NATIONAL INFUSION CENTER ASSOCIATION

STARTING AN INFUSION CENTER: ILLINOIS REGULATORY LANDSCAPE

LET'S DIVE IN

Thank you for reviewing NICA's resource, "Starting an Infusion Center: Illinois 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 Illinois'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, Illinois 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), physician assistants (PAs)) 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.

Generally, APRN's, registered professional nurses, and licensed practical nurses may administer infusion medications if within their education and experience.[1] Registered professional nurses or APRN's also may (but may not be required to) delegate medication administration to other licensed nurses.[2] PAs may perform medication administration delegated to them by their collaborating physicians via written collaborative agreements where such administration is, among other things, within the collaborating physician's specialty.[3] Among other requirements, PAs and their collaborating physicians must file such agreements with the Department of Financial and Professional Regulation.[4]

PAs and APRNs generally may prescribe controlled substances pursuant to written collaborative agreements with collaborating physicians where prescribing is commensurate with the PA or APRN's education and experience.[5] A written collaborative agreement must describe the PA or APRN's relationship with the collaborating physician and describe the categories of care, treatment, and procedures that the PA or APRN may provide, including the prescribing of controlled substances.[6] Where collaborating physicians do delegate the prescribing and administrating of controlled substances, a number of requirements apply. For example, the

---

[1] 225 Ill. Stat. 65/65-30(3) (regarding APRN's); 225 Ill. Stat. 65/60-35(4) (regarding registered nurses); 225 Ill. Stat. 65/55-30(a)(3) (stating that licensed practical nursing scope of practice includes, without limitation, implementing aspects of the plan of care).

[2] 225 Ill. Stat. 65/50-75(b)(2), (c)(1).

[3] 225 Ill. Stat. 95/4.3.

[4] 225 Ill. Stat. 95/7(a); 225 Ill. Stat. 95/7.5.

[5] 225 Ill. Stat. 65/65-35(a); 225 Ill. Stat. 95/7.5.

[6] *See* 68 Ill. Admin. Code § 1300 Ex. A (example APRN collaborative agreement).

collaborating physician must have a valid Illinois controlled substance license and federal registration to delegate authority and file a notice of delegation of prescriptive authority with certain state agencies.[7] The PA or APRN must obtain a mid-level practitioner controlled substance license, and the collaborating physician must periodically review the PA or APRN's medication orders.[8]

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. Illinois law permits physicians to delegate the ordering of Schedule II controlled substances to PAs or APRNs pursuant to collaborative agreements, but restricts the scope of delegation. For example, PAs and APRNs may only prescribe 30-day supplies of Schedule II controlled substances specifically identified in the collaborative agreement and that the collaborating physician routinely prescribes. Any continuation after 30 days requires prior approval of the collaborating physician. Further, collaborating physicians may not delegate prescribing of Schedule II controlled substances that are injectable or otherwise administered.[9]

Collaborating physicians need not be personally present where services are rendered pursuant to the collaborative relationship with nurses or PAs. Rather, the collaborating physician only need be available for consultation via in-person or electronic means as described in the collaborative agreement or guidelines.[10]

Unlike PAs, APRNs that meet extensive educational requirements may obtain full practice authority, and so have the ability to prescribe controlled substances without a written collaborative agreement.[11] However, where full practice authority requirements are not met, a written collaborative agreement is required.

Corporate Structure and Ownership

Illinois follows the "Corporate Practice of Medicine" doctrine, which prohibits a general business corporation (i.e. a non-professional organization) from practicing medicine.[12] Illinois law also generally prohibits directly or indirectly splitting any professional services fees, except among professional practice owners or professional organizations. [13] This effectively prohibits a general business corporation from employing physicians or exercising control over physician medical decision-making (i.e. via contractual relationships). As a result, physicians or physician professional entities must own clinics that employ physicians. However, these same restrictions

[7] 225 Ill. Stat. 65/65-40; 225 Ill. Stat. 95/7.5.

[8] *See* 225 Ill. Stat. 65/65-40; 225 Ill. Stat. 95/7.5.

[9] *See* 225 Ill. Stat. 65/65-40; 225 Ill. Stat. 95/7.5.

[10] 225 Ill. Stat. 65/65-35(b) (regarding APRNs); 225 Ill. Stat. 95/4-4.3 – 3.5 (regarding PAs).

[11] *See* 225 Ill. Stat. 65/65-43. APRNs with this full authority are not subject to the requirements discussed below, although restrictions do apply to prescribing of benzodiazepines and Schedule II narcotic drugs, like opioids.

[12] 225 Ill. Stat. 60/3.

[13] 225 Ill. Stat. 95/21(a)(11); 225 Ill. Stat. 65/70-5(b)(28); 225 Ill. Stat. 60/22.2(a).

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 or fee splitting provisions where physicians do not actually exercise control over the clinic.

Clinic Licensing

Illinois separately licenses healthcare facilities (*e.g.*, hospitals, outpatient surgical sites), including locations housing major medical equipment in excess of approximately three-and-a-half million dollars.[14] However, an exemption exists for facilities operated as part of provider practices. Many physician clinics likely will not qualify as healthcare facilities, and so will not be subject to separate licensure. Free-standing clinics would only require licensure if they meet the monetary threshold for major medical equipment. Given the high dollar requirement, it is unlikely that most free-standing clinics would require licensure.

Pharmacy Licensing

The Illinois Board of Pharmacy exempts licensed practitioners supplying drugs to their patients from pharmacy licensure.[15] Clinics that wish to dispense drugs to persons beyond their patient population may consider obtaining a pharmacy license. Pharmacists and pharmacies may not pay prescribers, among others, compensation related to referrals of prescribers patients, unless an exception applies.[16] As discussed below, certain compensation arrangements may implicate this (and similar laws) and should be carefully reviewed.

Fraud and Abuse

Illinois law prohibits directly or indirectly accepting any compensation for professional services not personally rendered, or splitting fees as discussed above. Compensation methodologies under management agreements or other types of agreements could implicate this prohibition depending on the specifics of the arrangement. Illinois law allows for fair market value fees for certain administrative services (*e.g.*, billing and collection services) where certain requirements are met.

---

[14] Ill. Health Fac. & Serv.'s Review Bd, *Revised CON Review Thresholds*, July 1, 2018, https://www2.illinois.gov/sites/hfsrb/ApplicationsForms/Documents/revisedthresholdmemo2018.pdf (last visited Feb. 14, 2019).

[15] 225 Ill. Stat. 85/4(a).

[16] 225 Ill. Stat. 85/23.

Illinois has its own state analogue to the federal Physician Self-Referral Law (*see* federal module on fraud and abuse laws). Although this law applies to a broader set of services (*e.g.*, to all healthcare procedures and services provided through a healthcare worker) and broader category of providers (*e.g.*, nurses, PAs, and others), the law only applies to certain types of investment interests and where patients are referred outside the healthcare worker's office or group practice. [17] Clinics should carefully review their financial relationships and structure clinics in compliance with this (and the federal) law.

[17] *See* 225 Ill. Stat. 47/1 *et seq.*; 77 Ill. Admin. Code § 1235.100.