

NICA MINIMUM STANDARDS FOR IN-OFFICE INFUSION

A threshold for minimum standards in
infusion practice and quality of care.



NICA

NATIONAL
INFUSION CENTER
ASSOCIATION

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DISCLAIMER

The National Infusion Center Association (NICA) is pleased to present the 1st edition of the NICA Minimum Standards for In-Office Infusion for use in facilities that are preparing and administering parenteral therapies.

The standards outlined in this document were established per industry guidance and documented best practices among facilities represented on NICA's Advisory Committee. These standards are intended to establish a minimum threshold for various operational and clinical aspects associated with the preparation and administration of parenteral medications in an effort to support safe, consistent, high-quality care across access points. The practice of infusion/injection therapy may change

as new information becomes available or in response to changes in the regulatory environment. As such, the minimum standards presented in this document are current as of the date of publication and are subject to change. Changes to these minimum standards will be reflected periodically in an updated version.

The information contained in this document is intended for reference. These standards are intended to support—not supersede—medical malpractice insurance coverage, state regulation, rules, or statute including, but not limited to: Nursing Practice Acts, Board of Nursing rules, regulatory oversight determinations. Defer to your state's regulation, rules, requirements,

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INTRODUCTION

To promote patient safety, consistent quality of care, and establish foundational standards of practice, the National Infusion Center Association (NICA), in collaboration with its Board of Directors and Advisory Committee comprised of thought-leaders and subject matter experts, developed a set of minimum standards of practice for the preparation and administration of non-hazardous provider-administered intravenous and injectable products in an outpatient setting.

This document is the result of a collaborative effort in 2018 and 2019 by representatives from nine organizations heavily engaged in outpatient infusion/injection. It has been developed to assist facilities engaging in the preparation and administration of provider-administered intravenous/injectable medications in providing patients with access to safe, consistent, high-quality infusion preparations and an optimal infusion/injection experience in a safe environment.



With the expansion of the outpatient infusion/injection market, and an explosion in the number of “med-spas” and “hydration clinics”, it is no longer reasonable to expect consistent quality of care across the national infusion delivery channel. NICA believes that a standardization in practice and quality of care, at least by establishing minimum thresholds, is necessary to support continued patient safety and responsible expansion of the delivery channel.

THESE MINIMUM STANDARDS ARE INTENDED TO:

- Reduce disparities in quality of care across outpatient care settings;
- Ensure that the public is protected from unscrupulous, incompetent and unethical practitioners; and,
- Offer some assurance to the public that the individuals preparing and administering parenteral medications have been educated in the procedures and demonstrated competency in providing infusion/injection services in a safe, consistent, and effective manner.

The following list outlines these industry-accepted minimum standards relating to the preparation and administration of non-hazardous infusion/injectable medications, including biologics and specialty medications in an outpatient setting.

These minimum standards apply to all outpatient facilities in which venous access is established and consumers are receiving solutions through intravenous (IV) infusion, subcutaneous (SC) infusion, IV push, or injection.

GLOSSARY OF TERMS

Active Ingredient

An active ingredient is any component that provides pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or function of the body. ([The U.S. Food and Drug Administration](#))

Beyond-Use Date (BUD)

For the purposes of this document, Beyond Use Date refers to the time by which a multi use vial of medication, once accessed, or medication preparation, once mixed, must be used before it is at risk of chemical degradation, destabilization, contamination, and/or permeability of the medication container (see “Medication Container”). The BUD is determined by the individual that first accessed the multi use vial, or prepared the medication, based on the date and/or time the medication vial is accessed or the medication is prepared.

Biological Product

Include a wide range of products such as vaccines, blood and blood components,

allergens, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. (See “*Therapeutic Biological Products*”) ([The U.S. Food and Drug Administration](#))

Biological products can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues. Biological products are isolated from a variety of natural sources – human, animal, or microorganism – and may be produced by biotechnology methods and other cutting edge technologies. Gene based and cellular biologics, for example, often are at the forefront of biomedical research, and may be used to treat a variety of medical conditions for which no other treatments are available.

