Wisconsin Department of Safety and Professional Services Division of Policy Development 4822 Madison Yards Way PO Box 8366 Madison WI 53705-8366



Phone: 608-266-2112 Web: http://dsps.wi.gov Email: dsps@wisconsin.gov

Tony Evers, Governor Dan Hereth, Secretary

VIRTUAL/TELECONFERENCE MEETING INTERDISCIPLINARY ADVISORY COMMITTEE

Virtual, 4822 Madison Yards Way, Madison Contact: Brad Wojciechowski (608) 266-2112 October 22, 2025

The following agenda describes the issues that the Committee plans to consider at the meeting. At the time of the meeting, items may be removed from the agenda. Please consult the meeting minutes for a record of the actions of the Committee.

AGENDA

9:30 A.M.

OPEN SESSION - CALL TO ORDER - ROLL CALL

- A. Adoption of Agenda (1-2)
- B. Approval of Minutes of August 27, 2025 (3)
- C. Conflicts of Interest, Scheduling Concerns
- D. Introductions, Announcements and Recognition Discussion and Consideration
- E. Administrative Matters Discussion and Consideration
 - 1. Department, Staff and Committee Updates
 - 2. Election of Officers
 - 3. Committee Members Committee Member Status
 - a. Englebert, Doug Controlled Substances Board Representative
 - b. Kane, Amanda K. Board of Nursing Representative
 - c. Schmeling, Gregory Medical Examining Board Representative
 - d. Streit, Tara E. Physician Assistant Affiliated Credentialing Board Representative
 - e. Watkins, Alexis Cosmetology Examining Board Representative
 - f. Weitekamp, John G. Pharmacy Examining Board Representative
 - 4. Alternates
 - a. Bloom, Alan Controlled Substances Board Representative
 - b. Edwards, Jacqueline K. Physician Assistant Affiliated Credentialing Board Representative
 - c. Malak, Jennifer L. Board of Nursing Representative
 - d. McIntosh, Dana Cosmetology Examining Board Representative
 - e. Wilson, Christa M. Pharmacy Examining Board Representative
 - f. Yu, Emily S. Medical Examining Board Representative

- F. IV Hydration Clinics Discussion and Consideration (4-16)
 - 1. Draft IV Hydration Guidance Document
- G. Future Topics Discussion and Consideration
- H. Public Comments

ADJOURNMENT

NEXT MEETING: DECEMBER 10, 2025

MEETINGS AND HEARINGS ARE OPEN TO THE PUBLIC, AND MAY BE CANCELLED WITHOUT NOTICE.

Times listed for meeting items are approximate and depend on the length of discussion and voting. All meetings are held virtually unless otherwise indicated. In-person meetings are typically conducted at 4822 Madison Yards Way, Madison, Wisconsin, unless an alternative location is listed on the meeting notice. In order to confirm a meeting or to request a complete copy of the board's agenda, please visit the Department website at https://dsps.wi.gov. The board may also consider materials or items filed after the transmission of this notice. Times listed for the commencement of any agenda item may be changed by the board for the convenience of the parties. The person credentialed by the board has the right to demand that the meeting at which final action may be taken against the credential be held in open session. Requests for interpreters for the hard of hearing, or other accommodations, are considered upon request by contacting the Affirmative Action Officer or reach the Meeting Staff by calling 608-267-7213.

VIRTUAL/TELECONFERENCE INTERDISCIPLINARY ADVISORY COMMITTEE MEETING MINUTES AUGUST 27, 2025

PRESENT: Doug Englebert, Amanda Kane, Gregory Schmeling, Tara Streit, Dana McIntosh

(arrived at 9:35), John Weitekamp

ABSENT: Alexis Watkins

STAFF: Brad Wojciechowski, Executive Director; Whitney DeVoe, Legal Counsel;

Nilajah Hardin, Administrative Rule Coordinator; Brenda Taylor, Board Services

Supervisor; and other DSPS Staff

CALL TO ORDER

Doug Englebert, Chairperson, called the meeting to order at 9:32 a.m. A quorum of five (5) members was confirmed.

