

**Clinical Checklist for Infusion Therapy Services in a Diagnostic and Treatment Center
04/14/2021**

1.	Facility Staffing:	Met	Not Met
	<p>Provision of Services by Skilled Professionals-</p> <p>Skilled professional services are authorized, delivered, and supervised only by health care professionals who meet the appropriate qualifications and who practice according to their scope of practice as defined in NYS law and regulation and standards of applicable professional organizations. Duties and responsibilities are based on these standards and are clearly delineated in job descriptions, contracts/agreements, and/or facility policy.</p> <p>a) Appointment of a Medical Director:</p> <ul style="list-style-type: none"> - Responsible to the operator for all professional, organizational, and administrative aspects of the scope, adequacy and quality of care provided to patients in the center. - Responsible for appointments to the medical staff, credentialing, and staffing needs. - Responsible for the development of policy & procedures. Reviews annually or as necessary. - Has oversight of the quality assurance performance improvement program, infection control committee, and reporting obligations. <p>b) Physician (MD), Physician Assistant (PA) or Nurse Practitioner (NP):</p> <ul style="list-style-type: none"> - Responsibilities and scope of service stated in medical bylaws/policies consistent with scope of practice as defined by NYS law and regulation, practitioner competencies and standards set forth by relevant professional association(s). - Must be immediately available in accordance with facility policies approved by the Department. <p>c) Administrator:</p> <ul style="list-style-type: none"> - Provides oversight and implementation of the organization's operations. <p>d) Nurse Manager:</p> <ul style="list-style-type: none"> - A registered nurse (RN) nurse manager of infusion services must provide oversight of all patient care services and personnel. - Ensures safe staffing to meet the needs of the patients based on patient acuity, type of access and infusion, standards of care set by relevant professional associations, patient immune status, and presence/absence of communicable disease(s). - Role may include Administrative duties. - Takes a leadership role in the quality assurance performance improvement and infection control activities of the facility. <p>e) RN:</p> <ul style="list-style-type: none"> - Responsibilities and scope of service stated in policy consistent with scope of practice as defined by NYS law and regulation, practitioner competencies and certification standards set forth by relevant professional association(s). - Provides direct oversight and hands on patient care, including assessment and monitoring, IV infusion administration, line care, medication 		

	<p>administration, response to adverse events and patient education. Ensures documentation of all patient care that is provided.</p> <ul style="list-style-type: none"> - Participates in the quality assurance performance improvement and infection control activities of the facility. <p>f) LPN:</p> <ul style="list-style-type: none"> - Responsibilities and scope of service stated in policy consistent with scope of practice as defined by NYS law and regulation, practitioner competencies and standards set forth by relevant professional association(s). - Under the direct supervision of an RN. - Per NYS Education Department State Board for Nursing and NYCRR Title 10 section 400.15 & 700.4, indicates LPN's MAY NOT administer of blood and blood products, intravenous anti-neoplastic (Chemo) agents, or a bolus of medication by intravenous push. - Not authorized to access central lines. 		
2.	Staff Personnel/Credential File: Education, Experience and Competence:	Met	Not Met
	<ul style="list-style-type: none"> - NYS Nursing licensure: RN and LPN - Pre-employment health physical and applicable immunizations. - Annual health physical and applicable immunizations. - IV certifications/specific competency-based training - Oncology and/or infusion therapy certification of RNs for Chemotherapy administration as applicable. - ACLS and BLS for MDs and RNs taking care of adult patients, PALS and BLS for MDs and RNs taking care of pediatric patients, BLS only for LPNs and unlicensed personnel. - Job descriptions for all staff that include patient care responsibilities, education, and experience requirements. - Orientation of facility policies and skills competency specific to Job Description and title - Ongoing training and education including competencies related to duties, patient care, and infection control. - Performance evaluation and competency assessments - Physician, PA and/or NP credentials: <ul style="list-style-type: none"> • They are qualified by training, experience, and administrative ability to assume responsibility for the position. • Have NYS licensure and DEA privileges 		
3.	Operational Requirements and Clinical Policies and Procedures:	Met	Not Met
	<p>Facility has obtained all licenses, certifications and/or permits required to carry out proposed services. Examples might include: Limited Transfusion Permit for transfusion of blood administration, onsite pharmacies, etc.</p> <p>Facility Operating Certificate accurately reflects the type(s) of infusions the facility is approved to administer. Examples include:</p> <p>a) Primary Care</p> <ul style="list-style-type: none"> - Normotonic IV solutions for hydration - Electrolyte replacement <p>b) Other Medical Specialties</p> <ul style="list-style-type: none"> - Chemotherapy 		

- Biologicals
- Others

Policies & Procedures are developed and in conformance with professionally recognized standards including:

- a) Types of infusions to be administered in the facility, including exclusion criteria for patients and infusions not appropriate for the setting, and those infusions that are allowed only if certain conditions are met.

