

# Massachusetts Board of Registration in Nursing

## Advisory Ruling on Nursing Practice

**Title:** Infusion Therapy

**Advisory Ruling Number:** 92-04

**Authority:**

The Massachusetts Board of Registration in Nursing (Board) is created and authorized by Massachusetts General Laws (M.G.L.) c. 13, §§ 13, 14, 14A, 15 and 15D, and G.L. c. 112, §§ 74 through 81C to protect the health, safety, and welfare of the citizens of the Commonwealth through the regulation of nursing practice and education. In addition, M.G.L. c.30A, § 8 authorizes the Board to make advisory rulings with respect to the applicability to any person, property or state of facts of any statute or regulation enforced or administered by the Board. Each nurse is required to practice in accordance with accepted standards of practice and is responsible and accountable for his or her nursing judgments, actions, and competency. The Board's regulation at 244 CMR 9.03(6) requires all nurses to comply with any other law and regulation related to licensure and practice.

**Date Issued:** April 23, 1992

**Date Revised:** July 10, 2002, March 14, 2007, September 12, 2012, May 13, 2015, May 17, 2023

**Scope of Practice:**

Registered Nurse and Licensed Practical Nurse for Infusion Therapy  
Registered Nurse for Intra-osseous Device Insertion and Removal

**Purpose:**

To guide the practice of licensed nurses (Registered Nurses (RNs) and Licensed Practical Nurses (LPNs)) whose practice may include infusion therapy.

**Advisory:**

Nurses licensed by the Massachusetts Board of Registration in Nursing (Board) are expected to engage in the practice of nursing in accordance with accepted standards of practice. The nurse must only assume those duties and responsibilities within the scope of practice for which necessary knowledge, skills and abilities have been acquired and maintained. Upon receipt of an order from an authorized prescriber, the nurse may perform infusion therapy as part of an overall comprehensive plan of care to treat various conditions.

The Infusion Therapy standards of practice apply to any patient population and setting where vascular, and intraosseous, access devices are inserted and/or managed and where infusions therapies are administered<sup>1</sup>. Clinician decisions related to infusion therapy practice including

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<sup>1</sup> Infusion Nurses Society. Infusion Therapy Standards of Practice. (2021). Journal of Infusion Nursing. p.S59.

device and /or product selection, are never influenced by commercial and /or conflict of interest.<sup>2</sup>

Consistent with organizational policy and procedure and competency attainment, RNs practice may include:

- Short and midline peripheral intravenous device insertion and removal
- Use of adjunct aids such as ultrasound for vein identification and selection
- Intra-osseous device insertion using impact-driven or powered drill technique
- Intra-osseous device removal
- Use of an existing intravenous or other infusion device for the administration of medication, hydration, nutrition, blood products, or obtaining a blood sample
- Monitoring the patient
- Maintenance of the infusion site
- Infusion of an intravenous solution where medication is compounded (prepared, mixed, packaged and labeled) in a pharmacy or obtained from a 503B outsourcing facility that complies with compounding standards and regulations<sup>3</sup>
- In emergent situations, if manufacturer's instructions permit, reconstitution and admixture of a solo medication with an intravenous solution if used within one hour of admixture<sup>4</sup>.

Consistent with organizational policy and procedure and competency attainment, LPNs practice may include:

- Short and midline peripheral intravenous device insertion and removal
- Use of adjunct aids such as ultrasound for vein identification and selection
- Use of an existing intravenous or other infusion device for the administration of medication, hydration, nutrition, blood products, or obtaining a blood sample
- Monitoring the patient
- Maintenance of the infusion site
- Infusion of an intravenous solution where medication is compounded (prepared, mixed, packaged and labeled) in a pharmacy or obtained from a 503B outsourcing facility that complies with compounding standards and regulations<sup>5</sup>
- In emergent situations, if manufacturer's instructions permit, reconstitution and admixture of a solo medication with an intravenous solution<sup>6</sup>

### ***Settings of Practice:***

It is the Board's position that infusion therapy must meet the same standard of practice regardless of the setting where it is performed, and individuals receive safe, consistent, high

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<sup>2</sup> Ibid.

<sup>3</sup> Infusion Nurses Society. Infusion Therapy Standards of Practice. (2021). Journal of Infusion Nursing. p.S59.

<sup>4</sup> USP 797 FAQs (November 1, 2022) retrieved from: [USP General Chapter 797](#)

<sup>5</sup> Infusion Nurses Society. Infusion Therapy Standards of Practice. (2021). Journal of Infusion Nursing. p.S59.

<sup>6</sup> Ibid.

quality infusion preparations and an optimal infusion experience in a safe environment<sup>7</sup>. When applicable, settings must be licensed in accordance with 105 CMR 140 Licensure of Clinics<sup>8</sup>.

