Wisconsin Department of Safety and Professional Services
Division of Policy Development
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Tony Evers, Governor
Dan Hereth, Secretary

VIRTUAL/TELECONFERENCE MEETING
INTERDISCIPLINARY ADVISORY COMMITTEE
Virtual, 4822 Madison Yards Way, Madison
Contact: Brad Wojciechowski (608) 266-2112
February 26, 2025

The following agenda describes the issues that the Council 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 Council.

AGENDA

9:30 A.M.

OPEN SESSION – CALL TO ORDER – ROLL CALL

A. Adoption of Agenda (1-2)

B. Approval of Minutes of October 22, 2024 (3-4)

C. Conflicts of Interest, Scheduling Concerns

D. Introductions, Announcements and Recognition – Discussion and Consideration

E. Administrative Matters – Discussion and Consideration

1. Department, Staff and Council Updates
2. **Meeting Dates (5)**
3. **Annual Policy Review (6-8)**
4. **Election of Officers (9)**
5. Section Members – Term Expiration Dates
   a. Schmeling, Gregory – Medical Examining Board Representative
   b. Kane, Amanda K. – Board of Nursing Representative
   c. Streit, Tara E. – Physician Assistant Affiliated Credentialing Board Representative
   d. Weitekamp, John G. – Pharmacy Examining Board Representative
   e. Alexis Watkins– Cosmetology Examining Board Representative
   f. Doug Englebert– Controlled Substances Board Representative
6. Alternates
   a. Yu, Emily S. – Medical Examining Board Representative
   b. Edwards, Jacqueline K. – Physician Assistant Affiliated Credentialing Board Representative
   c. Sabourin, Shelly R. – Board of Nursing Representative
   d. Wilson, Christa M. – Pharmacy Examining Board Representative
   e. Dana McIntosh – Cosmetology Examining Board Representative
   f. Bloom, Alan – Controlled Substances Board Representative

F. IV Hydration Clinics – Discussion and Consideration

1. Rules, Regulations and Guidance from Other States **(10-56)**
2. Rough Draft IV Hydration Guidance Document **(57)**

G. Future Topics – Discussion and Consideration

H. Public Comments

ADJOURNMENT

NEXT MEETING: APRIL 30, 2025

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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
OCTOBER 22, 2024

PRESENT: Alan Bloom, Clarence P. Chou *(arrived at 9:07 a.m.)*, Amanda Kane, Tara Streit, Alexis Watkins, John Weitekamp

ABSENT: Doug Englebert, Kris Ferguson

STAFF: Brad Wojciechowski, Executive Director; Whitney DeVoe, Legal Counsel; Renee Parton, Administrative Rule Coordinator; Dialah Azam, Board Administrative Specialist; and other DSPS Staff

CALL TO ORDER

Brad Wojciechowski, Executive Director, called the meeting to order at 9:03 a.m. A quorum of five (5) members was confirmed.

ADOPTION OF AGENDA

Amendments to the Agenda

- **CHANGE** D.4.f from *Vacant* to *Alan Bloom*

MOTION: Tara Streit moved, seconded by Alexis Watkins, to adopt the Agenda as amended. Motion carried unanimously.

APPROVAL OF MINUTES OF AUGUST 22, 2024

MOTION: Amanda Kane moved, seconded by John Weitekamp, to approve the Minutes of August 22, 2024, as published. Motion carried unanimously.

(Clarence Chou arrived at 9:07 a.m.)

ADMINISTRATIVE MATTERS

Election of Officers

Chairperson

NOMINATION: John Weitekamp nominated Doug Englebert for the Office of Chairperson. Doug Englebert accepted the nomination.

Brad Wojciechowski, Executive Director, called for nominations three (3) times.

Doug Englebert was elected as Chairperson by unanimous voice vote.

Vice Chairperson

NOMINATION: Tara Streit nominated herself for the Office of Vice Chairperson. Tara Streit accepted the nomination.

Brad Wojciechowski, Executive Director, called for nominations three (3) times.

Tara Streit was elected as Vice Chairperson by unanimous voice vote.

Secretary

NOMINATION: John Weitekamp nominated himself for the Office of Secretary. John Weitekamp accepted the nomination.

Brad Wojciechowski, Executive Director, called for nominations three (3) times.

John Weitekamp was elected as Secretary by unanimous voice vote.

ELECTION RESULTS	
Chairperson	Doug Englebert
Vice Chairperson	Tara Streit
Secretary	John Weitekamp

RULES, REGULATIONS AND GUIDANCE RELATED TO IV HYDRATION CLINICS IN OTHER STATES – DISCUSSION AND CONSIDERATION

MOTION: John Weitekamp moved, seconded by Tara Streit, to designate Tara Streit to work with DSPS staff on drafting a guidance document for IV Hydration Clinics. Motion carried unanimously.

ADJOURNMENT

MOTION: Tara Streit moved, seconded by Alan Bloom, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 11:23 a.m.

INTERDISCIPLINARY ADVISORY COUNCIL
2025 MEETING DATES

Meeting Date	Start time	Location	Agenda Item Deadline
Wednesday, February 26, 2025	9:30 AM	Virtual	**2/14/25**
Wednesday, April 30, 2025	9:30 AM	Virtual	**4/18/25**
Wednesday, June 25, 2025	9:30 AM	Virtual	**6/13/25**
Wednesday, August 27, 2025	9:30 AM	Virtual	**8/15/25**
Wednesday, October 22, 2025	9:30 AM	Virtual	**10/10/25**
Wednesday, December 10, 2025	9:30 AM	Virtual	**11/28/25**

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request: Brenda Taylor, Board Services Supervisor		**2) Date when request submitted: 12/1/2024**	
3) Name of Board, Committee, Council, Sections: All Boards			
4) Meeting Date: First Meeting of 2025	**5) Attachments:** ☒ Yes	**6) How should the item be titled on the agenda page?** Administrative Matters: Annual Policy Review	
7) Place Item in: ☒ Open Session	**8) Is an appearance before the Board being scheduled?** ☒ No	**9) Name of Case Advisor(s), if applicable:** N/A	

10) Describe the issue and action that should be addressed: Board SharePoint Site: https:/dsps.boards.wisconsin.gov/

Please be advised of the following Policy Items:

1. **In-Person and Virtual Meetings:** Depending on the frequency of scheduled meetings, discussion topics, and member availability, DSPS may host one or more in-person meetings. Virtual connection options are available for all board meetings.