Examples include but are not limited to:

- the exclusion of pregnant women and/or children;
- infusion of specific cardiac IV medications only if setting has cardiac monitoring or telemetry capacity with staff trained and competent to interpret cardiac rhythms;
- under what circumstances colonized patients with multi-drug resistant organisms will or will not be treated in the outpatient setting; and/or
- which classes or specific fluids/ medications require the onsite presence of a physician/PA/NP who is immediately available during administration and recovery.

All infusions of medications under study or being administered under emergency use authorization must have an authorized prescriber onsite at all time while patients are onsite receiving these medications.

- b) Policies and procedures for the care and monitoring of patients receiving specific type(s) of infusions, and condition being treated, to be administered in the setting:

- Chemotherapy agents
- Antibiotic/antifungal therapy
- Biologicals
- Steroid treatment
- IV fluids
- Nutritional supplementation
- Parenteral nutrition
- MS and other autoimmune IV therapy agents
- Blood and blood products
- Pain Management
- IV push medications: Iron etc.
- Other types of IV Infusions

- c) Type of access to be used in an outpatient setting, including care protocols:

- Peripheral
- Midline
- Central line
- PICC line
- Implantable ports

- d) Clinic Equipment:

- Calibration and regular maintenance of machines or equipment
- Set up, programming, and usage of pumps and other equipment
- Disinfection between patients (point of care HCT machines, chairs).
- Routine maintenance.