ADOPTION OF AGENDA

MOTION: Amanda Kane moved, seconded by John Weitekamp, to adopt the Agenda

as published. Motion carried unanimously.

APPROVAL OF MINUTES OF JUNE 25, 2025

MOTION: John Wietekamp moved, seconded by Tara Streit, to approve the Minutes

of June 25, 2025, as published. Motion carried unanimously.

(Dana McIntosh arrived at 9:35)

Draft IV Hydration Guidance Documents

MOTION: Amanda Kane moved, seconded by Tara Streit, to acknowledge receipt of

comments from the participating boards and the public. Motion carried

unanimously.

MOTION: Gregory Schmeling moved, seconded by Douglas Englebert, to approve

the IV Hydration Guidance Document draft, with amendments and

comments discussed at the August 27, 2025 meeting, for further review by

the participating boards. Motion carried unanimously.

ADJOURNMENT

MOTION: Gregory Schmeling moved, seconded by Amanda Kane, to adjourn the

meeting. Motion carried unanimously.

The meeting adjourned at 10:35 a.m.

State of Wisconsin Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request:				2) Date when reque	st submitted:			
Brad Wojciechowski, Executive Director				10/8/2025				
				Items will be considered late if submitted after 12:00 p.m. on the				
deadline date which is 8 business days before the meeting 3) Name of Board, Committee, Council, Sections:								
Choose an item. Interdisciplinary Advisory Committee								
4) Meeting Date:		chments:			tled on the agenda page?			
10/22/2025	⊠ Yes I		IV Hydra	/ Hydration Clinics – Discussion and Consideration				
		0	1)	Draft IV Hydration (Guidance Document			
7) Place Item in:		8) Is an appearance before the Board being 9) I			9) Name of Case Advisor(s), if applicable:			
□ Open Session	scheduled? (If yes, please Appearance Request for No				<click add="" advisor="" case="" here="" name="" or<="" td="" to=""></click>			
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11) Authorization								
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BLAIN					10/8/2025			
Signature of person making this request					Date			
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Executive Director signature (Indicates approval for post agenda deadline items)				Date				
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Directions for including supporting documents: 1. This form should be saved with any other documents submitted to the Agenda Items folders.								
2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director.								
3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.								

- 1 JOINT ADVISORY OPINION OF THE WISCONSIN EXAMINING BOARDS OF
- 2 MEDICAL, NURSING, PHARMACY, AND COSMETOLOGY, AND THE PHYSICIAN
- 3 ASSISTANT AFFLIATED CREDENTIALING BOARD, AND THE WISCONSIN
- 4 CONTROLLED SUBSTANCES BOARD
- 5 It is the overall duty of each Board to improve the profession they supervise, both within and
- 6 outside its own profession, to bring about a better relationship between the profession and the
- 7 general welfare of this state. Each Board is empowered to set standards of professional competency
- 8 and conduct for the profession it supervises. With these principles in mind, the Interdisciplinary
- 9 Advisory Committee (Committee) consisting of the Wisconsin Medical Examining Board,
- 10 Pharmacy Examining Board, Board of Nursing, Physician Assistant Affiliated Credentialing
- 11 Board, Cosmetology Examining Board and Controlled Substances Board was established to
- discuss issues of mutual concern.
- 13 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.
- 17 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
- 20 harm to the residents of Wisconsin, the Committee puts forth this guidance document. This
- 21 guidance document is based upon the existing laws of Wisconsin and sets forth the relevant
- 22 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
- 25 hydration businesses into three main stages: assessment, compounding, and administration. The
- 26 guidance below is meant to assist licensees in understanding the existing laws and regulations
- 27 implicated at key stages.

BACKGROUND

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- 29 Prior to discussion of the specific stages, the Committee believes it is crucial to highlight that
- 30 services offered by IV hydration therapy businesses constitute the practice of medicine and surgery.
- 31 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

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.