2. **Attendance/Quorum:** Thank you for your service and commitment to meeting attendance. If you cannot attend a meeting or have scheduling conflicts impacting your attendance, please let us know as soon as possible. A quorum is required for Boards, Sections, and Councils to meet pursuant to Open Meetings Law. Connect to / arrive at meetings 10 minutes before posted start time to allow for audio/connection testing, and timely Call to Order and Roll Call. Virtual meetings include viewable onscreen materials and A/V (speaker/microphone/video) connections.

3. **Walking Quorum:** Board/Section/Council members must not collectively discuss the body's business outside a properly noticed meeting. If several members of a body do so, they could be violating the open meetings law.

4. **Mandatory Training:** All Board Members must complete Public Records and Ethics Training, annually. Register to set up an account in the Cornerstone LearnCenter online portal or Log in to an existing account.

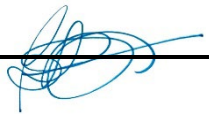
5. **Agenda Deadlines:** Please communicate agenda topics to your Executive Director before the agenda submission deadline at 12:00 p.m., eight business days before a meeting. (Attachment: Timeline of a Meeting)

6. **Travel Voucher and Per Diem Submissions:** Please submit all Per Diem and Reimbursement claims to DSPS within 30 days of the close of each month in which expenses are incurred. (Attachment: Per Diem Form) Travel Vouchers are distributed on travel approval.

7. **Lodging Accommodations/Hotel Cancellation Policy:** Lodging accommodations are available to eligible members for in-person meetings. Standard eligibility: the member must leave home before 6:00 a.m. to attend an in-person meeting by the scheduled start time.
    a. If a member cannot attend a meeting, they must cancel their reservation with the hotel within the applicable cancellation timeframe.
    b. If a meeting is changed to occur remotely, is canceled, or rescheduled, DSPS staff will cancel or modify reservations as appropriate.

8. **Inclement Weather Policy:** In inclement weather, the DSPS may change a meeting from an in-person venue to a virtual/teleconference only.

11) Authorization



12/02/2024

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**

Timeline of a Meeting

8 business days prior to the meeting: All agenda materials are due to the Department by 12:00 pm, 8 business days prior to the meeting date.

7 business days prior to the meeting: The draft agenda page is due to the Executive Director. The Executive Director transmits to the Chair for review and approval.

5 business days prior to the meeting: The approved agenda is returned to the Board Administration Specialist for agenda packet production and compilation.

4 business days prior to the meeting: Agenda packets are posted on the DSPS Board SharePoint site and on the Department website.

Agenda Item Examples:

- Approval of the Agenda and previous meeting Minutes
- Open Session Items
  - Public Hearings (relating to Administrative Rules)
  - Administrative Matters
  - Legislation and Policy Matters
  - Administrative Rules Matters
  - Credentialing Matters
  - Education and Exam Issues
  - Public Agenda Requests
  - Current Issues Affecting the Profession
  - Public Comments
- Closed Session items
  - Deliberations on Proposed Disciplinary Actions
    - Stipulations
    - Administrative Warnings
    - Case Closings
    - Monitoring Matters
    - Professional Assistance Procedure (PAP) Issues
  - Proposed Final Decisions and Orders
  - Orders Fixing Costs/Matters Relating to Costs
  - Credentialing Matters
  - Education and Exam Issues

Thursday of the Week Prior to the Meeting: Agendas are published for public notice on the Public Notices and Meeting Minutes website: **publicmeetings.wi.gov**.

1 business day after the Meeting: "Action" lists are distributed by staff detailing board actions on closed session business.

5 business days after the Meeting: "To Do" lists are distributed to staff to ensure that board decisions are acted on and/or implemented within the appropriate divisions in the Department. Minutes approved by the board are published on the the Public Notices and Meeting Minutes website: **publicmeetings.wi.gov**.

Department of Safety and Professional Services
PER DIEM REPORT

INSTRUCTIONS: Record board-related activities by date, indicate relevant purpose code, the duration of time spent in B-code activities, location, and activity description. Only one $25.00 per diem payment will be issued on any given calendar day. Submit one form per month and within 60 days of the last activity being reported. Send completed forms to your Board's Administrative Specialist.

Purpose Codes:

A CODE **Official meetings including Board Meetings, Hearings and Examinations and Test Development Sessions** (automatic day of per diem) Examples: board, committee, board training or screening panels; Senate Confirmation hearings, legislative and disciplinary hearings, or informal settlement conferences; test administration, test review or analysis events, national testing events, tour of test facilities, etc.

B CODE **Other** (One (1) per diem will be issued for every five (5) hours spent in category B, per calendar month): i.e., review of disciplinary cases, consultation on cases, review of meeting materials, board liaison work, e.g., contacts regarding Monitoring, Professional Assistance Procedure, Credentialing, Education and Examinations

Name of Examining Board or Council	Board or Council Member's Name
Month Year	Employee ID Number

Date	Purpose Code **A or B**	Duration of **B activity** **Hours: Minutes**	Where Performed **(Home, DSPS, or City, State)**	Activity **Describe Activity Performed (see purpose codes)**
TOTALS				

CLAIMANT'S CERTIFICATION The Board/Council member named above, certifies, in accordance with § 16.53, Wis. Stats., that this account for per diem, is just and correct; and that this claim is for service necessarily incurred in the performance of duties required by the State, as authorized by law. (Rev.04/24)

