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IV Hydration Therapy Business – Recent Guidance Highlights Legal Implications in this Fast-Growing Industry

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Intravenous (IV) hydration therapy has gained popularity in recent years as a wellness treatment, aimed at those seeking to boost energy, improve immunity, enhance athletic performance, or even find hangover relief. This therapy involves delivering nutrients, and sometimes prescription medications directly into the bloodstream. Results are touted as being immediate absorption, faster relief and more predictable outcomes. But as with any invasive procedure, there are risks for those giving and receiving IV hydration therapy.

Recently, the Wisconsin Department of Safety and Professional Services, Interdisciplinary Advisory Committee (Committee) issued a joint advisory opinion regarding IV hydration therapy businesses. This Committee consists of members from the Wisconsin Medical Examining Board, Pharmacy Examining Board, Board of Nursing, Physician Assistant Affiliated Credentialing Board, Cosmetology Examining Board and Controlled Substances Board. With the increase of IV hydration therapy businesses in Wisconsin, and a concern over the lack of industry specific guidelines regarding the operation of these businesses along with the potential harm to Wisconsin residents, the Committee found it necessary to issue a guidance document. This guidance document relies upon existing laws in Wisconsin, and the standards of care implicated by owning and/or working in an IV hydration therapy business. The Committee also specifies that while this guidance is meant to address IV hydration clinics, it may also apply to other services offered by healthcare professionals - think weight-loss clinics, med-spas, testosterone clinics, etc.

Key Takeaways

- **Practice of Medicine**

  Perhaps the most important take-away from this guidance is that the Committee views the services offered by IV hydration therapy businesses as constituting the practice of medicine. The Committee's belief therefore limits who can provide these services to individuals licensed to practice medicine under Wis. Stat. §448.03. This statute provides: "no person may practice medicine or surgery, or attempt to do so, or make a representation as authorized to do so, without a license to practice medicine or surgery except of any person lawfully practicing within the scope of a license, permit, registration, certificate, or certification granted to practice. . . professional or practical nursing. . . to practice as a physician assistant under subch. IX. . . or as otherwise provided by statute."

- **Licensure Implications**

The Committee understands the IV hydration therapy business model is to offer patients, including on a walk-in basis, a menu of pre-selected mixtures, or "cocktails" of additives to basic IV saline. It is assumed some basic health screening occurs prior to the selection and administration of the IV and the Committee is concerned these basic health screenings and selection of IVs are being performed by unlicensed individuals or licensees whose scope of practice does not allow for the practice of medicine or surgery.

Only physicians, NPs, or PAs are authorized to assess a patient and determine if IV therapy should be prescribed as a treatment. As a result, if a registered nurse (RN) or licensed practical nurse (LPN) is tasked with doing the initial assessment, diagnosing and prescribing (i.e. choosing) the IV "cocktail," they would be considered to be practicing outside the scope of their license and can result in disciplinary action against the license holder. Furthermore, the physician, physician assistant, or nurse practitioner who oversees the practice may also face discipline if a nurse is found to be practicing outside the scope of their license.

However, an RN or LPN with the proper training and upon receipt of an appropriate order for IV hydration therapy, may administer this treatment. The RN should perform a nursing assessment of the patient while undergoing IV hydration therapy, which includes monitoring the patient's vital signs. A part of the administration and monitoring of the patient, the RN is expected to document all nursing acts. This nursing assessment is, however, outside the scope of practice of an LPN.

- **Documentation Considerations and HIPAA**

The Committee also make clear that the patient must be assessed prior to ordering any IV hydration therapy treatment. Any recommendation for IV hydration therapy may only be prescribed by a physician licensed to practice in Wisconsin, a physician assistant licensed pursuant to Wis. Stat. §448.974, or an advanced practice nurse prescriber (APNP) licensed pursuant to Wis. Stat. §441.16.

The standard of care requires that, after evaluating the patient and making treatment recommendations, a comprehensive medical record must be created, which includes informed consent. These medical records must be stored in compliance with state and federal law. Failure to properly store and protect these medical records subjects the IV hydration therapy business and license holders to HIPAA civil monetary penalties and discipline of their professional licenses. Wisconsin also has rules and regulations governing documentation and privacy of medical records, which must be followed.

- **IV Hydration Therapy Business Ownership**

Wisconsin has a strong Corporate Practice of Medicine (CPOM) doctrine which prohibits business entities from providing medical services though the professionals they employ. By determining that the services offered by IV hydration therapy businesses constitute the practice of medicine and surgery, the Committee has thus limited who can own this type of business. Under Wis. Stat. §448.01(9)(d) the practice of medicine means to offer, undertake, attempt or do or hold oneself out in any manner as to constitute the practice of medicine. Which means, an unlicensed individual or someone whose license does not permit for the practice of medicine (i.e. registered nurse) cannot own an IV hydration therapy business.

Conclusion

Individuals owning and practicing in an IV hydration clinic must hold the appropriate professional license and only practice within the scope of practice allowed by their license. Policies and procedures should be put in place to ensure compliance with HIPAA as well as overall operation of an IV hydration therapy business. While opening and operating an IV Hydration Therapy business can be an in interesting and rewarding endeavor, it should not be done without a full understanding of the rules and regulations involved. Consulting with an experienced attorney to review a business model is important to ensure compliance with relevant laws and regulations.

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