



STARTING AN INFUSION CENTER: **NEW YORK** REGULATORY LANDSCAPE



LET'S DIVE IN

Thank you for reviewing NICA's resource, "Starting an Infusion Center: New York 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 New York'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, New York 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?

infusion clinics with non-physician practitioners (*e.g.*, physician assistants (PA), registered nurse practitioners) 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.

New York allows PAs and registered nurse practitioners supervised by physicians to perform medical services that are within the scope of the supervising physician's ordinary practice if such services are appropriate for the mid-level practitioner's training, education, and experience. Generally, nurse practitioners may only perform such medical services if in accordance with a written practice agreement and written practice protocol with the supervising physician. The agreement must, among other things, specifically address resolution of any disagreement between the physician and registered nurse practitioner regarding a diagnosis or treatment within the scope of both practitioners' practices.

Some infusion clinics may prescribe or dispense controlled substances in conjunction with a therapy regime. New York law allows PAs to prescribe controlled substances to patients under the care of their supervising physician. Registered nurses also may prescribe drugs pursuant to collaborative relationships¹ or to practice agreements and protocols after having obtained a prescribing certificate from the Department of Health.

Corporate Structure and Ownership

New York follows the "Corporate Practice of Professions" doctrine, which prohibits general business corporations (i.e. non-professional organizations, such as limited liability corporations) from practicing licensed professions, which includes employing licensed practitioners or

¹ Provisions regarding the nurse prescribing authority pursuant to collaborative practice arrangements sunset in June 2021.

exercising control over their professional decision-making.² Unlike in many other states, this prohibition applies to the all licensed professions (*e.g.*, nurses, PAs), as well as physicians. Thus, only professional entities (*e.g.*, professional corporations, partnerships, or limited liability companies) owned and operated by physicians may provide medical services through a corporate entity. Certain licensed healthcare entities such as diagnostic and treatment centers may also employ licensed professionals.

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 doctrine or run afoul of prohibitions regarding fee splitting (discussed below).

Clinic Licensing

In New York, persons may not create diagnostic and treatment centers, such as infusion practices, without receiving a certificate of need from the Department of Health.³ New free-standing clinics must undergo full review by the Department to obtain a certificate of need, although the level of review required may vary based on the amount of equipment purchased and extension of existing services. The certificate of need process can be costly, and clinics should carefully consider costs and timing associated with establishing clinics.

Pharmacy Licensing

The New York Board of Pharmacy exempts healthcare practitioners legally authorized to prescribe drugs from pharmacy licensure as long as such practitioners do not own a pharmacy. However, practitioners may not dispense more than a seventy-two-hour supply of drugs, except in limited circumstances (*e.g.*, dispensing drugs pursuant to an oncological or AIDS protocol). Certain dispensing and record-keeping requirements also apply. Clinics that wish to dispense longer days' supply of outpatient prescription drugs may consider obtaining a pharmacy license.

Fraud and Abuse

New York prohibits any person from offering or accepting any payment for patient referrals for Medicaid services, unless the activity is allowed under federal law, or directly or indirectly splitting or dividing any fees received for furnishing medical care or services.⁴ Persons also may not engage in any for-profit business that refers patients to physicians or facilities for medical

² N.Y. office of Prof., Bd. of Regents Committee on Prof. Practice, *Corporate Practice of the Professions* (Sept. 1998), available at <http://www.op.nysed.gov/corp/corppractice.htm>.

³ See N.Y. Pub. Health Law § 2801-a.

⁴ N.Y. Educ. Law § 6531; N.Y. Soc. Serv. Law § 366-d.



care.⁵ Compensation methodologies under management agreements or other types of agreements could implicate this prohibition depending on the specifics of the arrangement.

New York has its own state analogue to the federal Physician Self-Referral Law that applies more broadly (*e.g.*, is not limited to just physicians, but applies to PAs, nurses, and pharmacists, too) and to a broader range of activities (*e.g.*, services for all payers). The law specifically addresses referrals for “pharmacy services”, which includes dispensing drugs based on prescriptions or other legal authority⁶. Practitioners should carefully review their financial relationships and structure clinics in compliance with this (and the federal) law. Practitioners must disclose financial interests that implicate this law in any entities with which they have financial relationships.⁷

⁵ N.Y. Pub. Health Law § 4501.

⁶ N.Y. Pub. Health Law § 238-a.14.

⁷ N.Y. Pub. Health Law § 238-d; 10 N.Y. Reg. 34-1.5, 1.6 (sample disclosure form).