Board Member Approval & Date: _____

TOTAL DAYS CLAIMED: _____ @ $25.00 = _____ Supervisor Approval & Date: _____

INTERDISCIPLINARY ADVISORY COUNCIL

2024 Elections

2024 OFFICERS	
Chairperson	Doug Englebert
Vice Chairperson	Tara Streit
Secretary	John Weitekamp

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request: Whitney DeVoe, Board Counsel		**2) Date when request submitted:** 2/14/25 **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: Interdisciplinary Advisory Committee			
4) Meeting Date: 02/26/2025	**5) Attachments:** ☒ Yes ☐ No	**6) How should the item be titled on the agenda page?** Rules, Regulations and Guidance related to IV Hydration Clinics in Other State – Discussion and Consideration	
7) Place Item in: ☒ Open Session ☐ Closed Session	**8) Is an appearance before the Board being scheduled?** ☐ Yes ☒ No	**9) Name of Case Advisor(s), if applicable:**	
10) Describe the issue and action that should be addressed: Discussion and consideration of other states rules, regulations, and guidance related to IV hydration clinics.			
11) **Authorization**			
Whitney DeVoe			**02/14/25**
Signature of person making this request			**Date**
Supervisor (Only required for post agenda deadline items)			**Date**
Executive Director signature (Indicates approval for post agenda deadline items)			**Date**

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.**

JOINT STATEMENT OF THE KENTUCKY BOARDS OF MEDICAL LICENSURE, NURSING AND PHARMACY REGARDING RETAIL IV THERAPY

The retail IV therapy business model is rapidly expanding across the country. Many clinics engaging in this therapy are adopting business and/or practice models without realizing IV therapy constitutes the practice of medicine, nursing and/or pharmacy. Many of these establishments do not have appropriately licensed and qualified staff to perform the necessary tasks and satisfy minimum statutory and regulatory requirements of practice. The Kentucky Board of Medical Licensure, Kentucky Board of Nursing, and Kentucky Board of Pharmacy acknowledge and appreciate the work of their colleagues at the South Carolina Boards of Medical Examiners, Pharmacy and Nursing, the Alabama Board of Medical Examiners, and the Mississippi State Board of Medical Licensure for rendering thoughtful and well-reasoned guidance on the issues presented herein. Kentucky licensees are encouraged to review the guidance offered in those states and to consider its application within the Commonwealth of Kentucky.

Typical Retail IV Therapy Business Model

The typical retail IV therapy business model offers to walk-in patients a menu of pre-selected mixtures ("cocktails") of additives to basic IV saline. The cocktails include amino acids, vitamins, minerals, and some prescription drugs like Pepcid, Toradol, and Zofran. The cocktails are offered to patients for the treatment of conditions such as dehydration, migraine relief, hangover recovery, nausea relief, athletic recovery, appetite regulation, and inflammation support.

Although a physician (MD/DO) may be associated with the business, the physician is usually not on the premises. Instead, the business uses the physician's National Practitioner Identification ("NPI") number to acquire the IV supplies and additives, and the physician issues "standing orders" directing the administration of IVs.

Commonly, a patient walks into the business, reviews a menu of treatment options, completes a health questionnaire, and undergoes a precursory evaluation (including pulse oximetry, heart rate, blood pressure, review of medications and allergies) with an employee, usually an employee nurse. The employee will discuss the patient's symptoms and treatment goals. The employee recommends an IV cocktail, with or without additives, based on "standing orders" prepared by a physician. The employee mixes the IV bag and

administers the IV therapy. The employee assesses the patient's treatment and observes any complications. Once the IV therapy is complete, the employee removes the IV catheter and applies a dressing. The patient is then discharged.

The signatory Boards are concerned whether qualified individuals are making appropriate diagnoses and administering these IVs in a legal manner based upon their statutorily defined scopes of practice. Notably, operation of retail IV therapy clinics implicates multiple areas of the Kentucky Pharmacy Practice Act, including compounding, dispensing, storage, safeguarding and administration of sterile products.

Licensees Scope of Practice

The FDA defines compounding as the combining, mixing or alteration of ingredients of a drug pursuant to a prescription to create a medication tailored to the needs of an individual patient. Although compounded drugs can serve an important medical need for certain patients, they also present a risk to patients because of instances when in which medications, primarily injectable medications that are intended to be sterile have endangered public health. Compounded drugs are not FDA-approved. The FDA has not reviewed these drugs to evaluate their safety, effectiveness, or quality before they reach patients.

Pursuant to federal law, compounding may be performed by a licensed pharmacist in a state-licensed pharmacy, or federal facility, or by a physician. Regardless of where compounding occurs, in a pharmacy or physician's office, federal and state law apply.

The retail IV therapy business model implicates the practice of medicine, nursing and/or pharmacy. The practice of these professions requires a license, and the scope of practice is defined by statutory schemes specific to each profession. A license to practice these professions is specific to the licensee and is not a "plus one" – i.e., the licensee may not "train and delegate" their professional scope of practice to any other unlicensed person. Only licensed professionals may diagnose a patient, assess his or her symptoms, recommend and administer an IV for the treatment of the patient's condition and compound medications.

Licensees of the Kentucky Board of Medical Licensure, Kentucky Board of Nursing, and the Kentucky Board of Pharmacy are cautioned to practice within their statutorily defined scope of practice and to neither aid nor abet the unlicensed practice of others.

Medical Practice Act

There is no question that the services being provided by IV retail clinics constitutes the practice of medicine or osteopathy. The practice of medicine or osteopathy in Kentucky is defined as "the diagnosis, treatment, or correction of any and all human conditions, ailments, diseases, injuries, or infirmities by any and all means, methods, devices, or instrumentalities." *See* KRS 311.550(10). Physicians must practice within acceptable and

prevailing medical practices and are individually responsible and accountable for their clinical decisions. The Kentucky Board of Medical Licensure adopts by reference herein its "Board Opinion Regarding 'Practice Drift'" (published December 20, 2023) and encourages its licensees to review that opinion. Physicians may prescribe and administer medications, including compounded medications, but they may not delegate the prescribing, compounding or administration of such medications to other unlicensed persons.

If the IV therapy treatment is pursuant to a lawful prescription, it may be prepared for immediate use, i.e., administration within four hours. However, the preparation cannot include more than three different sterile products. Otherwise, under the Food, Drug and Cosmetic Act, the preparation of the IV therapy treatment would need to comply with the USP 797, including the facility and engineering controls that include the use of isolators, air exchange requirements, precise pressure differentials, humidity control and cleanroom suites with access doors and seals. Despite USP 797 not applying entirely to the compounding of three or fewer sterile products that will be administered in fewer than four hours, there are provisions of USP 797 that under federal law still govern. Those standards are found on pages 5-7 of this document but include specific training requirements and the use of aseptic techniques.

