NATIONAL INFUSION CENTER ASSOCIATION

STARTING AN INFUSION CENTER: CALIFORNIA REGULATORY LANDSCAPE

LET'S DIVE IN

Thank you for reviewing NICA's resource, "Starting an Infusion Center: California 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 California'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, California 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 (PA), nurse practitioners (NPs)) 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 (i.e. education, training, and experience) when providing infusion services, or ordering or administering drugs.

California law allows nurses to administer (but not furnish) medications and therapeutic agents ordered by and within the licensed practice of a physician.[1] PAs and NPs also may administer, furnish and order drugs in limited circumstances. PAs and NPs may only furnish or order drugs under physician supervision and pursuant to standardized procedures or protocols developed with their supervising physicians.[2] Among other things, these procedures and protocols dictate scope of practice for ordering and administering of drugs and must specify the drugs that each practitioner may order or furnish and in what circumstances, and the level of supervision required for such activities.[3] For Schedule II controlled substances, procedures and protocols must identify the exact diagnosis or illness for which such drugs may be furnished. PAs and NPs may only furnish or order Schedule II (and Schedule III, for NPs) controlled substances pursuant to patient-specific protocols approved by treating or supervising physicians, unless the practitioner is a PA who has completed an approved controlled substances course.[4]

Standardized procedures and protocols need not require direct physician supervision (i.e. the physician to be physically present at the site of care). Restrictions do apply, however, regarding how many non-physician practitioners physicians may supervise at a given time.

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[1] Cal. Bus. & Prof. Code §§ 2725(b)(2), 3502.1.

[2] NPs must apply to the Board of Nursing to obtain a furnishing number. Cal. Bd. of Registered Nursing, *Advance Practice and Certification*, https://www.rn.ca.gov/applicants/ad-pract.shtml (last visited Feb. 1, 2019).

[3] Cal. Bus. & Prof. Code § 2836.1(a).

[4] Cal. Bus. & Prof. Code §§ 4111(f)(2), 3502.1; *see also* Dep't of Consumer Affairs, Physician Assistant Bd., *Frequently Asked Questions for Physician Assistants*, https://www.pac.ca.gov/licensees/licensee_faq.shtml (last visited Feb. 1, 2019); Cal. Code Reg. tit. 16, § 1399.610.

Furthermore, the physician's physical presence is required when PAs perform medical services. So, clinics must be mindful that infusion services and administration do not constitute medical services (and so require the physician's physical presence).[5] Clinics should consider staffing ratios and conduct case-by-case determinations to ensure that any such practitioners are properly acting within their scope of practice when staffing clinics with non-physician practitioners (*e.g.*, pursuant to practice agreements properly drafted and filed with the appropriate state boards).

Corporate Structure and Ownership

California follows the "Corporate Practice of Professions" doctrine, which prohibits general business corporations (i.e. non-professional organizations, such as limited liability corporations) from practicing medicine and other professions.[6] This prohibits a general business corporation from employing physicians or exercising control over their clinical decision-making. (i.e. via contractual relationships). As a result, professional entities must own clinics that employ physicians. California guidance is less clear on whether this prohibition applies to nurse practitioners or other mid-level practitioners. Counsel should be consulted before a general business entity employs a nurse practitioner or physician assistant.

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. California has issued comprehensive guidance on the types of decisions physicians must maintain control over when utilizing a management company.

Clinic Licensing

California does not separately license clinics owned or leased and operated as a clinic or office by healthcare practitioners, except in limited circumstances (*e.g.*, surgical clinics, chronic dialysis clinics).

Pharmacy Licensing

The California Board of Pharmacy does not issue pharmacy licenses to persons authorized to write prescriptions and non-pharmacists may not manage or supervise any pharmacy.[7] However, prescribers may dispense necessary drugs directly to their patients in their offices where storage, labeling, record-keeping, and other requirements are met. Only a seventy-two

[5] *See* Cal. Bus. & Prof. Code § 3502.1.

[6] Med. Bd. of Cal., *Corporate Practice of Medicine*, http://www.mbc.ca.gov/Licensees/Corporate_Practice.aspx (Feb. 1, 2019).

[7] Cal. Bus. & Prof. Code §§ 4111(a)(1), 4329.

hour supply may be provided for Schedule II drugs, and only where the patient is not expected to require any additional controlled substance beyond that time frame.[8] An exception to some of these requirements does exist for prescribers who dispense parenteral chemotherapeutic agents, biologicals, or delivery systems to treat cancer.[9]

Fraud and Abuse

California prohibits any licensed healthcare provider from offering or accepting any payment or compensation, including ownership dividends or interests, for patient referrals.[10] Compensation methodologies under management agreements or other types of agreements could implicate this prohibition depending on the specifics of the arrangement. For example, an exception applies for compensation based on a percentage of gross revenue if the compensation is commensurate with the value of services provided (and the services do not relate to patient referrals).[11]

California has its own state analogue to the federal Physician Self-Referral Law that applies more broadly (*e.g.*, services most payers, except workers' compensation) (*see* federal module on fraud and abuse laws), but the law does not apply to pharmacy services or drugs.[12] Physicians should carefully review their financial relationships and structure clinics in compliance with this (and the federal) law. All practitioners (i.e. not just physicians) must disclose in writing to patients any significant financial interests in any organization to which the practitioner refers a patient for services and advise the patient on freedom of choice, unless an exception applies (*e.g.*, providers operating under certain capitated payment arrangements).[13]

[8] Cal. Health & Safety Code § 11158(b).

[9] Cal. Bus. & Prof. Code § 4171.

[10] Cal. Bus. & Prof. Code § 650(a).

[11] Cal. Bus. & Prof. Code § 650(b).

[12] Cal. Bus. & Prof. Code § 650.01. The law does apply to home infusion therapy, so practitioners should consider this law in referring for any home infusion therapy services.

[13] Cal. Bus. & Prof. Code § 654.2; Cal. Bus. & Prof. Code § 650.01(f).