



FLORIDA HEALTHCARE
LAW FIRM

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Dear Friends,

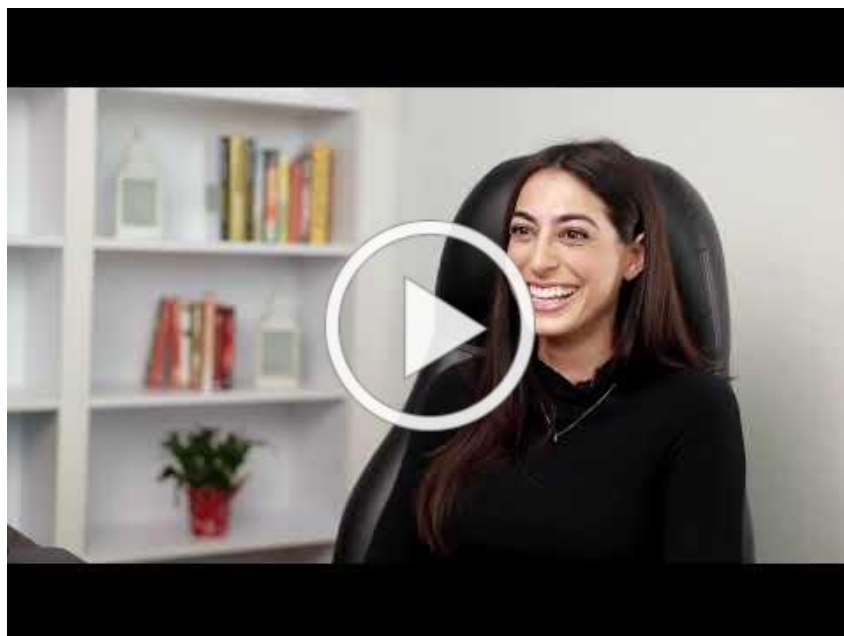
Healthcare business experts know this: "There's a huge difference between the law and the landscape." That's confusing, because most people will ask "Is this ok?" meaning does applicable law allow it? Experts in healthcare law and business, however, know that understanding the law is simply one step in the process of advising a healthcare business person on how to create a sustainable healthcare enterprise.

What the heck does "landscape" mean? It means the way laws are interpreted and applied by people that matter, especially law enforcement and special investigate units (SIU) of insurers. To have a sustainable healthcare business, you simply MUST know not just the laws, but how they're likely to be applied. And the application of those laws changes all the time! No joke. Healthcare law and business is not a "set it and forget it" affair. Nor it is a "one size fits all" affair. It's one of the most regulated industries anywhere! And the laws and interpretations and application of those laws changes regularly.

The last thing on earth any serious healthcare business person wants is to be "right" (because they were told what the laws were, but not how they were likely to be applied) but to have to spend \$1M to defend against criminal law enforcement. Because it's healthcare business and law, there is no way effective way to avoid being looked at. And there is no guarantee that the way all healthcare lawyers think about an issue will be shared by an ambitious person in law enforcement or an SIU. But all healthcare business owners have the right (should demand) being advised about how their business plan is likely to be viewed and how to protect their business against that.

Jeff Cohen

Amanda Howard on Paper & People



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Facebook Advertising: No-No's for Healthcare Businesses

Facebook has a long list of things it doesn't allow to be posted. While some things are obvious, others are not. And what gets flagged may be confusing to posters. That's not surprising, as Facebook is known for using bots to review ads for denial or approval. The problem with using bots is that bots may flag suspicious information, and only a human can understand the true context of it. Fortunately, if you appeal a decision to deny your ad, Facebook will usually allow for human review. To bypass this and just for better practices, before your practice or business posts an ad on Facebook, be aware of what's not allowed on Facebook to lessen your chances of being denied:

Wait! Why you must have your marketing contract reviewed before signing it

Starting a new business? Opening a new profit line in your existing business? Thinking about hiring a marketing team to help drive clients your way? Be cautious, because a



signed contract means nothing until you have a dispute. And if you didn't take a close look at that contract before signing, but now the relationship has soured, you're not going to have an easy route forward.

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No Surprise Act AKA Good Faith Estimates

The Centers for Medicare & Medicaid Services ("CMS") effective January 1, 2022 has ramped up the new No Surprise Act ("NSA") or often called the "Good Faith Law". This law shall apply to group health plans, health insurers, health care providers and health care facilities ("Providers"). The NSA requires health care providers to be proactive and reactive as it relates to providing patients who are self-pay or shall receive out-of-network bills from their health insurance a pre-bill outlining the services they are intending to receive and could potentially receive.

IV Hydration Industry News

With the growth of IV hydration therapy, many clinic owners wonder, do I need a sterile hood if I'm mixing bags in the clinic? Well, that depends. It depends on whether you are a physician, mixing outside of a manufacturing instructions, and more.

The FDA and state Boards of Pharmacy govern "compounding" facilities. When a facility is mixing, adulterating, or diluting, they're considered to be "compounding". This is not the case if you do so in accordance with directions on approved labeling provided by the product manufacturer.

Physicians fall under an exception, however. The FDA says that licensed physicians are exempt from 503A pharmacy laws and the FD&C Act if they are done in a clean and sterile environment, compounded based on a valid prescription, and compounded by the physician. So, it has to be compounded for a patient who presents with an immediate need for the product or because "it would not be safe for the patient to take the drug home for self-administration, and it would be more convenient for the physician to have the drug in his or her office to administer immediately upon diagnosis, rather than asking the physician to order the drug and have the patient return to the health care practitioner for administration."

This guidance would exempt licensed physicians from requirements to utilize a hood for compounding. If you're not a physician, then you should follow FDA guidance on safe practices for compounding.

Free Webinar

Join Attorney Jeff Cohen for an exclusive event hosted by the American IV Association. Attorney Cohen will present live in a lunch n' learn format to share frontline insights about the emergence of the IV hydration therapy industry and how the future of this industry is shaping up from a business perspective. His presentation will include:

- The industry's silent partners
- Understanding the need for and how the industry can self-regulate

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- State & Federal regulatory landscape and the future
- Key considerations for working with compounding pharmacies



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