Nurse Practice Act

A nurse's practice should be consistent with the Kentucky Revised Statutes Chapter 314, evidence based, and within established standards of practice. Nurses are responsible and accountable for their decisions regarding the implementation of patient care orders based upon the individuals' educational preparation and clinical competence in nursing. See KRS 314.021(2). The Kentucky Board of Nursing adopts by reference its Advisory Opinion Statement 15- "Role of Nurses in the Supervision and Delegation of Nursing Tasks to Unlicensed Personnel" and encourages its licensees to review that opinion.

IV therapy is a treatment. An Advanced Practice Registered Nurse (APRN) may be authorized to prescribe and administer certain medications. See KRS 314.011(8) and 314.042(6)(c). Prior to determining and ordering a course of treatment, the APRN should establish a practitioner-patient relationship, see KRS 218A.010(41), and conduct a good-faith prior examination, see KRS 218A.010(18), to assess a patient's medical history. Such assessments may be conducted by a Registered Nurse (RN) using a standardized review document as noted within protocols or standing orders that have been created by the facility/agency/office providing IV hydration services. The standardized review must be approved by the prescribing practitioner. An APRN may order and stock nonscheduled legend drugs for the specific purpose of prescribing them for the direct administration.

It is within the scope of an RN or a licensed practical nurse to administer medication and treatment if it has been lawfully prescribed by a physician, physician assistant, dentist, or APRN. See KRS 314.011(6)(c) and (10)(c).

If the IV therapy treatment is pursuant to a lawful prescription, it may be prepared for immediate use, i.e., administration within four hours. However, the preparation cannot include more than three different sterile products. Otherwise, under the Food, Drug and Cosmetic Act, the preparation of the IV therapy treatment would need to comply with the USP 797, including the facility and engineering controls that include the use of isolators, air exchange requirements, precise pressure differentials, humidity control and cleanroom suites with access doors and seals. Despite USP 797 not applying entirely to the compounding of three or fewer sterile products that will be administered in fewer than four hours, there are provisions of USP 797 that under federal law still govern. Those standards are found on pages 5-7 of this document but include specific training requirements and the use of aseptic techniques.

Pharmacy Practice Act

The Board of Pharmacy has received numerous inquiries regarding IV hydration therapy by non-practitioners and is troubled about the safety of this practice. By adding drugs or vitamins to the IV bag, these individuals at IV therapy clinics are compounding. "Compound" or "compounding" is defined by the Kentucky Pharmacy Practice Act as the preparation or labeling of a drug pursuant to or in anticipation of a valid prescription drug order, including but not limited to packaging, intravenous admixture, or manual combination of drug ingredients. At the federal level, the Food and Drug Administration (FDA) defines compounding as "the process of combining, mixing, or altering ingredients to create a medication tailored to the needs of an individual patient." Compounding is the responsibility of a licensed pharmacist. Because of this requirement, a Board of Pharmacy permit is required for any place where prescription drug orders are compounded under the supervision of the pharmacist. The only exception to this is when a physician is compounding in their practice or a physician, pharmacist or APRN is compounding for immediate use.

If the IV therapy treatment is pursuant to a lawful prescription, it may be prepared for immediate use, i.e., administration within four hours. However, the preparation cannot include more than three different sterile products. Otherwise, under the Food, Drug and Cosmetic Act, the preparation of the IV therapy treatment would need to comply with the USP 797, including the facility and engineering controls that include the use of isolators, air exchange requirements, precise pressure differentials, humidity control and cleanroom suites with access doors and seals. Despite USP 797 not applying entirely to the compounding of three or fewer sterile products that will be administered in fewer than four hours, there are provisions of USP 797 that under federal law still govern. Those standards are found on page 5-7 of this document but include specific training requirements and the use of aseptic techniques.

Non-practitioners, including but not limited to RNs, EMTs, and LPNs, may not possess and/or store legend medications of any type. This prohibition includes overnight storage in any non-permitted location, including but not limited to a home or vehicle.

USP 797 Standards[1]—the FDA Enforceable Standard for all Practitioners

In relation to pharmaceutical compounding, USP (United States Pharmacopeia) is the FDA recognized standard of care in relation to all things compounding, to include sterile compounding found in USP 797, and has been adopted by the FDA as the enforceable standard. Furthermore, all sterile compounding performed by pharmacists is subject to the requirements outlined in 201 KAR 2:076. For purposes of USP 797, sterile compounding is defined as combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance to create a sterile medication. This chapter applies to all persons who prepare compounded sterile preparations (CSPs) and all places where CSPs are prepared for human and animal patients. This includes, but is not limited to, pharmacists, technicians, nurses, physicians, veterinarians, dentists, naturopaths, and chiropractors in all places including, but not limited to, hospitals and other healthcare institutions, medical and surgical patient treatment sites, infusion facilities, pharmacies, and physicians' or veterinarian practice sites. The compounding facility must designate one or more individuals as a designated person(s). This individual is responsible and accountable for the performance and operation of the facility and personnel in the preparation of CSPs and for performing other functions as described in USP 797.

"Immediate Use" does not negate following USP 797. Certain provisions still apply.
The concept of "immediate use" is being interpreted to allow the compounding of IVs to circumvent USP requirements, especially for sterility and training. USP <797>'s "immediate use" provision governs the emergency preparation of a sterile drug product, and in certain circumstances, this provision allows for the preparation of a sterile product to be made outside of full USP compliance. This provision is not a workaround for the quality and safety standards that govern sterile product preparation.

Standards for Immediate-Use of Compounded Sterile Preparations

All the following conditions shall be met before a compounded sterile preparation may be prepared for immediate use:

Aseptic techniques, processes, and procedures are followed, and written SOPs are in place to minimize the potential for contact with nonsterile surfaces, introduction of

[1] "United States Pharmacopeial Convention. General chapter <797> pharmaceutical compounding—sterile preparations (2023).

particulate matter or biological fluids, and mix-ups with other conventionally manufactured products or CSPs.

