



Intravenous Therapy Services in Florida:

Top 10 Things Providers Need to Know to Protect Their License, Livelihood and Liberty in Florida.

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Intravenous therapy (“IV”) businesses in Florida have been growing in popularity over the last few years. Particularly popular are on demand services where providers go into a patient’s home to provide IV therapy to help with Covid 19 recovery, a flu recovery or a hangover. Some IVs are hydration or vitamins. But other types of IV therapy can involve prescription medicine for nausea or a migraine or even controlled substances. Before licensed providers or business people gets themselves involved in this business they need to understand the regulatory framework for providing such services in Florida. Below is our top ten list of issues for such businesses:

1. Do you have the right providers doing the services?

Advance practice registered nurses (APRNs) and physician assistants (PAs) may provide IV therapy services without a physician onsite in Florida. Also, an APRN, in some instances, may practice independently without a protocol physician. While IV therapy may be within the scope of practice of a registered nurse (RN), it is less clear under what circumstances the service can be provided and you would have to assess the specific facts of the service and supervision. While paramedics can perform IV therapy under their license, the instances are limited and may not match a private IV therapy business model. It is important to evaluate the exact types of services and make sure that the licensed providers are able to provide the services.

2. Do you have the proper level of physician supervision?

Even if the services have the proper type of providers an issue may arise as to whether they have the necessary physician supervision. For example, must the physician be onsite when IV therapy is being provided by a provider who is not an APRN or a PA? It is important to assess this and provide the proper documentation and training for any medical directors or protocol physicians.

3. Do you have the right licenses in order to go into a patient’s home?

An area where we see continuing confusion in Florida is what types of licenses one must have to provide care in a patient’s home. A nurse practitioner or physician (acting alone) may be able to provide the same care in a patient’s home under their individual license that they can provide in a practice setting. Once more providers are added to the business this could trigger the need for a home health or a nurse registry license, however. There are other arrangements, such as providing treatment from a mobile clinic, that may not require such a license, but the law is less clear and fact-specific analysis is required. We think this is a developing area of regulation and should be monitored for these types of businesses.

4. *Do you need a special license to operate if you are owned by a business person instead of an investor?*

In Florida unlicensed persons may own a medical business, but unless an exception exists, they may need to obtain a Florida Health Care Clinic license before starting services. This usually takes a few months and requires fees, background checks, financial projections prepared by a CPA, specific medical director requirements, and an in-person inspection by the Agency for Health Care Administration (“AHCA”). The business may be exempt under various exemptions or if it does not “tender charges for reimbursement.” Whether your owners have health care licenses, and if so, what licenses they hold needs to be disclosed to your legal counsel so this issue can be assessed.

5. *Do you know how to handle any biomedical waste created in the provision of your services?*

IV therapy services generate biomedical waste. You should ensure that you and anyone working in your business are trained in and familiar with the requirements for maintaining and disposing of such waste in a safe, compliant manner. Florida has special rules and permitting requirements for the handling and disposal of biomedical waste. There are possible exemptions to these rules, but you will need to carefully assess the facts and waste generation of your business to determine if the permitting rules or an exemption applies.

6. *Do you need any special permits to purchase medicine in the name of your business?*

Another consideration is how your business will obtain the medications you administer. As discussed below, if you intend to purchase controlled substances, you must make sure you are duly authorized to do so. Once you are authorized to obtain the medications, you may want to consider applying for a health care clinic establishment permit, which is a permit in Florida that allows you to obtain medications in the name of your business. Doing so can help limit your personal liability.

7. *Do you need a DEA registration?*

A DEA registration is required to prescribe, dispense, or administer controlled substances. Failing to obtain the appropriate DEA registration can result in stiff penalties and possible criminal sanctions. Before you purchase controlled substances, you should ensure you have proper licensure. You should also keep in mind that with very limited exception, a new DEA registration is required for each of your practice locations. Obtaining your DEA registration requires applications and fees and may require up to 60 days of processing time. It is important to make sure any other providers working with you are compliant with these requirements as well.

8. *Do you have a legal entity set up through which to properly operate?*

It is common business practice to operate your business through a legal entity so that you separate out your individual liabilities from your business liabilities. You may be able to form an entity through a filing with the state of Florida and the payment of a fee. It may benefit you to work with your lawyer to make sure your entity is properly formed and that it has the right taxation and is the right entity for your intended purposes, however. Improper formation or a lack of observance of entity formalities could allow a creditor to pierce through the entity and hold you personally liable.

If you have more than one owner you will want to document the ownership arrangement between or among the owners in an operating agreement or shareholders’ agreement as applicable. A lack of a business agreement among owners could lead to confusion. It may be better to set out the terms of how you will resolve disagreements on the front end to save you time, money and frustration later.

9. *Do you have the proper insurance for your business?*

To help protect yourself and your business, you should look into obtaining insurance. Possible insurances to consider are medical malpractice coverage, general liability insurance, and vehicle insurance. General liability insurance is particularly important for physical clinics and vehicle insurance is important for mobile operations. You will want to work with your insurance agent to obtain sufficient coverage. Physicians and APRNs in independent practice should keep in mind that they have statutorily required insurance minimums.

10. *Do you have the proper consent forms?*

Florida has strong informed consent laws, which require certain elements in your informed consents. Consents must be in writing and signed by the patient or their representative, among other things. You will want to make sure your business has compliant informed consents and you should consider creating a separate consent for each service you provide. In addition to strengthening your compliance, good informed consents can help to limit your and your business' liability, should a lawsuit be filed against you. At a minimum, you should ask your legal counsel to review these forms.

This top ten list is intended as an illustrative but not an exhaustive list of issues to resolve in starting an IV therapy business. Your attorney may have additional issues to consider based on your particular business plan. The time to consult is before starting such a business and seeing the first patient.