JOINT ADVISORY OPINION OF THE WISCONSIN EXAMINING BOARDS OF MEDICAL, NURSING, PHARMACY, AND COSMETOLOGY, THE PHYSICIAN ASSISTANT AFFLIATED CREDENTIALING BOARD, AND THE WISCONSIN CONTROLLED SUBSTANCES BOARD REGARDING IV HYDRATION THERAPY BUSINESS

It is the overall duty of each Board to improve the profession they supervise, both within and outside its own profession, to bring about a better relationship between the profession and the general welfare of this state. Each Board is empowered to set standards of professional competency and conduct for the profession it supervises. With these principles in mind, the Interdisciplinary Advisory Committee (Committee) consisting of the Wisconsin Medical Examining Board, Pharmacy Examining Board, Board of Nursing, Physician Assistant Affiliated Credentialing Board, Cosmetology Examining Board and Controlled Substances Board was established to discuss issues of mutual concern.

In recent years, Wisconsin has seen an increase in the intravenous (IV) hydration therapy business, and the Wisconsin Department of Safety and Professional Services (DSPS) has seen an increase in questions from healthcare professionals concerning the legal requirements for IV hydration therapy businesses.

IV hydration therapy businesses provide patients with IV fluids with or without prescription medications, vitamins, minerals and/or amino acids. Because of the concern over the lack of any industry-specific guidelines or laws regarding the operation of these businesses and the potential harm to the residents of Wisconsin, the Committee puts forth this guidance document. **This guidance document is based upon the existing laws of Wisconsin and sets forth the relevant laws and standards of care implicated by IV hydration therapy businesses within the context of a retail or "on-demand" business setting.**[1]

For purposes of this guidance document, the Committee has divided the practice occurring at IV hydration businesses into three main stages: assessment, compounding, and administration. The guidance below is meant to assist licensees in understanding the existing laws and regulations implicated at key stages.

BACKGROUND

Prior to discussion of the specific stages, the Committee believes it is crucial to highlight that services offered by IV hydration therapy businesses constitute the practice of medicine and surgery.

[1] This guidance is meant to specifically address the emerging market for IV Hydration therapy or businesses offering IV Hydration therapy services. Underlying principles established in this guidance may be applicable to other services offered by healthcare professionals. Please contact private counsel to review your specific business model for compliance with relevant laws and regulations.

The practice of medicine and surgery is defined as meaning:

> [t]o examine into the fact, condition or cause of human health or disease, or to treat, operate, prescribe or advise for the same, by any means or instrumentality … [t]o apply principles or techniques of medical sciences in the diagnosis or prevention of any of the conditions described in par. (a) and in sub. (2) … [t]o penetrate, pierce or sever the tissues of a human being … [t]o offer, undertake, attempt or do or hold oneself out in any manner as able to do any of the acts described in this subsection.

See Wis. Stat. § 448.01(9). Further, pursuant to Wis. Stat. § 448.03, "[n]o 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 for "[a]ny person lawfully practicing within the scope of a license, permit, registration, certificate, or certification granted to practice… professional or practical nursing or nurse-midwifery under ch. 441… to practice as a physician assistant under subch. IX… or as otherwise provided by statute."

At its core, the IV hydration therapy business model involves offering patients, including on a walk-in basis, a menu of pre-selected mixtures ("cocktails") of additives to basic IV saline. The cocktails may include fluids with or without prescription medications, vitamins, minerals and/or amino acids. Some basic health screening generally occurs prior to the selection and administration of the IV. It is of concern to the Committee that the basic health screening 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.

Although many IV hydration therapy businesses may have a physician, physician assistant (PA) or advanced practice nurse prescriber (APNP) associated with the business, in some instances a registered nurse (RN) may be the only licensed health care professional interacting with the patient. The Committee wants to make clear that a registered nurse (RN), or any individual not holding the proper credential, undertaking the diagnosing and prescribing of medications falls outside an RN's scope of practice[2] and can result in disciplinary action against not only the RN's license, but also the physician, PA, or APNP overseeing the practice.