- Aseptic processing: A method by which separate, sterile components (e.g. drugs, containers, or closures) are brought together under conditions that maintain their sterility. The components can either be purchased as sterile or, when starting with nonsterile components, can be separately sterilized prior to combining (e.g. by membrane filtration or by autoclave).
- Aseptic technique: A set of methods used to keep objects and areas free of microorganisms and thereby minimize infection risk to the patient. It is accomplished through practices that maintain the microbe count at an irreducible minimum.
- Facilities that prepare CSPs must develop SOPs for the compounding process and other support activities. SOPs must include the types of CSPs that are prepared. A designated person(s) must ensure that SOPs are appropriate and are implemented, which includes ensuring that personnel demonstrate competency in performing every procedure that relates to their job function. All personnel who perform or oversee compounding or support activities must be trained in SOPs.
- SOPs must be reviewed initially and at least every 12 months by the designated person(s) to ensure that they reflect current practices, and the review must be documented. Any changes or alterations to an SOP must be made only by a designated person(s) and must be documented. Revisions to SOPs must be communicated to all personnel involved in these processes and procedures, and personnel should document acknowledgement of the communication.

- Personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and the facility's SOPs.
  - Personnel compounding only immediate-use CSPs must complete training as required by the facility's SOPs.
  - Before beginning to compound CSPs independently or have direct oversight of compounding personnel, personnel must complete training and be able to demonstrate knowledge of principles and competency of skill for performing sterile manipulations and achieving and maintaining appropriate environmental conditions ***as applicable*** to their assigned job functions. This must be completed initially and at least every 12 months in at least the following:
    - Hand hygiene
    - Cleaning and disinfection
    - Calculations, measuring, and mixing
    - Aseptic technique
  - All compounding personnel must be trained to:
    - Recognize potential problems, deviations, failures, or errors associated with preparing a CSP (e.g. those related to equipment, facilities, materials, personnel, the compounding process, or

testing) that could potentially result in contamination or other adverse impact on CSP quality
        - Report any problems, deviations, failures, or errors to the designated person(s)
    - If the facility has only one person in the compounding operation, that person must document that they have obtained training and demonstrated competency, and they must comply with the other requirements of this chapter.
- 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.
- 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.
    - A conventionally manufactured single-dose container is a container closure system that holds a sterile product for parenteral administration (injection or infusion) that is not required to meet the antimicrobial effectiveness testing requirements.
    - Single-dose containers: A container of sterile product for parenteral administration (e.g. injection or infusion) that is designed for use with a single patient as a single injection/infusion. A single-dose container usually does not contain a preservative. See <659>, *Injection Packaging Systems, Single-dose container.*
- Administration begins within 4 hours following the start of the preparation. If administration has not begun within 4 hours following the start of preparation, it must be promptly, appropriately, and safely discarded.
    - Administration: The direct application of a sterile product or preparation to a single patient by injecting, infusing, or otherwise providing a sterile product or preparation in its final form.
- Unless directly administered by the person who prepared it or administration 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.

Acceptable and Prevailing Practices

Delegation

Neither a business nor business owner can lawfully exercise control over the independent professional clinical judgment of a licensed healthcare professional. Licensees are responsible for practicing within their scope of practice and exercising their professional

judgment within the standards of acceptable and prevailing practice of their individual profession.

Delegation of one's professional clinical judgment and responsibilities to unqualified and unlicensed persons is prohibited. In that vein, licensees are cautioned against the use of "standing orders" that may allow unqualified and unlicensed employees to exercise discretion, make diagnoses, and prescribe and compound IV medications under guise of a licensee's authority. The Food, Drug and Cosmetic Act only authorizes pharmacists and physicians to compound drugs. Compounding for immediate use is the only exception and this practice is authorized to be performed by an APRN. Utilizing a standing order to bypass this federal requirement is unlawful. The issuance of standing orders by a practitioner to the RN to follow does not satisfy the physician's legal duties to the patient. Nor does it satisfy a PA's or APRN's duty to the patient. The use of standing orders in what is supposed to be an individualized assessment, diagnosis and treatment of patients at a retail IV therapy business creates a situation in which the physician is aiding and abetting the unlawful practice of medicine by the RN.

The diagnosis of the patient's condition and the recommendation of IV therapy constitutes the practice of medicine. This act is outside the scope of practice for an RN. Only a physician, PA or APRN has the statutory authority to diagnose a patient and make the decision to provide medication, by injection or otherwise.

The discussion with the patient and recommendation of an IV and additives thereto, including "cocktails" and prescription drugs, are also outside the scope of practice of an RN. Only a licensed physician, PA or APRN may diagnose a patient, assess his or her symptoms, and recommend IV treatment for the patient's condition.

While some retail IV therapy businesses have a physician owner, co-owner, investor, or associate, it has been reported that the physician or another licensed practitioner may not actually evaluate the patient. Instead, a physician, PA, or APRN may be a "medical director," "on staff," or "available," but only the RN treats the patient, aside from the patient's specific request for medications. This is insufficient to establish a valid practitioner-patient relationship which is required before the administration of prescribed drugs.

Purchasing Legend Drugs

IV therapy fluids are legend drugs and must be purchased under a qualified practitioner's authority. As with other legend drugs, to satisfy legal requirements, a qualified licensed practitioner must establish a valid practitioner-patient relationship, make an *individualized differential diagnosis necessitating IV therapy*, develop a treatment plan, and prescribe IV fluids for a specific patient. The adding of drugs or vitamins to a prescription IV bag is a compounding practice and must be performed in accordance with Kentucky Board of Pharmacy laws.

Legend drugs should only be purchased from wholesalers licensed with the Kentucky Board of Pharmacy, and compounded drug products should only be purchased from 503B outsourcing facilities licensed by the Kentucky Board of Pharmacy. 503B outsourcing facilities sell compounded drug product directly to licensed healthcare facilities or practitioners where it is used as office stock for an APRN or physician to administer directly to a patient or for a pharmacy to dispense pursuant to a prescription. No compounded drug product may be resold, transferred, or redistributed unless authorized under state and federal law. The Kentucky Board of Pharmacy issued an opinion-declaratory ruling specifically for pharmacies acquiring 503B compounded drug products. This guidance also applies to physicians and APRNs purchasing compounded drug products from 503B outsourcing facilities. If a compounded drug product from a 503B outsourcing facility is obtained, no further manipulation may occur except for products being administered in an acute care facility by a healthcare provider or if the product is labeled with a patient specific label. Adding additional compounded drug product or legend drugs to the compounded drug product procured from the 503B outsourcing facility in any other setting is considered adulteration and is prohibited.

