



STARTING AN INFUSION CENTER: **TEXAS** REGULATORY LANDSCAPE



LET'S DIVE IN

Thank you for reviewing NICA's resource, "Starting an Infusion Center: Texas Regulatory Landscape." One of the most commonly asked questions we receive is, "How do I go about starting an infusion center?" In addition to state specific regulations, there are also federal regulations to consider. These can be found in our free resource, "Starting an Infusion Center: The Federal Regulatory Landscape." Some state specific regulations that any prospective infusion center provider must understand include:

- **Who may provide infusion services and order or administer infusion drugs?**
- **Corporate structure and ownership**
- **Clinic Licensing**
- **Pharmacy Licensing**
- **Fraud and abuse**

Additional considerations in starting an infusion center include:

- **Is there sufficient demand in your market?**
- **What does the competitive landscape look like?**
- **What potential barriers to entry exist?**

Whether you're hoping to open a free-standing infusion center, or incorporate an infusion center into an existing clinical practice, the following content will elaborate upon aspects of the State of Texas's regulatory landscape that you should be aware of.

The content in the following resource is meant to be used as general guidance and should not be construed as legal advice. NICA is not responsible for damages resulting from the use of this material.

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NATIONAL INFUSION CENTER ASSOCIATION – Overview of Establishing an Infusion Center, Texas Regulatory Landscape

Overview. There are a number of state laws that will influence how an infusion clinic can be structured. Scope of practice restrictions may impose limits on who may provide infusion services, who may order infusion drugs, and who may administer such drugs. Licensure requirements need to be considered. State fraud and abuse laws also dictate certain compensation and referral arrangements among practitioners and clinics.

Who may provide infusion services and order or administer infusion drugs?

Staffing infusion clinics with non-physician practitioners (i.e. advanced practice registered nurses (APRN)) allows clinics to reduce the number of employed or contracted physicians and associated costs. But, clinics must be careful to ensure that non-physician practitioners do not exceed their scope of practice when providing infusion services, or ordering or administering drugs.

Non-physician clinicians may provide some infusion services to patients if the services are within the clinician's scope of practice. Texas determines practitioners' scope of practice on a case-by-case basis based on:

- The accepted scope of practice for the nurse's specialty area (i.e. as defined by national professional specialty or nursing organizations recognized by the Texas Board of Nursing);
- Education (i.e. has the practitioner received instruction on the therapy); and
- Experience (*e.g.*, previous patient populations and practice settings, specialties, and roles).

Clinics should conduct a case-by-case determination to ensure that any such practitioners are properly acting within their scope of practice when staffing clinics with non-physician practitioners.

Generally, registered nurses may administer infusion medications prescribed by physicians or APRNs or physician assistants via supervising physicians when such administration is within their scope of practice.¹ Supervising physicians need not be on site when nurses administer such medications.

¹ Tx. Bd. of Nursing, Position Statements 15.1: Nurses Carrying out Orders from Physician's Assistant; 18.18: Nurses Carrying out Orders from Advanced Practice Registered Nurses; 15.3: LVNs Engaging in Intravenous Therapy, Venipuncture, or PICC Lines, *available at* https://www.bon.texas.gov/pdfs/practice_dept_pdfs/position_statements_pdfs/positionstatements2014.pdf (last visited Oct. 4, 2018).

APRNs may prescribe drugs if a prescriptive authority agreement is in place. Prescriptive authority agreements need not describe the exact steps that an advanced practice registered nurse must take with respect to each specific condition, disease, or symptom, but their complexity likely will vary based on the APRN's education and experience. Although many infusion drugs are not Schedule II controlled substances, some infusion clinics may prescribe or dispense Schedule II controlled substances in conjunction with a therapy regime. Texas law prohibits physicians from delegating the ordering of Schedule II controlled substances to nurse practitioners, except in extremely limited circumstances unlikely to apply in the outpatient infusion setting (i.e. hospital facility practices, terminal illness). Nurse practitioners may not prescribe more than a 90-day supply of controlled substances (CIII-V) without consulting the delegating physician and cannot delegate their prescriptive authority (although they may delegate administration).

Corporate Structure and Ownership

Texas follows the "Corporate Practice of Medicine" doctrine, which prohibits a general business corporation (i.e. a non-professional organization, such as a limited liability corporation) from practicing medicine. This also prohibits a general business corporation from employing physicians or exercising control over physician medical decision-making (i.e. via contractual relationships).² As a result, physicians or physician professional entities must own clinics that employ physicians.³ However, these same restrictions do not apply to non-physician clinicians (i.e. APRNs). Thus, a general business corporation may own an infusion clinic staffed by APRNs.

If physicians want to engage a non-physician entity to manage their infusion clinic, the physicians must maintain adequate control of their clinics. Contractual compensation structures (*e.g.*, non-physician receipt of clinic revenue or profits) or decision-making authority (*e.g.*, non-physician power to contractually bind the clinic, selection of medical staff) may implicate the corporate practice of medicine doctrine where physicians do not actually exercise control over the clinic.

Clinic Licensing

Texas does not require a license to operate an outpatient infusion clinic.

Pharmacy Licensing

The Texas Board of Pharmacy exempts licensed practitioners supplying drugs to their patients from pharmacy licensure as long as such practitioners do not own a pharmacy. However, recordkeeping requirements will apply.⁴ Clinics that wish to dispense drugs to persons beyond their patient population may consider obtaining a pharmacy license.

² 22 Tex. Admin. Code §177.17.

³ See 7 Tex. Bus. Org. Code § 301.003(3)(A).

⁴ See Tex. Occ. Code § 164.054.

Fraud and Abuse

Texas prohibits any person from directly or indirectly offering or receiving any fee for the referral of a patient, regardless of payer.⁵ Texas law allows arrangements permitted under the federal Anti-Kickback Statute, although patient disclosure requirements apply.⁶ Compensation methodologies under management agreement or other types of agreement could implicate this prohibition depending on the specifics of the arrangement.

⁵ A Medicaid-specific and federal health care program law applies in Texas, too. *See* 1 Tex. Admin. Code § 371.1669.

⁶ *See* 7 Tex. Bus. Org. Code §§ 102.001, .006, .051; *see also* Tex. Occ. Code § 164.055; 22 Tex. Admin. Code § 217.12(6)(J).