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| | <p>e) Admission criteria:</p> <ul style="list-style-type: none"> – Types of patients to treat in an outpatient setting, including exclusion criteria addressing acuity, allergy and medication reaction history and other relevant factors. – Physician order – History and physical indicating reason for infusion – Laboratory studies – Current Medications – Allergy history – Consent for treatment including risks and benefits of treatment. <p>f) Plan of Care:</p> <ul style="list-style-type: none"> – Diagnosis and care issues – Interventions – Treatment plan <p>g) Comprehensive assessment of patients (by Nursing and Medical Providers):</p> <ul style="list-style-type: none"> – Initial assessment with a reassessment prior to each treatment. – A review of all prescription and over the counter medication and supplements the patient is currently taking to identify any potential adverse effects and drug reactions, including significant side effects and/or drug interactions. – Check lab work (e.g., electrolyte panel, white blood cell, kidney, liver) before treatment, as applicable. <p>h) Drugs, services, and treatments are administered only as ordered by an authorized prescriber (physician, physician assistant, nurse practitioner). Drugs, services, and treatments are ordered by authorized prescribers consistent with plan of care established and periodically reviewed by the attending physician.</p> <p>i) Nursing administration:</p> <ul style="list-style-type: none"> – Infusions administered per MD/PA/NP order. – Follows all policies and procedures based on standards set forth by a professional association. – Performs medication verification and inspects medication integrity per policy. – Performs insertion site care, dressing changes, catheter flushes, transfer set changes etc. per facility policy. – Monitors the patients during the infusion per facility policy according to infusion type, patient safety, patency and/or the prevention of potential adverse events. – Follows established facility protocols for adverse events including, but not limited to the following: Phlebitis, Infiltration, Extravasation, Occlusion, Air Embolism, Infection and Adverse Reactions. – Access site is visualized during treatment. – Documents treatment, including any abnormal or adverse events. – Follows strict infection control protocols and wears the appropriate PPE. – Maintains the Physical Environment: Patient spacing, isolation, visitation etc. <p>j) Pharmaceuticals:</p> <ul style="list-style-type: none"> – Preparation of an Infusion medication in an appropriate pharmacy. Mixing substances for infusions need to be done in a pharmacy under a laminar hood. (Reference to general USP 797). – If no pharmacy onsite, has an agreement and/or contract for services. – Appropriate delivery of the Infusion medication from the pharmacy to the DTC. | | |
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	<ul style="list-style-type: none"> - Adequate storage, security, and monitoring of infusion medications. - Safe disposal of infusion medications and/or supplies. - NYS Board of Pharmacy (BoP) Acknowledgement and/or Licensing approval if needed for proposed services. - Development of protocols for the monitoring of adverse infusion reactions and/or medication errors, including but not limited to: <ul style="list-style-type: none"> • Management of Infusion reaction • Management of Allergic Reaction • Documentation requirements • Defective and/or compromised medication, infusion device(s) and pumps • Protocol for documentation and review through QAPI 		
4.	Infection Prevention and Control Program, Plan and Policies:	Met	Not Met
	<p>Consistent with NYCRR Title 10, Section 702.4 the DTC must establish an infection control committee that is responsible for establishing plans, policies, and procedures for investigating, controlling, and preventing infections in the facility. The infection control program should be based on accepted national standards & best practices and has as its goals the prevention and control of infections and communicable diseases. Policies should include:</p> <ul style="list-style-type: none"> - Hand Hygiene - Injection and Medication Safety. - Aseptic and sterile technique. - Medication and supply storage and security. - Standard, contact, universal and other Infection Control precautions, including the need to isolate or segregate patients due to infectious diseases or decreased immunity. - Infusion equipment use, maintenance and disinfection. - Blood borne pathogens, spills, and exposures. - Handling and disposal of hazardous waste, medical waste, and sharps. - General cleaning & disinfection, including terminal cleaning. - Communicable disease reporting and infection tracking. - Staff and patient education <p>There should be evidence of monitoring adherence to infection control policies, the occurrence of health care associated infections, quality assurance and performance improvement activities related to infection control issues and meetings of the infection control committee.</p>		
5.	Emergency Plan:	Met	Not Met
	<p>The facility should develop and implement an emergency plan/policy to address various emergency scenarios, based on services provided, utilizing current professionally recognized standards and evidence-based protocols to ensure the safety of staff, patients, and visitors.</p> <ul style="list-style-type: none"> - Staff to have ACLS/ PALS or BLS according to job description and duties. - Staff to be trained on protocols for recognition and treatment of anaphylaxis and other known or potential adverse events/responses to infusions requiring urgent/emergent intervention. - MD/mid-level practitioners are available onsite or immediately available to assess patients, provide care and prescribe emergency treatment consistent with policies, procedures, and protocols for administration of various infusion therapies. 		

	<ul style="list-style-type: none"> - Emergency cart containing medications and equipment appropriate to treat reasonably foreseeable medical emergencies or adverse reactions that might occur, and the population served, (e.g. anaphylaxis, cardiopulmonary arrest, etc. requiring a defibrillator, airways, Ambu bag, epinephrine, atropine, etc. - Emergency procedures to address operational emergencies including but not limited to internal (power outage) disaster events, external (snowstorm) disaster events, the need to evacuate, etc. - Emergency call system - Have an established transfer agreement with a local hospital. 		
6.	Quality Assurance and Performance Improvement Plan:	Met	Not Met
	<p>The DTC must develop, implement, evaluate, and maintain an effective, ongoing, facility-wide, data-driven QAPI program related to Infusion services, including: focus on indicators related to improved outcomes, the use of emergent care services, hospital admissions; and actions that address the DTC's performance across the spectrum of care, including the prevention and reduction of medical errors.</p> <ul style="list-style-type: none"> - The monitoring of quality indicators including staffing, reporting and review of adverse reactions, medication errors, patient complaints/grievances, infection control and other identified indicators. - Periodic review of quality data and outcomes by quality team. - Maintain documentary evidence of its QAPI program and be able to demonstrate its operation to NYS DOH. 		
7.	Patient Medical Record:	Met	Not Met
	<p>The record must include:</p> <ul style="list-style-type: none"> - Patient Demographics and identification - The patient's history with a current comprehensive assessment, including at time of admission: diagnosis, clinical notes, plans of care, and physician orders. - Allergies and contraindicated medications. - All interventions, including medication administration, treatments, and services, and responses to those interventions. - Discharge summaries at end of treatment. <p>If possible, an electronic medical record with direct access to the primary physician and the patient's pharmacy about interactions of drugs.</p>		