Patient Choice of Drugs

The participation of the patient in the selection of the IV additives is problematic because the patient is not a practitioner. A patient is not licensed to practice medicine. A patient cannot enter a doctor's office or hospital and demand an IV any more than a patient can direct his or her own appendectomy. Even physicians are prohibited from treating themselves except in emergency situations.

Comprehensive Medical Record

The physician, PA, or APRN must personally evaluate the patient, diagnose the patient, and make the treatment recommendations. The physician, PA, or APRN must further create a comprehensive medical record that complies with the standard of care. If the physician, PA, or APRN decides to prescribe IV therapy, he or she must issue a prescription, and only then may the IV therapy be administered. It is the obligation of the physician, PA, or APRN to exercise their medical judgment in determining that the treatment will actually benefit the patient. A licensed person other than the physician, PA, or APRN may administer the IV only if administration of IVs is within that licensee's scope of practice.

Conclusion

Licensees must protect themselves and the public by ensuring that their participation in any business venture constituting the practice of medicine, nursing, or pharmacy complies with legal requirements and satisfies all applicable professional standards. Public health and safety require no less.

Despite the proliferation of IV hydration clinics around the state, the diagnosis of a condition that results in the ordering of IV-delivered drugs, amino acids, or vitamins is unambiguously the practice of medicine. Likewise, the storage and administration of these medications constitutes both the practice of pharmacy and the practice of nursing. Failure to be licensed by the Boards as required is a violation of Kentucky law and can be punished. Meanwhile, failures by licensees to follow the laws governing their practice(s) could result in disciplinary proceedings and sanctions by their respective boards; by law, sanctions may include monetary fines, probation of a license, suspension of a license, or even revocation of a license, as set forth in each of the practice acts.

William C. Thornbury, Jr., M.D.
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Audria Denker, DNP, RN, FAADN

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BOARD OPINION
REGARDING "PRACTICE DRIFT"

LEGAL AUTHORITY

Pursuant to KRS 311.602, the following Board opinion is issued to assist Board licensees in determining what actions would constitute unacceptable conduct under the provisions of KRS 311.595 and/or KRS 311.597. The Board has decided to publish this opinion because it addresses issues of significant public and medical interest.

DEFINITION

As used in this opinion, "practice drift" means a physician's shift away from the scope of the specialty in which he/she formally trained (in traditional medical education and training pathways) into the scope of another specialty.

OPINION

A license to practice medicine or osteopathy in the Commonwealth of Kentucky provides the licensee the privilege of practicing the full scope of medicine or osteopathy. This privilege comes with substantial responsibility and commensurate accountability. Therefore, it is incumbent upon the licensee, who shifts from their primary and formally trained area of practice expertise to another, to ensure that they are able to meet and conform to all acceptable and prevailing standards of any practice area/specialty in which they engage. Relevant to this responsibility, the Board may discipline a license for any departure from, or failure to conform to, the standards of acceptable and prevailing medical practice within the Commonwealth of Kentucky. *See* KRS 311.595(9) and KRS 311.597(4).

When investigating cases, the Board holds the licensee accountable to the acceptable and prevailing medical practices of the specialty in which the licensee engaged as impetus for a grievance. For instance, a board-certified orthopedic surgeon offering hormone therapy will be held to the acceptable and prevailing medical practices within the specialty of endocrinology; and a board-certified emergency medicine physician offering botox, lasers and cosmetic procedures will be held to the acceptable and prevailing medical practices within the specialty of aesthetic dermatology or plastic and reconstructive surgery.

The Board cautions licensees who engage in practice drift. Licensees should consider the quality of training programs offered outside of traditional education and training pathways and should carefully consider whether the education and/or training offered would be comparable to the rigor and quality of a formal education, residency or fellowship training, or board certification within a practice specialty. The Board expects licensees to conform to the acceptable and prevailing medical practices associated with specialists in those fields.

Published as Board Opinion on December 20, 2023.

GUIDANCE REGARDING IV HYDRATION THERAPY FROM THE MISSISSIPPI STATE BOARD OF MEDICAL LICENSURE

The proliferation of retail IV hydration therapy businesses causes the Board concern for public safety. Many clinics or spas engaging in this therapy are adopting business and/or practice models without realizing IV hydration therapy constitutes the practice of medicine, but those establishments do not have qualified staff legally authorized to perform the necessary tasks and satisfy minimum statutory and regulatory requirements. The Board staff regularly receives inquiries concerning the legal requirements and limits for IV hydration spas and clinics. The number of inquiries received is concerning, because this is NOT a complex issue.

To be clear and avoid any possible basis for misunderstandings: (1) IV hydration therapy constitutes the practice of medicine.[1] (2) IV fluids are legend drugs that must be purchased using a practitioner's DEA number. (3) Just as with any other medication, to satisfy legal and regulatory requirements, a practitioner with prescriptive authority must establish a valid practitioner/patient relationship, take an appropriate history, make a diagnosis necessitating IV therapy, develop a plan, and prescribe IV fluids for a specific patient. (4) After such a lawful prescription has been issued, qualified personnel such as Registered Nurses may administer IV fluids and monitor a patient for potential side effects. (5) Any IV hydration therapy practice or business model that does not satisfy these requirements is unlawful. (6) Licensees of this Board must at all times remain mindful that neither a business nor business owner can lawfully exercise control over the manner in which a physician provides medical services, nor interfere with the independent exercise of a physician's medical judgment.[2]

"Knowingly performing any act which in any way assists an unlicensed person to practice medicine," is unprofessional conduct and grounds for discipline. Miss. Code Ann. § 73-25-29. Such unprofessional conduct includes apparently common practices, such as participating in an IV hydration therapy spa or clinic in a position such as "medical director" without ensuring qualified personnel are performing each required task, and attempting to

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[1] "The practice of medicine shall mean to suggest, recommend, prescribe, or direct for the use of any person, any drug, medicine, appliance, or other agency, whether material or not material, for the cure, relief, or palliation of any ailment or disease of the mind or body, or for the cure or relief of any wound or fracture or other bodily injury or deformity . . . ." Miss. Code Ann. § 73-25-33.

