

What Are the Legal Risks Involved with An IV Therapy Business? Part Two

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In our first article about IV therapy, we discussed what IV therapy is, why it's popular, and who can own an IV therapy practice. There are many more questions that practitioners of IV therapy need to review with an experienced healthcare attorney. We'll discuss some of the following IV therapy legal compliance topics below:

- Who can prescribe, prepare, and administer IV therapy?
- What referral laws apply to IV therapy?
- What rules and regulations govern the marketing of IV therapy?

We strongly suggest you make an appointment to discuss the topics listed above – and all healthcare regulations that govern IV therapy in your state – with healthcare lawyers with a record of service in the healthcare industry.

- What is the business structure of the IV therapy practice – and does the business structure comply with the corporate practice of medicine laws?
- Does the manner and delivery of the IV therapy make a difference – in a hospital, at a medical office, at home, or through a mobile app?
- What notices, consent issues, and contracts are involved – between physician and patient?
- Does the Federal Drug Administration (FDA) have to approve the IV therapy solution?
- What state agencies and medical boards have oversight over IV therapy?

IV practices also need to review any medical malpractice issues, business issues, contractual issues, and other health, financial, and legal considerations.

IV HYDRATION THERAPY – LEGAL STRATEGIES

In today's video, we discuss some of the legal perils involving IV hydration therapy and potential legal strategies and solutions.

Who can prescribe, prepare, and administer IV therapy?

Generally, a physician prescribes the IV therapy, a pharmacist prepares the IV solution, and a registered nurse administers the

IV therapy to the patient.

The states differ on which other healthcare professionals can participate in each phase of the IV therapy treatment. Some orders can be delegated from one healthcare professional to another; but others may not. For example, an emergency medical technician may also (you need to check with your lawyer) administer IV therapy to a patient. Many states do not authorize EMT administration of IV therapy.

Other agencies that have oversight over IV therapy include the US FDA, state medical boards, state pharmacy boards, and state health and human services departments. There are also additional rules for prescribing IV therapy through a telemedicine interview as opposed to an in-person interview of a patient.

For example, Cal. Code Regs. tit. 16 § 2542.1 provides that:

The Board will consider a licensed vocational nurse as competent to start and superimpose intravenous fluids via primary or secondary infusion lines who has completed one of the following:

- An approved intravenous therapy course
- A submitted certification that meets specific medical board and California Business and Professions Code requirements.

According to the American MedSpa Association, in addition to the corporate practice of medicine issues, the chain of care (including prescription and administration of the IV therapy) must be consistent with the diagnosis and treatment requirements of the procedure. An entity that has the legal authority to provide IV therapy must conduct an examination of the patient to determine the health status of the patient.

As we recently discussed, California has modified its supervision and delegation requirements for registered nurses.

The American MedSpa Association also states that a non-physician provider can be a physician's assistant (PA), nurse practitioner (NP), or registered nurse (RN). In some states, a licensed practical nurse (LPN) or a licensed vocational nurse (LVN) may also have the authority to administer the IV therapy. Just a few states authorize an EMT or a paramedic to administer IV fluids.

Supervision rules can include being on the site while the IV solution is administered – to being immediately available in case there is an emergency.

For example, [as we discussed above] in California, an RN may administer the IV therapy under the supervision of either a physician, PA or NP. An LVN will be considered competent to start and superimpose IV fluids via a primary or secondary line if the LVN has completed either a nursing board-approved intravenous therapy course or submitted certification to prove that the LVN has the knowledge, skills, and abilities to safely administer IV services.

In New York, an LPN must be under the *“direct supervision of a physician, PA, RN, or NP. LPNs must be trained to administer IV therapy.”*

CALIFORNIA'S NEW SCOPE OF PRACTICE LAW FOR NURSE PRACTITIONERS – PART ONE

California passed a new law, effective January 1, 2023, that permits nurse practitioners in specific settings to provide care (under certain conditions) that does not meet “standardized procedures.”

What referral laws apply to IV therapy?

The medical practices that provide IV hydration/vitamin therapy must also comply with laws designed to place patient safety before the profits of the medical practice. The laws (some civil, some criminal) generally provide that a doctor must refer

patients to related services such as diagnostic labs and IV therapy services based on what is in the best interest of the patient. Some of the laws that we've also discussed that govern medical referrals include:

- **Stark Law.** This law prohibits doctors from referring patients to a designated health service (one in which the physician has a financial interest or a family member has a financial interest) unless certain Stark exceptions are met.
- **The Anti-Kickback Statute (AKS).** This law prohibits medical practices, such as IV therapy practices, from providing incentives (such as cash payments, directorships, or vacations) in return for the physician referring patients to the medical practice. The AKS does authorize certain safe harbors which may make the referral legal.
- **The False Claims Act.** This law prohibits medical providers from submitting false bills to Medicare, Medicaid, and other federal agencies. The law encompasses both Stark Law and the AKS. This means that a medical practice that is charged with a Stark Law or AKS violation may also be charged with violating the False Claims Act.

California has its own False Claims Act that generally applies to false claim submissions to Medicaid.

What rules and regulations govern the marketing of IV therapy?

There are different laws and regulations that govern how medical practices including IV therapy practices can market their product and services. One federal agency that regulates false advertising is the Federal Trade Commission (FTC). We have [a short video](#) on FTC oversight of IV therapy online. IV therapy mixtures generally contain water, minerals, vitamins, and amino acids – that are administered through an IV drip. So, for starters, the marketing must be truthful as to what products are in the IV solution and how the solution is administered.

The FTC does review company websites, social media, and print marketing materials. A website or marketing brochure that claims, as one company did according to [an FTC enforcement action](#) in 2018, that their IV mixture can cure specific diseases such as congestive heart failure, diabetes, or cancer – without any scientific evidence to support the claim – will likely result in a warning letter from the FTC and possible enforcement action. A settlement with the company was reached that prohibits the company from making false or unsubstantiated claims that its IV cocktails:

- *"Are an effective treatment for any of the diseases included in the complaint.*
- *Produce fast, lasting results.*
- *Cure, mitigate, or treat any diseases, unless the claim is supported by competent and reliable scientific evidence."*

The settlement order also prohibited the company ***"from making any express or implied health, safety, or efficacy claims unless they are not misleading and are supported by scientific evidence."***

FTC enforcement also can require that companies prohibit misrepresentations about the healthcare professionals involved in designing, testing, and approving the IV products.

Companies that fail to comply with FTC warning letters can be forced to suspend production of their products – along with other consequences.

IV therapy is becoming a popular treatment for many patients. While there are opportunities for profit for the medical practices that prescribe and administer the solutions and the pharmacies that prepare the solutions – there are numerous legal compliance issues. Medical practices need to understand who can prescribe IV therapy, who can prepare the mixture, and who can administer the solution. The practices need to understand when referrals are legal and when referrals are not legal. All marketing claims must be honest and comply with legal requirements.

IV therapy practices should [contact](#) Cohen Healthcare Law Group, PC to review the federal and state legal compliance issues. Our [experienced healthcare attorneys](#) advise physicians, nurses, pharmacies, and other healthcare providers about healthcare

compliance laws and regulations.

Contact our healthcare law and FDA attorneys for legal advice relevant to your healthcare venture.