### **Definitions**

**Asepsis and infection control** means a nurse licensed by the board shall adhere to standard precautions and to principles of asepsis and infection control, and shall not place a patient, himself or herself, or others at risk for the transmission of infectious diseases<sup>9</sup>.

**Aseptic Technique**: A set of infection prevention actions aimed at protecting patients from infection during invasive clinical procedures and management of indwelling medical devices.<sup>10</sup>

**Authorized prescriber** means a person who holds current and valid controlled substances registrations issued by the United States Drug Enforcement Administration (DEA) and the Drug Control Program of the Massachusetts Department of Public Health (MCSR)<sup>11</sup>.

**Beyond-Use-Date (BUD)** means the date and time after which a compounded sterile preparation (CSP) shall not be used, stored, or transported. The date is determined from the date and time the preparation is compounded.<sup>12</sup>

**Compounded sterile preparation (CSP)**: A preparation intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance<sup>13</sup>.

**Compounding**: the process of combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug or bulk drug substance to create a sterile medication<sup>14</sup>. Introducing items into the intravenous solution is compounding and it is not within the scope of nursing practice unless in an emergency situation and for immediate patient administration. The 503B products need to meet the requirements of the FDA and the facilities, where they are compounded, need to be properly registered.<sup>15</sup>

**ISO Class 5 environment**: means an atmospheric environment that contains less than 100 particles, 0.5 microns or larger in diameter per cubic foot of air, according to ISO standards. It is a super clean cleanroom classification<sup>16</sup>.

**Infusion/IV administration** means spiking the IV solution, attaching the tubing to the infusion access site, and calculating the infusion rate.

### **Competence Acquisition**

Licensed nurses whose practice includes infusion therapy must:

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<sup>7</sup> National Infusion Center Association. (2019). Minimum standards for in-office infusion.

Retrieved from: <https://infusioncenter.org/2019-06-19-nica-minimum-standards-for-in-office-infusion/>

<sup>8</sup> Massachusetts Bureau of Healthcare Safety and Quality. 105 CMR 140 Licensure of Clinics.

<sup>9</sup> Massachusetts Board of Registration in Nursing. 244 CMR 9.00 Standards of conduct. (14) Asepsis and Infection Control. Retrieved at <https://www.mass.gov/regulations/244-CMR-900-standards-of-conduct-for-nurses>

<sup>10</sup> Ibid. p. S56.

<sup>11</sup> Massachusetts Board of Registration in Nursing. 244 CMR 10.00 Definitions and Severability. Retrieved at <https://www.mass.gov/doc/244-cmr-1000-definitions-and-severability/download>

<sup>12</sup> USP 797 Pharmaceutical Compounding – Sterile Preparations (rev November 1, 2022) accessed at <https://www.usp.org/compounding/general-chapter-797>

<sup>13</sup> Ibid

<sup>14</sup> Ibid

<sup>15</sup> Rogers, G. IV spa hydration, should I be doing this? (2022). Nebraska Nursing News. 39:4, pp 4-13.

<sup>16</sup> Sentry Air Systems, Inc. Best practices for advance spiking of IV bags. Posted June 28, 2021 by Sentry Air. Retrieved at <https://www.sentryair.com/blog/industry-applications/iv-bag-preparation/best-practices-for-advance-spiking-of-iv-bags/>

- Assume only those responsibilities for which they have education, experience, and current clinical competency to perform, and that are in compliance with established standards of nursing practice and organizational policy and procedure.
- Possess initial and ongoing competence as evidenced by documented completion of didactic and clinical continuing education programs, employing agency education programs, and/or certification by a recognized body of infusion therapy experts in the following:
  - Pre-insertion assessment and placement
  - Ongoing assessment and monitoring of indwelling catheter
  - Infection prevention and standard precautions including hand hygiene and the use of appropriate personal protective equipment (PPE)
  - Identification, prevention, and management of complications
  - Patient /caregiver education including the prescribed infusion therapy, the overall plan of care, the goals of treatment, self-monitoring for signs and symptoms of infusion-related complications and how to access health care services as needed<sup>17</sup>
  - Use of technical and medical equipment required for medication preparation and/or administration
  - Removal of catheter
  - Documentation of assessment, insertion, response to treatment and removal, as applicable
  - Surveillance/quality improvement/outcome measure participation and contribution
  - Use of adjunct aids such as ultrasound for vein identification and selection when applicable.

Docking and activation of proprietary bag and vial systems in accordance with the manufacturer's labeling for *immediate* administration to an individual patient is not considered compounding and may be performed outside of an ISO Class 5 environment<sup>18</sup>.