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 practice² 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:

• A physician licensed to practice medicine and surgery in this state as defined in Wis. Stat. § 448.01(5).

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 PA licensed pursuant to Wis. Stat. § 448.974.
- An APNP licensed pursuant to Wis. Stat. § 441.16³.

74 If telehealth is utilized to complete an initial patient assessment, then all practitioners must

- adhere to the same standard of care as an in-person visit. ⁴ Additionally, if a practitioner
- determines during a telehealth assessment that a telehealth visit cannot meet the standard of care
- for the medical condition presented or additional in person evaluation is necessary, the
- practitioner shall see the patient in person or make an appropriate referral to meet the minimum
- standard of care. Please note, certain conditions may be hard to evaluate without an in-person
- assessment including an assessment of necessary organ systems. An assessment consisting
- 81 merely of a simple questionnaire without an appropriate clinical assessment would not meet the
- standard of care and is considered unprofessional conduct pursuant to Wis. Admin. Code § Med
- 24.07(2). Patient assessment needs shall be evaluated on a case-by-case basis and shall occur in
- person if the standard of care necessitates it. A patient assessment should include at minimum a
- 85 history and physical exam. Although a nurse may complete certain delegated portions of the
- assessment, a patient assessment should not rely solely on findings from a nursing assessment.
- As part of the assessment, the practitioner may diagnose the patient's condition and shall make
- 88 recommendations consistent with the findings from the history and physical as to treatment.
- 89 Treatment recommendations may include a discussion with the patient surrounding which
- 90 therapies, including the addition of specific additives, may be appropriate to treat the patient's
- 91 condition. These discussions should include a description of risks, benefits and alternative
- options. To be clear, this constitutes the practice of medicine and should only be undertaken by a
- 93 practitioner with statutory authority to diagnose and treat. The discussion with a patient and
- 94 recommendation shall be provided by the practitioner.
- 95 Following the assessment, the practitioner may prescribe the appropriate therapy or treatment.
- 96 Standing orders may be permitted when a legitimate patient-practitioner relationship has been
- 97 established that includes individualized assessment and diagnosis.

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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.

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COMPOUNDING

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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

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

⁴ Telehealth is only acceptable if it meets established regulations. See Wis. Admin. Code chs. Med 24, PA 3 and N 8.

- 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.⁵
- 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
- 126 conditions be met, including,

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- 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.
 - 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.⁶

⁵ See 21 U.S.C. § 353a(e).

⁶ Handling of sterile hazardous drugs must comply with USP <800> as well.

- The provision of USP <797> allowing for immediate use should not be viewed as a workaround
- 149 for the standards governing sterile product preparation. Failure to comply with these standards
- may result in unsanitary and unsafe conditions for patients.⁷

ADMINISTRATION

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- Upon receipt of an order for IV hydration therapy, an individual with appropriate training and
- experience⁸, 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.

160 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.
- 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.

168 ACKNOWLEDGEMENT SECTION

- These materials may have been consulted in the preparation of the above document.
- 170 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
- 172 KENTUCKY.GOV, Joint Statement of the Kentucky Boards of Medical Licensure, Nursing, and Pharmacy Regarding
- 173 Retail IV Therapy (March 28, 2025), available at https://kbn.ky.gov/KBN%20Documents/Joint%20Statement%20-
- 174 %20IV%20Hydration%20Clinics.pdf

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⁷ 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

⁸ 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.

