



# STARTING AN INFUSION CENTER: NEW JERSEY REGULATORY LANDSCAPE



# LET'S DIVE IN

Thank you for reviewing NICA's resource, "Starting an Infusion Center: New Jersey 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 Jersey'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 Jersey 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 (*e.g.*, physician assistants (PAs), advanced practice nurses, registered professional nurses) 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 Jersey allows advance practice nurses, registered professional nurses, and PAs to perform infusion services 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, advanced practice nurses, registered professional nurses, and PAs may administer infusion medications either prescribed by a physician, or as a part of a designated medical regime designed by a physician.<sup>1</sup> Advanced practice nurses may prescribe drugs if an established joint protocol is in place with a physician.<sup>2</sup> PAs may prescribe medications pursuant to appropriate supervising physician delegation.<sup>3</sup> Prescriptive authority and supervision requirements should be thoroughly reviewed and assessed for each individual clinician’s role in the infusion clinic.

### **Corporate Structure and Ownership**

In general, Corporate Practice of Medicine (“CPM”) doctrines prohibit general business corporations (i.e. non professional organizations as limited liability companies or corporations) from practicing licensed professions, which includes employing licensed practitioners or exercising control over their professional decision-making. New Jersey’s CPM doctrine prohibits corporations from employing physicians to provide medical services unless the corporation meets a defined exception.<sup>4</sup> One of the exceptions to the CPM doctrine is for an entity to be licensed by the New

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<sup>1</sup> See N.J.S.A.45:11-23(b); N.J.S.A. 45:9-27.16; N.J.A.C. 13:37-7.

<sup>2</sup> N.J.A.C. 13:37-7.

<sup>3</sup> N.J.S.A. 45:9-27.16 and 45:9-27.19.

<sup>4</sup> N.J.A.C. 13:35-6.16.

Jersey Department of Health as a health care facility.<sup>5</sup> New Jersey's CPM prohibits a partnership, professional association, or limited liability company from employing a physician unless the entity is solely composed of health care professionals.<sup>6</sup>

New Jersey allows entities to employ a licensed health care professional as a director of the professional entity to carry out policies and procedures, but the director must be licensed to conduct all services offered at the premises.<sup>7</sup> Additionally, business entities are banned from obtaining licensure to provide professional nursing services, but employment of licensed nursing professionals is allowed.<sup>8</sup>

### **Clinic Licensing**

In New Jersey, persons may not establish health care facilities without appropriate licensure or receipt of a certificate of need from the New Jersey Department of Health.<sup>9</sup> Free standing infusion clinics require a health care facility license as an ambulatory care facility.<sup>10</sup> New freestanding clinics must undergo full review by the Department to obtain a certificate of need, including review of facility plans and submission of regulatory compliance history.<sup>11</sup> The certificate of need process, as well as the health care facility licensing process, can be costly and clinics should carefully consider costs and timing associated with establishing clinics. If the infusion services are provided by a physician in his or her private practice, the ambulatory care facility license is not required.<sup>12</sup>

### **Pharmacy Licensing**

The New Jersey Board of Pharmacy exempts healthcare practitioners legally authorized to prescribe drugs from pharmacy licensure. However, practitioners may not dispense more than a seven-day supply of drugs, except in limited circumstances.<sup>13</sup> Certain dispensing and record keeping requirements also apply. Physicians practice sites that store pharmaceuticals for administration must abide by New Jersey Board of Medical Examiners regulation pertaining to storage and safety policies and procedures.<sup>14</sup> Licensed health care facilities that store and dispense pharmaceuticals require either an institutional pharmacy permit from the New Jersey Board of Pharmacy ("BOP")<sup>15</sup> or a written agreement with the pharmacist-in-charge of a retail pharmacy

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<sup>5</sup> N.J.A.C. 13:35-6.16(f)(4).

<sup>6</sup> N.J.A.C. 13:35-6.16(f)(2).

<sup>7</sup> N.J.A.C. 13:35-6.16(d).

<sup>8</sup> N.J.S.A. 45:11-37.

<sup>9</sup> N.J.A.C. 13:39-9.2.

<sup>10</sup> N.J.A.C. 10:58A-1.2.

<sup>11</sup> N.J.A.C. 8:33-2.2. See New Jersey Department of Health, *Certificate of Need and Facility Licensing*, <https://www.nj.gov/health/healthfacilities/certificate-need/> (last visited October 22, 2019).

<sup>12</sup> N.J.S.A. 26:2H-2.

<sup>13</sup> N.J.S.A. 45:9-22.11.

<sup>14</sup> N.J.A.C. 13:35-6.16.

<sup>15</sup> N.J.A.C. 13:39-9.3.

licensed by the BOP to direct, control, and supervise the pharmaceutical services provided to the facility.<sup>16</sup>

## **Fraud and Abuse**

New Jersey has its own state analogue to the federal Physician Self-Referral Law that applies more broadly (all licensees of the Board of Medical Examiners) and to a broader range of activities (no limitation based on patient payor status). New Jersey prohibits a practitioner (i.e. physician, chiropractor, or podiatrist) from referring a patient to health service in which the practitioner, or a member of his or her immediate family, has a financial interest.<sup>17</sup> An exception does apply for services provided in practitioner's office and billed directly by practitioner.<sup>18</sup>

New Jersey Board of Medical Examiners ("BME") prohibits any licensees regulated by the BME from giving or receiving anything of value that a reasonable person would recognize as having been given or received in appreciation for or to promote conduct of the licensee.<sup>19</sup> Additionally, New Jersey prohibits any person from offering or accepting any kickback, rebate, or bribe in connection with the furnishing of Medicaid items or services.<sup>20</sup> Compensation methodologies under management agreements or other types of agreements could implicate this prohibition depending on the specifics of the arrangement.

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<sup>16</sup> N.J.A.C. 13:39-9.8.

<sup>17</sup> N.J.A.C. 13:35-6.17.

<sup>18</sup> N.J.S.A. 45:9-22.5.

<sup>19</sup> N.J.A.C. 13:35-6.17.

<sup>20</sup> N.J.S.A. 30:4D-17(a)-(c).