrate competencies as defined by the contracting organization;
 - 3) Services are provided per professional standards of practice;
 - 4) How services and products are coordinated and evaluated; and,
 - 5) Responsibility for orientation of staff to the contracting organization's policies and procedures.
- ITNIV.5b When pharmacy services are provided under arrangement, the contract includes:
- 1) Hours services are available, including arrangements for services 24 hours-a-day, 7 days-a-week in the patient's home;
 - 2) Time frames for response to new referrals;
 - 3) Responsibility for:
 - a) Obtaining physician orders;
 - b) The initial and updated drug profiles and how information is made available to staff involved in a patient's care; and,
 - c) Maintaining controlled substance records according to state and federal law and regulation.
- ITNIV.5c Delivery of equipment and supplies when provided under arrangement the contract includes provisions for:
- 1) Ensuring clean and safe transport;
 - 2) Delivery prior to administration;
 - 3) Equipment set-up in patient's homes and related training;
 - 4) Adequately trained delivery staff; and,
 - 5) Appropriate documentation.

LEGEND: *Evidence Guidelines*

D - DOCUMENTATION

I - INTERVIEW

O - OBSERVATION

ITNIV.6

O: Alternate patient infusion service areas are private, clean, safe. (ITNIV.6a)

ITNIV.6	Infusion Therapy Nursing services are provided in a private, clean and safe alternate physical space or site.
----------------	--

ITNIV.6a When infusion services are provided in an alternate physical site, there is a safe and clean environment for patients and staff.

- 1) Space and patient privacy are adequate for the services being provided; and,
- 2) Physical facilities and resources permit effective and efficient function of the staff in the administration of drugs or biologicals.

Home Infusion Therapy Nursing Key Terms

Adverse event: Any untoward medical occurrence that may present during treatment with a pharmaceutical product, but which does not necessarily have a causal relationship with this treatment.

At-Risk Activity: Action or inaction that results in probable or unforeseen loss of health. The degree of at-risk health activity is associated with recognized professional standards of practice.

Alternate Infusion Site: A designated physical space other than the patient's home or residence where the infusion of medication occurs.

Home: Where a patient resides.

Mental Status: An individual's cognitive, affective and behavioral state takes into consideration factors including- general health, appearance, mood, speech, sociability, motor activity, emotional state and memory.

Products: Equipment (e.g. infusion pump) furnished by a DMEPOS supplier

Professional: Those individuals engaged in the delivery of healthcare whose education and training meets the requirements of professional activity most often defined by state practice acts and/or professional associations.

Supplies: Accessories, usually disposables (e.g. tubing, filters) required for continuous use of the equipment.