175 176 177	MISSISSIPPI STATE BOARD OF MEDICAL LICENSURE, Guidance Regarding IV Hydration Therapy from the Mississippi State Board of Medical Licensure (Sept. 5, 2023), available https://www.msbml.ms.gov/sites/default/files/news/IV%20Hydration%20Therapy%20Guidance%2009-05-23.pdf	pi at
178 179	NEBRASKA BOARD OF NURSING, <i>Advisory Opinion: IV/Infusion Therapy</i> (Nov. 2023), available https://dhhs.ne.gov/licensure/Documents/IVInfusion.pdf	at
180 181 182 183	OHIO BOARD OF PHARMACY, Joint Regulatory Statement of the State Medical Board of Ohio, Ohio Board of Pharmac and Ohio Board of Nursing Regarding Retail IV Therapy (May 15, 2025), available https://www.pharmacy.ohio.gov/documents/pubs/special/ivtherapy/joint%20regulatory%20statement%20on%20thew20operation%20of%20retail%20iv%20therapy%20clinics%20in%20ohio.pdf	at
184 185 186	RHODE ISLAND DEPARTMENT OF HEALTH, Rhode Island Department of Health Guidance Document Regarding the Operation of Medical Spas and Intravenous (IV) Therapy Businesses (July 2024), available https://health.ri.gov/sites/g/files/xkgbur1006/files/publications/guidance/Medical-Spa-and-IV-Therapy-Business.pd	at
187 188 189	SOUTH CAROLINA DEPARTMENT OF LABOR, LICENSING AND REGULATION, Joint Advisory Opinion of the Sou Carolina State Boards of Medical Examiners, Pharmacy, and Nursing Regarding Retail IV Therapy Businesses (Au 15, 2023), available at https://llr.sc.gov/med/Policies/Joint-Position-Statement-Retail-IV-Therapy.pdf	

- 1 JOINT ADVISORY OPINION OF THE WISCONSIN EXAMINING BOARDS OF
- 2 MEDICAL, NURSING, PHARMACY, AND COSMETOLOGY, AND THE PHYSICIAN
- 3 ASSISTANT AFFLIATED CREDENTIALING BOARD, AND THE WISCONSIN
- 4 CONTROLLED SUBSTANCES BOARD
- 5 It is the overall duty of each Examining Board to improve the profession they supervise, both
- 6 within and outside its own profession, to bring about a better relationship between the profession
- 7 and the general welfare of this state. Each Examining Board is empowered to set standards of
- 8 professional competency and conduct for the profession it supervises. With these principles in
- 9 mind, the Interdisciplinary Advisory Committee (Committee) consisting of the Wisconsin Medical
- 10 Examining Board, Pharmacy Examining Board, Board of Nursing, Physician Assistant Affiliated
- 11 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.
- 17 IV hydration therapy businesses provide patients with IV fluids with or without prescription
- medications, vitamins, minerals and/or amino acids. Based on inquiries received by DSPS, there
- 19 appears to be confusion among healthcare professionals and the public as it relates to
- 20 understanding the responsibilities of healthcare professionals engaged in these businesses.
- 21 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
- 23 puts forth this guidance document. This guidance document is based upon the existing laws of
- 24 Wisconsin and sets forth the relevant laws and standards of care implicated by IV hydration
- 25 therapy businesses within the context of a retail or "on-demand" business setting.¹
- 26 For purposes of this guidance document, the Committee has divided the practice occurring at IV
- 27 hydration businesses into three main stages: assessment, compounding, and administration. The
- 28 guidance below is meant to assist licensees in understanding the existing laws and regulations
- 29 implicated at keyeach stages. Please note, this is not an exhaustive list, but rather a list addressing
- 30 the most commonly raised practice concerns.

BACKGROUND

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- 32 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.
- 34 The practice of medicine and surgery is defined as meaning:

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.

[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 practice² 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 prescription labelthe manufacturer's instructions. Non-qualified individuals, including, but not limited to RNs or licensed practical nurses (LPNs), may not possess or store prescription drugs in any location not appropriately licensed by the Pharmacy Examining Board.

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.

ASSESSMENT

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- 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:
- 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. § 441.16³.