Clinician

Defined as a person qualified in the clinical practice of medicine, psychiatry, or psychology as distinguished from one specializing in laboratory or research techniques or in theory. ([Merriam Webster](#))

Compounding

Defined as the process of combining, mixing, or altering ingredients of a drug to create a medication tailored to the needs of an individual patient. Compounding includes the combining of two or more drugs. Compounded drugs are not FDA approved. ([The U.S. Food and Drug Administration](#))

As used in Section 503A (21 USC 353a(f)), compounding does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product’s manufacturer and other manufacturer directions consistent with that labeling. ([The U.S. Food and Drug Administration](#))

Dosage

In the context of this document, dosage refers to the amount of a medicine or drug that should be administered to a patient per the drug order. (See “*Drug Order*”)

Drug

Defined as a substance: (1) recognized by an official pharmacopeia or formulary; (2) intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease; (3) (other than food) intended to affect the structure or any function of the body; (4) intended for use as a component of a medicine but not a device or a component, part or accessory of a device. ([The U.S. Food and Drug Administration](#))

In general, the term “drugs” includes therapeutic biological products, or “biologics” (see “*Therapeutic Biological Products*”). Biological products are included within this definition and are generally covered by the same laws and regulations, but differences exist regarding their manufacturing processes (chemical process versus biological process).

Drug Order

Refers to an order, written or transmitted by other means of communication, for an ultimate user of any drug or device issued and signed by a Licensed Independent Practitioner. (See “*Licensed Independent Practitioner*”)

Expiration Date

Refers to the time period during which the product is known to remain stable and retain its strength, quality, and purity when stored according to the storage conditions outlined in the product’s label. (see “*Label*”) The expiration date is determined by the product’s manufacturer. ([The U.S. Food and Drug Administration](#))

The FDA regulations require drug applicants to provide stability testing data with a proposed expiration date and storage conditions upon submission of an application for FDA approval.

Facility

Refers to a site of care in which an order for medical treatments and services are provided.

Informed Consent

Refers to a process in which a health care provider educates a patient (or the patient’s surrogate if the patient lacks decision making capacity or declines to participate in making

decisions) about the risks, benefits, and alternatives of a given procedure or intervention and receives authorization or agreement to undergo a specific medical intervention. The patient must be competent to make a voluntary decision about whether to undergo the said procedure. ([The American Medical Association](#))

Label

The FDA approved label is the official description of a drug product which includes indication (what the drug is used for); who should take it; adverse events (side effects); instructions for uses in pregnancy, children, and other populations; and safety information for the patient. Labels are often found inside the drug product packaging. ([The U.S. Food and Drug Administration](#))

Licensed Independent Practitioner (LIP)

Defined as an individual, as permitted by law and regulation, and also by the organization, to provide care and services without direction or supervision within the scope of the individual’s license and consistent with the privileges granted by the organization. Each state has different laws defining who can practice without supervision. ([The Joint Commission](#))

Lyophilization (or freeze drying)

Defined as a process in which water is removed from a product after it is frozen and placed under vacuum, allowing the ice to change directly from a solid to vapor without passing through a liquid phase. Products are manufactured in the lyophilized form due to their instability when in solution. ([The U.S. Food & Drug Administration](#))

Medication

Defined as a substance used in treating disease or relieving pain. ([Merriam Webster](#))

Medication Dosage

Refers to the determination and regulation of the size, frequency, and number of doses of a medication.

Medication Container

Refers to a vessel that contains a medication or medication preparation (e.g., IV bag, vial, ampule).

Parenteral Medications

Refers to medications that are not delivered via the intestinal tract (i.e., any non oral means of administration), but is generally interpreted as relating to injecting a medication directly into the body, bypassing the skin and mucous membranes. The common parenteral routes of medication administration are intravenous

(IV), subcutaneous (SC), or intramuscular (IM).
([Nursing Times](#))

Preparation

In the context of this document, preparation refers to the act of diluting, mixing, reconstituting, or otherwise preparing a single medication (active ingredient) in accordance with the manufacturers' instructions or product labeling for administration to a single patient based on a specific order.

Rate of Administration

Refers to the rate at which a drug should be administered to achieve a medication dose over a period of time which has been demonstrated to be safe and therapeutically effective. Commonly expressed as volume or dosage to be administered per minute or per hour. Also known as "dosage rate".

Reaction Management Kit

Refers to an organized collection of medications, supplies, and equipment, necessary to address and manage a hypersensitivity reaction.