Moreover, IV hydration therapy fluids and additives are prescription drugs requiring purchase and storage by a qualified practitioner which may include a physician, PA, or APNP. Fluids and additives must be purchased from FDA licensed manufacturers, distributors licensed in the state where they are being purchased, or from compounding pharmacies designated and licensed as 503B compounding facilities. All qualified practitioners must store prescription drugs in compliance with the manufacturer's instructions.

ASSESSMENT

The patient must be assessed prior to ordering any IV hydration treatment. Practitioners who may order treatment appropriate to their area of competence as established by their education, training, or experience include:

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[2] It is not within the scope of practice for an RN or LPN to independently engage in acts that require independent medical diagnosis, or the ordering, compounding, or prescribing of IV fluids, IV medications, or IV therapeutic regimens. See Wis. Stat. § 441.001(4) and Wis. Admin. Code § N 6.03.

- A physician licensed to practice medicine and surgery in this state as defined in Wis. Stat. § 448.01(5).
- A PA licensed pursuant to Wis. Stat. § 448.974.
- An APNP licensed pursuant to Wis. Stat. § 441.16.[3]

Following the assessment, the practitioner may prescribe the appropriate therapy or treatment. Standing orders may be permitted when a legitimate patient-practitioner relationship has been established that includes individualized assessment and diagnosis.

To ensure the assessment complies with the standard of care, after evaluating the patient and making treatment recommendations, a comprehensive medical record must be created. Additionally, informed consent shall be obtained to be consistent with the standard of care. Informed consent should include, but not be limited to, the risks of additives to saline, the risks of IV fluids, and the risks of an IV itself. Medical records must be stored in compliance with state and federal law, including those with the Wisconsin Department of Health Services.

COMPOUNDING

After determining a course of treatment, a cocktail containing the additives ordered may need to be prepared. When an individual adds medications, vitamins, minerals and/or amino acids to IV bags, they are engaging in the practice of compounding, and federal and state law including section 503A of the Food, Drug, and Cosmetic Act apply. Application of these laws help ensure patients receive their treatment in sanitary conditions.

Pursuant to Wis. Stat. § 450.01(16), the practice of pharmacy includes the compounding, packaging, and labeling of drugs and devices. Further, pursuant to Wis. Stat. § 450.01(3), compound "means to mix, combine or put together various ingredients or drugs for the purpose of dispensing." Compounding does not include mixing, reconstituting or other such acts that are performed in accordance with directions contained in approved labeling by the product's manufacturer and other manufacturer directions consistent with labeling.[4]

The United States Pharmacopeia (USP) is the recognized publication that contains standardized requirements for compounding, including sterile compounding found in USP <797> and has been adopted by the FDA and the Wisconsin Pharmacy Examining Board as the enforceable standard. USP <797> applies to all individuals who prepare compounded sterile preparations (CSPs) and all places where CSPs are prepared for human and animal patients.

The utilization of the "immediate use" provision of USP <797> does not circumvent USP sterile compounding requirements. Additionally, the "immediate use" provision requires certain conditions be met, including:

- Aseptic techniques, processes, and procedures are followed, and written SOPs are in place to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, and mix-ups with other conventionally manufactured products or CSPs.
- Personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and the facility's SOPs.

[3] 2025 WI Act 17 will be effective 9/1/2026.

[4] See 21 U.S.C. § 353a(e).

- The preparation is performed in accordance with evidence-based information for physical and chemical compatibility of the drugs (e.g., approved labeling, stability and compatibility studies).
- The preparation involves not more than 3 different sterile products. **Please note, Saline Solution utilized in IV Hydration is a sterile product and must be included in this analysis.**
- Any unused starting component from a single-dose container must be discarded after preparation is complete. Single-dose containers must not be used for more than one patient.
- Administration begins within 4 hours following the start of preparation. If administration has not begun within 4 hours following the start of preparation, it must be promptly, appropriately, and safely discarded.
- Unless it is directly administered by the person who prepared it or administration is witnessed by the preparer, the CSP must be labeled with the names and amounts of all active ingredients, the name or initials of the person who prepared the preparation, and the 4-hour time period within which administration must begin.[5]

The provision of USP <797> allowing for immediate use should not be viewed as a workaround for the standards governing sterile product preparation. Failure to comply with these standards may result in unsanitary and unsafe conditions for patients.[6]

ADMINISTRATION

Upon receipt of an order for IV hydration therapy, an individual with appropriate training and experience[7], including an RN or LPN (consistent with the requirements of Wis. Admin. Code ch. N 6), may administer the treatment.

