



# STARTING AN INFUSION CENTER: **FLORIDA** REGULATORY LANDSCAPE



# LET'S DIVE IN

Thank you for reviewing NICA's resource, "Starting an Infusion Center: Florida 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 Florida'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.**

512.402.6955  
INFO@INFUSIONCENTER.ORG  
3307 NORTHLAND DR., STE. 160  
AUSTIN, TX 78731

## **NATIONAL INFUSION CENTER ASSOCIATION – Overview of Establishing an Infusion Center, Florida 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) or physician assistants) 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. 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, RNs may administer infusion medications prescribed by physicians or APRNs or physician assistants via supervising physicians.<sup>1</sup> RNs may also delegate administration to qualified licensed practical nurses. RNs need not be on site when qualified nurses administer such medications.<sup>2</sup>

APRNs may prescribe drugs if an established supervisory protocol is in place with a physician. APRNs may only prescribe or dispense controlled substances if the individual has graduated from a program leading to a master's or doctoral degree in a clinical nursing specialty area with training in specialized practitioner skills. PAs may prescribe medications pursuant to written protocol. A PA may only prescribe medications that are specifically listed on such protocol and may not prescribe more than a seven (7) day supply of Schedule II controlled substances. The supervising physician must notify the board of medicine prior to delegating prescriptive authority to a PA and may only supervise four (4) PAs at a time.

### **Corporate Structure and Ownership**

Florida does not have a corporate practice of medicine prohibition. Non-professional and professional entities may employ physicians, and general business corporations may own

---

<sup>1</sup> Fla. Admin. Code § 64B9-12.003.

<sup>2</sup> Fla. Admin. Code § 64B9-12.002.

infusion clinics in Florida. However, corporate structures and ownership may implicate patient brokering and fee-splitting prohibitions, and clinic licensing requirements. For example, certain contractual arrangements (*e.g.*, management services arrangements) and related compensation structures (*e.g.*, non-practitioner receipt of clinic revenue or profits) may implicate these laws as well as prohibitions on the unlicensed practice of healthcare professions.

### **Clinic Licensing**

Florida separately licenses healthcare clinics. However, Florida exempts many physician clinics from these licensure requirements. For example, Florida does not require physician-operated and wholly-owned group practices to obtain a license to provide physician services where certain requirements are met. This exception may allow many clinics integrated into group practices to operate without separate licensure.<sup>3</sup> Free-standing clinics may have a more difficult time with licensure exemption. Although additional exemptions exist (*e.g.*, for entities that employ 50 or more licensed physicians that bill under a single tax identification number, certain entities owned by corporations with at least \$250 million in total healthcare sales), free-standing clinics carefully should consider and review clinic licensing requirements to determine if Florida requires licensure. Obtaining a clinic license requires adherence to a thorough application process (*e.g.*, background screenings, inspections/surveys, information and documentation reporting) that may affect decision-making regarding a free-standing model.

### **Pharmacy Licensing**

The Board of Pharmacy exempts licensed practitioners supplying drugs to their patients from pharmacy licensure. Clinics that wish to dispense drugs to persons beyond their patient population may consider obtaining a pharmacy license. Subject to some exceptions, Schedule II or III controlled substances.

### **Fraud and Abuse**

Florida has its own state analogue to the federal Physician Self-Referral Law that applies more broadly (*e.g.*, services all payers), but the law does not apply to pharmacy services or drugs and specifically contains an exception for infusion therapy services for physician or physician group practice patients.<sup>4</sup> All practitioners (*i.e.* not just physicians) must disclose in writing to patients any investment interests in any entity to which the practitioner refers a patient and advise the patient on freedom of choice.<sup>5</sup>

---

<sup>3</sup> See Fla. Stat. § 400.9905(4)(g). Entities may apply to obtain a certificate of exemption. See Fla. Agency for Health Care Admin., *Health Quality Assurance Licensure Forms*, <http://www.fdhc.state.fl.us/MCHO/HQALicensureForms/index.shtml#hccexempt> (last visited Feb. 8, 2019).

<sup>4</sup> See Fla. Stat. § 456.053.

<sup>5</sup> See Fla. Stat. § 456.052.

Florida law prohibits any person from directly or indirectly offering or receiving any fee, including splitting any fee, for the referral of a patient regardless of payer.<sup>6</sup> Although an exception exists for financial arrangements for members of group practices, compensation methodologies under management agreements or other types of agreements could implicate this prohibition depending on the specifics of the arrangement. Similar to federal law, Florida law also prohibits kick-backs offered in exchange for referring or soliciting patients.<sup>7</sup> Compensation methodologies under management agreements or other types of agreement could implicate these prohibitions depending on the specifics of the arrangement. Clinics (and practitioners) should carefully review their financial relationships and structure clinics in compliance with this (and the federal) law.

---

<sup>6</sup> See Fla. Stat. § 817.505.

<sup>7</sup> See Fla. Stat. § 456.054.