Route of Administration

Refers to the way in which a drug is administered to a patient. (e.g., oral, topical, parenteral ("See *Parenteral Medications*").

Therapeutic Biological Product

Defined as a protein derived from living materials (e.g., cells or tissues) used to treat or cure a disease. Commonly referred to as a "biologic".
([The U.S. Food and Drug Administration](#))

NICA MINIMUM STANDARDS FOR OUTPATIENT INFUSION

The facility/employer must have a written institutional policy and/or procedure for at least the following:

- The preparation and administration of intravenous/injectable medications describing at a minimum:
 1. the role of personnel involved in each activity and personal protective equipment to be used;
 2. the delegation of these activities;
 3. the monitoring/supervision of delegated activities;
 4. performing medication preparation on open benchtop;
 5. performing medication preparations that may fall under Board of Pharmacy jurisdiction (See Minimum Standard No. 11); and,
 6. patient assessment.
- Assessing and documenting education and clinical competency among personnel performing preparation and administration activities.
 - Personnel involved in the preparation or administration of intravenous or injectable medications, including biological products, must be assessed on whether the individual has received adequate education on performing the procedure(s) and demonstrated clinical competence in performing the procedure(s).
 - To safeguard patients against risks or complications, such assessment must be documented in the employee's personnel file and updated at least annually.
- Developing and maintaining an up-to-date protocol for every medication administered in the facility, including at least: storage, handling, preparation, stability, administration, monitoring requirements (if applicable), and reporting requirements (if applicable).
- A policy for patient education. Such policy must include at a minimum:
 - Educational requirements outlined in the manufacturer product label
 - Any product specific requirements (e.g., drug safety program)
- The observation of patients receiving treatment. Such policy must include the periodic observation of patients receiving treatment and during a post-administration observation period (if applicable).
- Clinician-to-patient ratio. Ratios may vary, but should depend on clinician experience, availability and capability support staff, route of administration, drug mix, patient history and acuity.
- Medication storage, handling, and disposal.

- Labeling of prepared medications.
- Observation of patients receiving infusions. Including what constitutes an “observation” touchpoint and frequency of observation.
 - * Frequency may vary based on clinician experience, risk of reaction, patient history and acuity.
- The use and maintenance of the reaction management kit, including at least: (1) the use of medications and products contained in the kit; (2) a procedure for checking the kit at least monthly; and, (3) process for documenting the replacement of any expired drugs or items.
- Addressing, documenting, and reporting adverse events.
- Safe injection practices, infection control, and mitigating risk of exposure to bloodborne pathogens.
- Responding to, documenting, and reporting needle-stick injuries in the workplace.
- Documenting medication administration, which must comply with the principles of documentation. Such documentation must include, at a minimum:
 - ▣ Medication, dosage, route of administration, rate of administration, safety precautions utilized, vitals (collected at the following time points, at a minimum: baseline and post treatment or prior to discharge, if indicated)

A patient-specific drug order must be available from a Licensed Independent Practitioner (LIP) (e.g., physician, nurse practitioner) that details the following, at a minimum:

- Medication
- Medication dosage
- Route of administration
- Rate of administration
- Frequency and duration of administration
- Treatment monitoring requirements (as applicable)
- Pre-medication (if indicated)
- Orders for management of an acute infusion/injection reaction

Informed consent must be obtained and documented in the medical record prior to the delivery of care. It is important to recognize that obtaining informed consent is an educational process involving the patient in shared decision-making.

In obtaining informed consent, the health care provider should:

- Assess the patient’s ability to understand relevant medical information and the implications of treatment alternatives and to make an independent, voluntary decision.

- Present relevant information accurately and sensitively, in keeping with the patient’s preferences for receiving medical information. Information should include:
 - The diagnosis (when known)
 - The nature and purpose of recommended interventions
 - The burdens, risks, and expected benefits of all options, including forgoing treatment.
- Document the informed consent conversation, or written consent, and the patient’s (or surrogate’s) decision in the medical record in some manner.
 - * Updating informed consent at least annually is recommended.

The facility/employer must have a Licensed Independent Practitioner readily available, at least by phone, during medication administration.