[2] This Guidance is intended to offer only an overview of some of the issues raised by the operation of IV hydration therapy clinics and spas. States such as Alabama and South Carolina have published helpful documents which provide additional, extremely detailed guidance and commentary for practitioners. The Alabama State Board of Medical Examiners issued a Declaratory Ruling on July 21, 2022 concerning "retail IV therapy businesses." The Alabama Ruling is available at this link: https://www.albme.gov/uploads/pdfs/IVTherapy.Declaratory_Ruling_.pdf

On August 15, 2023, regulators in the State of South Carolina issued a "Joint Advisory Opinion of the South Carolina State Boards of Medical Examiners, Pharmacy, and Nursing Regarding Retail IV Therapy Businesses" that is available at this link: https://llr.sc.gov/med/Policies/Joint-Position-Statement-Retail-IV-Therapy.pdf Both the Alabama and South Carolina opinions are highly recommended and reflect that regulation of IV hydration therapy is not a problem limited to Mississippi, but is a nationwide issue of concern.

circumvent professional standards or regulatory requirements through the use of so-called "Standing Orders" that purport to permit registered nurses or other unqualified personnel to make diagnoses and prescribe IV medications. Delegation through such orders is insufficient to establish a valid licensee-patient relationship, constitutes unprofessional conduct, and is unlawful.

The Board's Administrative Code, Part 2640, Chapter 1, contains Rules Pertaining to Prescribing, Administering and Dispensing of Medication. Pursuant to Rule 1.11: "Prescriptions may not be written outside of a valid licensee-patient relationship." Elements of this valid relationship include:

- Verification of patient identity
- Conducting an appropriate history and physical examination of the patient that meets the applicable standard of care
- Establishing a diagnosis through the use of accepted medical practices, i.e., patient history, mental status exam, physical exam and appropriate diagnostic and laboratory testing
- Discussing diagnosis, risks, and benefits of various treatment options with the patient to obtain informed consent
- Insuring the availability of appropriate follow-up care, and
- Maintaining a complete medical record available to patient and other treating health care providers

Licensees must protect themselves and the public by ensuring that their participation in any business venture constituting the practice of medicine complies with legal and regulatory requirements, and satisfies all applicable professional standards. Public health and safety require no less.

Kenneth E. Cleveland, M.D.
Executive Director
MISSISSIPPI STATE BOARD
OF MEDICAL LICENSURE

Rhode Island Department of Health
Guidance Document Regarding the Operation of Medical Spas and Intravenous (IV) Therapy Businesses

Background

The Rhode Island Department of Health (RIDOH) is charged with implementing and enforcing laws for the protection of the public's health; this expansive authority includes oversight of healthcare facilities and healthcare professionals. The statutory authority for this regulatory oversight is largely set forth in Title 5 ("Businesses and Professions") and Title 23 ("Health and Safety") of the R.I. General Laws.

In the past few years, RIDOH has seen a proliferation of two new healthcare business types – medical spas and intravenous (IV) therapy businesses.

Medical spas, sometimes referred to as medspas or medispas, offer an array of services from traditional esthetic services (e.g., hairdressing, manicures) to traditional medical procedures (e.g., Botox, fillers, laser hair removal). For the purpose of this document, the term "medical spa" means an entity that offers or performs esthetic procedures that (a) do not require sedation; and (b) are directed at improving the person's appearance; and (c) do not meaningfully promote the proper function of the body or prevent or treat illness or disease. The term also refers to an entity that offers or performs any other esthetic procedure or treatment requiring the participation of a licensed healthcare professional.

Intravenous (IV) therapy businesses provide patients with IV fluids with or without medications, vitamins, minerals and/or amino acids. Sometimes these services are offered within a medical spa, but more often are a standalone business.

The services offered in these settings are advertised as being of minimal risk and thus are treated more as spa treatments rather than medical procedures; many of which intersect the specialties of medicine, nursing, and pharmacy. This framing makes it confusing for healthcare professionals and the public to understand the responsibilities of each specialty.

Furthermore, RIDOH has discovered many of these businesses operating without proper healthcare facility licensure and/or providers performing procedures that are not within their scope of practice nor adhering to the proper standard of care. Thus, patients receiving these medical treatments in these settings are at a higher risk for complications, including inadequate results (requiring additional procedures), infections, burns, and in extreme cases, death.

Based upon the foregoing, RIDOH's Division of Healthcare Quality and Safety (DHQS) in consultation with the professional boards of licensure and discipline, issue this guidance to

provide clarity on the licensure, ownership, standard of care, and standard of practice for healthcare professionals in medical spas and intravenous (IV) therapy businesses[1].

Questions regarding this guidance should be directed to Lauren Gareau at lauren.gareau@health.ri.gov or 401-222-4525.

Medical Spa and IV Therapy Business Ownership and Licensure

As medical spas and IV therapy businesses are an agglomeration of medical disciplines, the ownership structure of these facilities varies. In some instances, a dermatologist or plastic surgeon is the owner and in others, it is an esthetician. Some are owned by unlicensed investors. Determination for licensure is complex and heavily fact-dependent and it may be best for potential owners of medical spas and IV therapy businesses to seek legal counsel.

In Rhode Island the determination for the requirement of a healthcare facility license for a medical spa or IV therapy business is based on the ownership structure, services offered, and professional licensure (if any) held by the owners of the medical spa or IV therapy business.

In the event that the owner and/or operator holds no professional license or does not qualify for an exemption via a professional service corporation, **an organized ambulatory care facility license is needed.**

Certain professional license holders (e.g., physicians, dentists, registered nurses, physician assistants) are permitted to form a professional service corporation (PSC) under R.I. Gen. Laws Chapter 7-5.1. By forming a PSC, professional license holders can be exempt from an organized ambulatory care facility license (unless providing services within a mobile unit), under R.I. Gen. Laws Chapter 23-17, if the individuals of the PSC are owning and operating the business. Individuals who form a PSC may require prior written approval of the applicable board as discussed in R.I. Gen. Laws § 7-5.1-3.