If telehealth is utilized to complete an initial patient assessment, then all practitioners must adhere to the same standard of care as an in-person visit. ⁴ Additionally, if a practitioner determines during a telehealth assessment that a telehealth visit cannot meet the standard of care for the medical condition presented or additional in person evaluation is necessary, the practitioner shall see the patient in person or make an appropriate referral to meet the minimum standard of care. Please Certain conditions may be hard to evaluate without an inperson assessment including an assessment of necessary organ systems. An assessment consisting merely of a simple questionnaire without an appropriate clinical assessment would not meet the standard of care and is considered unprofessional conduct pursuant to Wis. Admin. Code § Med 24.07(2). Although telehealth may be utilized to perform the initial patient assessment, it is the Patient assessment needs shall be evaluated on a case-by-case basis and shall occur in person if the standard of care necessitates it. For the reasons stated above, recommendation of this the Committee recommends that patient assessment should be done in person, as the individual is on site, and as a complete medical assessment is difficult to conduct via telehealth. 5 Certain conditions may be hard to evaluate without an in-person assessment including an assessment of necessary organ systems. An assessment consisting merely of a simple questionnaire without an appropriate clinical assessment would not meet the standard of care and is considered unprofessional conduct pursuant to Wis. Admin. Code § Med 24.07(2). A patient assessment should include at minimum a history and physical exam. Although a nurse may complete certain delegated portions of the assessment, a patient assessment should not rely solely on findings from a nursing assessment.

As part of the assessment, the practitioner may diagnose the patient's condition and shall make recommendations consistent with the findings from the history and physical as to treatment.

Treatment recommendations may include a discussion with the patient surrounding which therapies, including the addition of specific additives, may be appropriate to treat the patient's condition. These discussions should include a description of risks, benefits and alternative options. To be clear, this constitutes the practice of medicine and should only be undertaken by a

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

⁴ Telehealth is only acceptable if it meets established regulations. See Wis. Admin. Code chs. Med 24, PA 3 and N 8.

⁵ This is a recommendation and not a requirement. Patient assessment needs shall be evaluated on a case by case basis.

- practitioner with statutory authority to diagnose and treat. The discussion with a patient and recommendation shall be provided by the practitioner.
- 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. The use of standing orders outside
- of an established practitioner-patient relationship for an individualized assessment, diagnosis and
- treatment of patients may be considered prescribing in a manner inconsistent with the standard of
- minimal competence pursuant to Wis. Admin. Code § Med 10.03(2)(c).
- 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
- 120 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.

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COMPOUNDING

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- 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." Federal law allows either a licensed pharmacist or a physician to perform
- eompounding. 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.⁶
- 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.
- 141 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
- 144 compounding requirements. Additionally, the "immediate use" provision requires certain
- conditions be met, including,

⁶ See 21 U.S.C. § 353a(e).

- 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.
 - 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.⁷
- 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.⁸

ADMINISTRATION

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- 171 Upon receipt of an order for IV hydration therapy, an individual with appropriate training and
- experience⁹, including an RN or LPN (consistent with the requirements of Wis. Admin. Code ch.
- 173 N 6), may administer the treatment.
- 174 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,

⁷ Handling of sterile hazardous drugs must comply with USP <800> as well.

⁸ 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

⁹ 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.

- 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.

179 **CONCLUSION**

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- 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.
- 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

- 188 These materials may have been consulted in the preparation of the above document.
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- 192 Retail IV Therapy (March 28, 2025), available at https://kbn.ky.gov/KBN%20Documents/Joint%20Statement%20-
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- 195 State Board of Medical Licensure (Sept. 5, 2023), available
- https://www.msbml.ms.gov/sites/default/files/news/IV%20Hydration%20Therapy%20Guidance%2009-05-23.pdf
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- 202 %20operation%20of%20retail%20iv%20therapy%20clinics%20in%20ohio.pdf
- 203 RHODE ISLAND DEPARTMENT OF HEALTH, Rhode Island Department of Health Guidance Document Regarding the
- 204 Operation of Medical Spas and Intravenous (IV) Therapy Businesses (July 2024), available at
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- 207 Carolina State Boards of Medical Examiners, Pharmacy, and Nursing Regarding Retail IV Therapy Businesses (Aug.
- 208 15, 2023), available at https://llr.sc.gov/med/Policies/Joint-Position-Statement-Retail-IV-Therapy.pdf