### **Practice**

Licensed nurses practice within their scope, are responsible and accountable for their nursing judgement, actions and competency and do not perform activities outside their scope of practice.

Therefore, the performance of IV hydration in non-traditional settings, such as a mobile unit or wellness clinic, must be consistent with applicable regulations, prevailing standards of care, and current national nursing guidelines specific to IV therapy.

The systematic patient assessment must be performed and documented by a registered nurse or duly authorized prescriber. The LPN may assess an individual's basic health status, records, and related health data<sup>19</sup>. The performance of infusion therapy is pursuant to the

<sup>17</sup> Infusion Nurses Society. Infusion Therapy Standards of Practice. (2021). Journal of Infusion Nursing. p.S35.

<sup>18</sup> USP 797 FAQs (November 1, 2022) retrieved from: [USP General Chapter 797](#)

<sup>19</sup> Massachusetts Board of Registration in Nursing 244 CMR 3.04 (2) (a). Accessed <https://www.mass.gov/doc/244-cmr-3-registered-nurse-and-licensed-practical-nurse/download>

orders of a duly authorized prescriber. The nurse must verify the orders from a duly authorized prescriber including the patient's name, valid order date, medication or substance name, dosage, route, specific administration directions and prescriber signature.

Settings may utilize standing orders/standing protocols from a duly authorized prescriber<sup>20</sup>. If standing orders/protocols are used, the guidance in Advisory Ruling 93-24 *Accepting, Verifying, Transcribing and Implementing Prescriber's Orders* must be implemented.

It is the Board's position that licensed nurses whose practice includes infusion therapy may not practice in a setting that does not have organizational policies and procedures that include:

- A requirement for safeguards to reduce the risk of medication errors<sup>21</sup>
- A requirement for informed consent.
- A requirement for a comprehensive, documented evaluation including allergies.
- Recommendations for self-care.
- Follow-up recommendations.
- Situations that require referral.
- A requirement for patient education
- Provisions for emergent care.
- Management of side effects.
- A requirement for documentation including response to treatment that is current, complete, accurate and legible in all records required by federal and state law.
- A requirement for proper medication storage in accordance with the manufacturer's product labeling and appropriate disposal of medications/medications preparations that have exceeded their BUD<sup>22</sup>.
- A requirement for adherence to applicable OSHA standards for healthcare providers, including:
  - Hazard Communication Standard
  - Bloodborne Pathogens Standard
  - Personal Protective Equipment (PPE)
  - Emergency Action standing order protocols
- Product evaluation, integrity, and defect reporting<sup>23</sup>
- A requirement for hand hygiene and aseptic techniques including scope of practice in place to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, and mix-ups with other conventionally manufactured products or compounded sterile preparations (CSPs).<sup>24</sup>
- Record keeping standards that ensure client confidentiality and record retention that is in compliance with medical records obligations (<https://www.mass.gov/service-details/medical-records-obligations>)

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<sup>20</sup> Massachusetts Board of Registration in Nursing Advisory Ruling 93-24 *Accepting, Verifying, Transcribing and Implementing Prescriber Orders*. Retrieved from: <https://www.mass.gov/doc/ar-9324-accepting-verifying-transcribing-and-implementing-medication-orders/download>

<sup>21</sup> Infusion Nurses society. (2021). Infusion therapy standards of practice. *Journal of Infusion Nursing*. P. S46.

<sup>22</sup> National Infusion Center Association. (2019). Minimum standards for in-office infusion. Retrieved from: <https://infusioncenter.org/2019-06-19-nica-minimum-standards-for-in-office-infusion/>

<sup>23</sup> Infusion Nurses Society. (2021) Infusion therapy standards of practice. *Journal of Infusion Nursing*. p. S45.

<sup>24</sup> USP 797 section 1.3

- Adherence to Standards of Conduct<sup>25</sup> including, but not limited to:
  - Advertising: a nurse licensed by the Board shall not engage in false, deceptive, or misleading advertising related to the practice of nursing.
  - Exercise of undue influence: A nurse licensed by the Board shall not exercise undue influence on a patient, including the promotion or sale of services, good, appliances or drugs, in such a manner as to exploit the patient for financial gain of the nurse or third-party.
  - Alteration or destruction of records
  - Security of Controlled Substances
  - Unlawful Acquisition and Possession of Controlled Substances
  - Possession of Controlled Substances
  - Identification Badge
  - Patient Confidential Information
  - Patient Dignity and Privacy.

In settings where IV therapy is the sole procedure being performed, the nurse must document and provide the patient with written pre and post IV infusion education which includes, but is not limited to, self-care instructions and follow-up recommendations inclusive of continued and emergency care needs.