An assessment of the patient must be performed, in accordance with state nursing practice acts, and documented prior to each treatment. Such assessment must include, at a minimum, the following:

- Confirm patient name, date of birth, diagnosis, medication to be administered, medication dose appropriate for patient/weight, administration protocol (infusion rate, requirements for filtration, monitoring requirements), pre-administration requirements (e.g., laboratory monitoring);

- Inform patient of the prescribed medication, route of administration, approximate time of treatment, pre-medications (if indicated), and provide the opportunity to ask questions;
- Collection of vitals (See Minimum Standard no. 6);
- Review medical history for previous 24 hours (including new medical diagnoses, recent hospitalizations, current medications taken, medication allergies, recent surgeries);
- Assess for contraindications specific to ordered treatment (e.g., fever, abnormal lab values)
- An assessment of education needs regarding diagnosis, prescribed treatment, route of administration, approximate duration of treatment, pre-medications (if indicated), etc.
- Obtain measured patient weight at initial appointment and reassessed at established intervals per facility policy. For patients receiving medications with weight-based dosing, weight must be measured and recorded at each treatment.

It is recommended that during patient assessments staff also:

- Confirm patient does not have an active infection and/or is currently taking antibiotics;
- Provide written information (e.g., FDA-approved patient medication guide) for review prior to initial treatment, and be made available at each subsequent treatment, ensuring that all questions are answered.

At a minimum, the following data must be collected and documented for every patient before treatment and after treatment (for IV and injectables without an observation period) or prior to discharge (for injectables with an observation period):*

- Temperature
- Blood pressure
- Heart Rate
- Oxygen saturation
- Respiratory Rate

* These guidelines for vitals collection do not supersede manufacturer or FDA guidelines. Some medications or patients may warrant additional collection points for vitals. Refer to medication guidelines and institutional medication protocols to determine if more comprehensive monitoring is indicated.

Patients receiving an intravenous infusion must be periodically observed, per institutional policy, until discharge. It is recommended to also provide patients with a way to notify a clinician (e.g., call button).

The preparation or administration of provider-administered parenteral medications, including therapeutic biological products, must be performed by licensed health care professionals within defined scope of practice, or delegated to personnel that have been designated by the facility/employer to perform the activity, and educated on and have demonstrated

clinical competency in the delegated activity.

The facility/employer must provide education and skill training relating to the preparation and administration of parenteral medications for all personnel involved in these procedures. Such education and skill training must include at a minimum:

1. Aseptic vs. clean technique;
2. personal protective equipment;
3. safe injection practices;
4. infection control;
5. drug action;
6. calculating weight-based drug dosages;
7. medication storage, handling, and disposal requirements;
8. establishing venous access;
9. routes of administration;
10. use of technical and medical equipment required for medication preparation and/or administration;
11. pre-medications,
12. expected monitoring;
13. hazards, including possible side effects and contraindications, for such therapy;
14. when to contact the prescriber; and,
15. how to use the reaction management kit and handle unexpected outcomes, adverse events, and emergencies.

Medications must be stored in accordance with manufacturer product labeling. Expired medications and medication preparations that have exceeded their Beyond-Use Date (BUD) must be disposed of appropriately.

Ensure that all parenteral medication preparations are safe, consistent, and high-quality.

- If dilution or reconstitution of a parenteral medication occurs outside of pharmacy settings, preparation should be performed by qualified personnel in accordance with manufacturer labeling and within a designated medication preparation area consisting of a hard, non-porous surface that is clean, uncluttered, and free from the following conditions:
 - Food in the designated preparation area;
 - Vermin (e.g., insects, rodents) observed in areas within or immediately adjacent to designated mixing/preparation area;
 - Visible microbial contamination (e.g., mold) in the preparation area;
 - Non microbial contamination in the preparation area (e.g., rust, glass particles or shavings, hairs);
 - Mixing/preparation of drugs while construction is underway in an adjacent area without adequate controls to prevent contamination of the mixing/preparation environment and drug; and,
 - Obvious contamination sources (e.g., standing water, water leakage, biohazardous materials or specimen).
- * A splash guard at least 12 inches tall is recommended to provide a physical barrier between the prep area and an adjacent sink.
- Limit preparations involving more than one active ingredient in a single container for IV/injection administration to pharmacy settings.
- If more than one medication container is being prepared for a single patient, prepare each medication container separately and label each container prior to the preparation of any subsequent container.
- Do not dilute or reconstitute parenteral medications by drawing up the contents into a commercially available, prefilled flush syringe.
- Single-dose vials should be entered no more than 2 times and used or discarded within one hour following initial entry.
- Dedicate a multi-dose vial to a single patient whenever possible.
 - If multi dose vials will be used for more than one patient, they should be restricted to a centralized medication storage area or designated preparation area and should not enter the patient treatment area.
 - After initial entry, label a multi dose vial with a Beyond Use Date (BUD) of 28 days (except for vaccines) from date of initial entry or manufacturer expiration date, whichever is sooner, and store according to the manufacturer's label.
 - If the BUD label is missing or illegible, or the sterility of the vial is compromised or questionable, discard immediately.