While the patient undergoes the IV administration, an RN should perform a nursing assessment of the patient including monitoring their vital signs. Please note that the performance of a nursing assessment is outside the scope of an LPN. An RN should monitor the patient for side effects, allergic reactions or any unusual or unexpected effects. An RN is expected to document all nursing acts performed by the RN as part of the administration and monitoring of the patient.

CONCLUSION

The practices engaged in at IV hydration clinics involve the practice of multiple professions. Individuals engaged in these practices must hold the appropriate license and practice within the scope of practice allowed by their credentials. Licensees who fail to follow the laws governing their practice could be subject to disciplinary proceedings as appropriate.

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[5]Handling of sterile hazardous drugs must comply with USP <800> as well.

[6] See FDA highlights concerns with compounding of drug products by medical offices and clinics under insanitary conditions https://www.fda.gov/drugs/human-drug-compounding/fda-highlights-concerns-compounding-drug-products-medical-offices-and-clinics-under-insanitary

[7] For example, if an electrolyte is being administered by IV, the IV should be administered using a volumetric infusion pump or rate-controller tubing to ensure the electrolytes are administered at an appropriate rate to avoid and prevent adverse reactions. The individual administering the IV in this case should have training and experience using these devices.

Licensees are charged with protecting the public by ensuring their practice complies with the laws and regulations of Wisconsin and any relevant federal regulations, including satisfying all applicable professional standards.

ACKNOWLEDGEMENT SECTION

The following materials may have been consulted in the preparation of the above document.

Arizona State Board of Nursing, *Advisory Opinion Intravenous Hydration and Other Therapies* (Revised date May 2024), Available at https://azbn.gov/sites/default/files/AO-IV-Hydration-Other-Therapies.pdf

Kentucky.Gov, *Joint Statement of the Kentucky Boards of Medical Licensure, Nursing, and Pharmacy Regarding Retail IV Therapy* (March 28, 2025), available at https://kbn.ky.gov/KBN%20Documents/Joint%20Statement%20-%20IV%20Hydration%20Clinics.pdf

Mississippi State Board of Medical Licensure, *Guidance Regarding IV Hydration Therapy from the Mississippi State Board of Medical Licensure* (Sept. 5, 2023), available at https://www.msbml.ms.gov/sites/default/files/news/IV%20Hydration%20Therapy%20Guidance%2009-05-23.pdf

Nebraska Board of Nursing, A*dvisory Opinion: IV/Infusion Therapy* (Nov. 2023), available at https://dhhs.ne.gov/licensure/Documents/IVInfusion.pdf

Ohio Board of Pharmacy, *Joint Regulatory Statement of the State Medical Board of Ohio, Ohio Board of Pharmacy, and Ohio Board of Nursing Regarding Retail IV Therapy* (May 15, 2025), available at https://www.pharmacy.ohio.gov/documents/pubs/special/ivtherapy/joint%20regulatory%20statement%20on%20the%20operation%20of%20retail%20iv%20therapy%20clinics%20in%20ohio.pdf

Rhode Island Department of Health, R*hode Island Department of Health Guidance Document Regarding the Operation of Medical Spas and Intravenous (IV) Therapy Businesses* (July 2024), available at https://health.ri.gov/sites/g/files/xkgbur1006/files/publications/guidance/Medical-Spa-and-IV-Therapy-Business.pdf

South Carolina Department of Labor, Licensing and Regulation, *Joint Advisory Opinion of the South Carolina State Boards of Medical Examiners, Pharmacy, and Nursing Regarding Retail IV Therapy Businesses* (Aug. 15, 2023), available at https://llr.sc.gov/med/Policies/Joint-Position-Statement-Retail-IV-Therapy.pdf