Licensed nurses cannot administer an infusion solution that the nurse has not procured, removed from the sealed container, and prepared. It is the Board's position that it is not possible to safely verify the contents of a solution that has been removed from its outer, sealed container.

However:

- During an emergency situation or in an operating room or treatment room, licensed nurses working in the same room, at the same time, attending to the same patient may collaboratively prepare an infusion solution for immediate patient administration. At a minimum, both are responsible for communicating to each other regarding the medication order, validating the integrity of the medication, dosing pursuant to the administration order, and documentation, in accordance with the policies of the organization.
- Licensed nurses may administer infusion solutions that have, by organizational policies, been prepared in an area designed for sterile admixture which have been labeled, repackaged, and resealed within the same admixture area (e.g., when pharmacy compounds a sterile IV admixture under a laminar-airflow hood in a cleanroom or at a clean bench<sup>26</sup>).
- To ensure safe IV admixture, some medications may require the solution, once mixed, be spiked, and primed at the time of compounding before being placed in a sealed, appropriately labeled container.

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<sup>25</sup> Massachusetts Board of Registration in Nursing. 244 CMR 9.00 Standards of Conduct. Retrieved at <https://www.mass.gov/regulations/244-CMR-900-standards-of-conduct-for-nurses>

<sup>26</sup> National Infusion Center Association. (2019). Minimum standards for in-office infusion. Retrieved from: <https://infusioncenter.org/2019-06-19-nica-minimum-standards-for-in-office-infusion/>

- When responsibility for patient care is transferred from one licensed nurse to another licensed nurse, labeled solutions may continue to infuse.

### **Documentation**

Documentation criteria must include

- Review and verification of informed consent that clearly informs the patient of the operator's qualifications, licensure and expected outcomes of the procedure.
- Assessment data inclusive of past medical, surgical, allergy and medical, surgical, allergy and medication histories.
- Exclusions from treatment criteria.
- Specifics of the infusion therapy performed and patient response.
- Directions for referral back to or consultation with the duly authorized prescriber of the infusion therapy.

### **The Nurse in the Management Role**

The nurse in a management role must ensure the availability of sufficient resources to provide for safe implementation, including, but not limited to organizational policies that provide for:

- Protocols for requiring and providing appropriate infusion therapy education
- Protocols for assessing and documenting the education received and validation for licensed nurses' initial and continued competency for each activity
- Nursing care responsibilities, including, but not limited to, hand hygiene, aseptic technique, patient assessment, monitoring, medication administration, potential complications, documentation criteria and patient education.
- A method and time frame of authenticating authorized prescriber orders, including standing orders and protocols. Methods for identification of medications and intravenous solutions and comparison to the authorized prescriber's order and infusions control device.
- Methods to verify the label of the medication name, dosage and concentration, total volume, BUD, route of administration, frequency, rate of administration and any other special instructions.<sup>27</sup>
- Emergency protocols including, but not limited to, immediate, on-site availability of emergency equipment, medications, and personnel.

### **References and professional nursing standards include, but are not limited to the following:**

Gorski, L.A., Hadaway, L. et. al. Infusion therapy standards of practice. Infusion Nurses Society. 8<sup>th</sup> Edition. Rev. 2021. Accessed at [www.ins1.org](http://www.ins1.org)

Association for Vascular Access (AVA) position paper *The Use of Seldinger or Modified Seldinger Technique, in Combination with Real-Time Imaging Modalities for Peripherally*

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<sup>27</sup> Gorski, L. A. Hadaway, L. et. al. Infusion therapy standards of practice. Infusion Nurses Society. 8<sup>th</sup> Edition. Rev. 2021. P s46. [www.ins1.org](http://www.ins1.org).

*Inserted Central Catheter and Midline Placements by Clinicians*; accessed 4/8/15 at <http://www.avainfo.org>

Infusion Nurses Society, Society of Pediatric Nurses, Air & Surface Transport Nurses Association, American Association of Critical-Care Nurses, Emergency Nurses Association, and the Beazley Institute for Health Law and Policy, Loyola University Chicago College of Law Consortium Paper; accessed 4/8/15 at [http://www.ins1.org/files/public/11\\_17\\_10\\_IOConsortium\\_paper\\_fixed\\_2010.pdf](http://www.ins1.org/files/public/11_17_10_IOConsortium_paper_fixed_2010.pdf)

National Infusion Center Association. (2019). Minimum standards for in-office infusion. Retrieved from: <https://infusioncenter.org/2019-06-19-nica-minimum-standards-for-in-office-infusion/>

USP 797 Pharmaceutical Compounding – *Sterile Preparations* (rev November 1, 2022) accessed at <https://www.usp.org/compounding/general-chapter-797>