- Disinfect critical sites, allowing the disinfectant to remain in contact with the surface for the appropriate contact time (per the disinfectant’s label) or to dry before inserting a device into the vial.
- Preparations of parenteral medications are *not* considered to be “compounding” and, therefore, exempt from USP Chapter <797> when:
 - ▢ Mixing, reconstituting, or other such acts occur in accordance with the directions in the FDA approved labeling;
 - ▢ The labeling information includes specific information regarding:
 - Diluent to be used
 - Final strength
 - Storage time
 - Container closure system
 - ▢ The starting components are conventionally manufactured sterile products; and,
 - ▢ No more than 3 different sterile products are used in the preparation;
 - ▢ Administration begins within 4 hours of initiating preparation; and,
 - ▢ Prepared as a single dose for an individual patient.
- Preparations of parenteral medications that deviate from instructions outlined in manufacturer labeling should be performed in accordance with state Board of Pharmacy rules, including:

1. compounded sterile products prepared outside the aforementioned conditions;
 2. compounded non sterile products;
 3. combining medications or ingredients to create a drug that is not FDA approved;
 4. batch preparation of medications; and/or
 5. preparation of medications for storage beyond 4 hours from the initiation of preparation.
 - * If no such rules exist, such activities should be performed in accordance with US Pharmacopeia (USP) General Chapter <797> pharmacy standards for compounding sterile products.
- Administration of parenteral medications should be performed in a safe manner in accordance with FDA-approved manufacturer guidelines and CDC guidance relating to infection control practices.

Prepared parenteral medications should not be stored for future use. Administration of parenteral medications should begin immediately, ideally within one hour of beginning preparation. If extenuating circumstances preclude immediate administration, USP Chapter <797> and manufacturer guidelines regarding stability and storage must be followed; however, storage should not exceed 4 hours.

Adjustments in infusion rate must be as directed by the LIP. The administering clinician may use their clinical judgment to decrease the infusion rate if indicated.

Personnel involved in preparing or administering parenteral medications must have current Basic Life Support Certification.

Medications, supplies, and equipment to manage a hypersensitivity reaction must be immediately available during each administration of a parenteral medication in a Reaction Management Kit. Reaction Management Kits must include, at a minimum:

- Medications: Epinephrine, corticosteroids, antihistamines, and IV fluids
- Resuscitation Equipment: barrier mask for CPR
- Breathing Support: Oxygen and delivery system or device

It is recommended that Reaction Management Kits also include:

- Resuscitation Equipment: a manual resuscitation pump or “self-inflating bag” that attaches to the CPR barrier mask, or a bag valve mask or manual resuscitator, capable of providing positive pressure ventilation.

The facility/employer should follow applicable OSHA standards for healthcare providers, including:

- Hazard Communication Standard
- Bloodborne Pathogens Standard
- Personal Protective Equipment (PPE)
- Emergency Action Standard

The facility/employer should follow industry guidance and standards relating to the administration of intravenous or injectable products, including:

- [CDC Safe Injection Practices to Prevent Transmission of Infections to Patients](#)
- [CDC Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care](#)
- [CDC Guidelines for the Prevention of Intravascular Catheter Related Infections, 2011](#)
- Institute for Safe Medication Practices (ISMP) [Safe Practice Guidelines for Adult IV Push Medications](#)
- [INS Infusion Therapy Standards of Practice](#) that relate to non-Oncology, in-office infusion therapy