R.I. Gen. Laws § 7-5.1-3 authorizes a combination of professional licenses to form a PSC (e.g., physician and dentist). At least one individual of the PSC must be able to perform the services they are offering to qualify for the exemption from an organized ambulatory care facility license. For example, a PSC that is comprised of nurses who are offering Botox at their medical spa would not qualify for an exemption from an organized ambulatory care facility license, as nurses are not able to examine, diagnose, prescribe, or administer Botox. In this example, the group of nurses would need to include a physician, physician assistant (PA), or certified nurse practitioner (CNP) in the ownership of the PSC to be exempt from an organized ambulatory care facility license.

[1] RIDOH and the boards acknowledge and appreciate the South Carolina Department of Labor, Licensing and Regulation and the Alabama Board of Medical Examiners for addressing many of the IV therapy business issues in their well-reasoned Advisory (South Carolina, Dated August 15, 2023) and Declaratory Ruling (Alabama, dated July 21, 2022). The issues raised in both are also an accurate representation of current IV practices in Rhode Island.

In some instances, a single provider or group of providers may form a PSC to be exempt from an organized ambulatory care facility license but then hire a management company that will actively operate the business with significant influence and no active involvement of the PSC members. This "leasing" of the PSC to circumvent the need for a facility license is a misrepresentation of the purpose of the law. Such arrangements will require the management company to receive an organized ambulatory care facility license and members of the PSC who engage in such practice may have adverse action taken against their professional license.

Medical spas and IV therapy businesses who elect to use a management company remain responsible for the limited services provided by the management company.

Medical spas whose business model involves providing, arranging to provide, offers to provide or in any other way provides for the delivery of direct nursing services in the home or in a location that is not the business's brick and mortar establishment (e.g., workplace, pool side, event space), **requires a home nursing care provider (HNCP) license regardless of professional license held**. An HNCP license requires a certificate of need (CON) pursuant to R.I. Gen. Laws Chapter 23-15.

Medical spas that wish to utilize a mobile unit and perform services in a van, trailer, or other **mobile method require an organized ambulatory care facility (OACF) license.** An OACF license requires prior Initial Licensure review and recommendation by the Health Services Council pursuant to R.I. Gen. Laws §§ 23-17-14.3 and 23-17-14.4, prior to issuance of the license by the Center for Health Facilities Regulation (CHFR).

There are various ways a healthcare business, like a medical spa or IV therapy business, can be structured. RIDOH, including the professional boards, does not provide advice or guidance on such matters and individuals should seek legal counsel for those questions.

Regardless of the ownership and/or professional license of the medical spa and/or IV therapy business, neither the business nor the business owner is permitted to exercise any control over the manner in which the physician, PA, or CNP provides medical services and must not interfere in the independent exercise of the responsible practitioner's medical judgment.

Standard of Care in Medical Spas and IV Therapy Businesses

Prior to the patient receiving any service or procedure in a medical spa or IV therapy business, the patient must first be assessed by a Rhode Island licensed practitioner[2]. Only the following individuals may diagnose, treat, correct, advise, or prescribe medication (including intravenous fluids) to a person for any human disease, ailment, injury, infirmity, deformity, pain, or other medical condition:

1. A physician licensed to practice allopathic or osteopathic medicine in this state, pursuant to the provisions of R.I. Gen. Laws Chapter 5-37.

[2] For the purpose of this document, the term "practitioner" means physician, physician assistant, and/or certified nurse practitioner.

2. A licensed physician assistant who is qualified by academic and practical training to provide medical and surgical services in collaboration with physicians and pursuant to the provisions of R.I. Gen. Laws Chapter 5-54.
3. A certified nurse practitioner licensed in accordance with R.I. Gen. Laws Chapter 5-34.
    a. **Only family practice CNPs and adult gerontology CNPs are permitted to participate in medical spas and IV therapy businesses.** All other CNP foci are prohibited from participating in medical spas and IV therapy businesses as the procedures are not within their scope of practice and training.
4. A dentist licensed to practice dentistry in the state and pursuant to R.I. Gen. Laws Chapter 5-31.1.
    a. Dentistry, as defined in R.I. Gen. Laws § 5-31.1-1(6), means the evaluation diagnosis, prevention, and/or treatment (nonsurgical, surgical, or related procedures) of diseases, disorders and/or conditions of the oral cavity, cranio-maxillofacial area and/or the adjacent and associated structures and their impact on the human body.

The physician, PA, CNP, or dentist must create a comprehensive medical record that complies with the standard of care. It is critical that the practitioner obtain informed consent and document the consent in the medical record. Informed consent is an educational process involving the patient in shared decision-making during which the practitioner should be able to determine if the patient has the ability to understand relevant medical information and the implications of treatment alternatives and to make an independent, voluntary decision. The practitioner must present relative information accurately and sensitively, in keeping with the patient's preferences for receiving medical information.

In addition to informed consent, the medical record must also include:

1. Patient history;
2. Examination results;
3. Records of drugs (including intravenous fluids) prescribed, dispensed, and/or administered;
4. A diagnosis;
5. The nature and purpose of recommended interventions;
6. The burden, risks, and expected benefits of all options, including foregoing treatment; and
7. Patient's decision.

Medical records must be stored for at least seven years[3].

Some medical spas may try to circumvent the necessity of a physical assessment by a practitioner through the use of standing orders. The issuance of standing orders in this scenario, by a practitioner for a registered nurse (RN) or other provider to follow, does not satisfy the requisite provider-patient relationship. **The use of standing orders for an individualized assessment, diagnosis and treatment of patients is considered unprofessional conduct and can result in disciplinary action on one's license.**

[3] See: https://health.ri.gov/medicalrecords/

Scope of Practice and Standard of Care Requirements for IV Therapy Businesses

The services offered at an IV therapy business fall under the practice of medicine[4] and require an evaluation, diagnosis, and treatment of the patient.

As stated previously, only physicians, physician assistants, and CNPs may diagnose, treat, correct, advise, or prescribe IV medication to a person for any human disease, ailment, injury, infirmity, deformity, pain, or other condition.

It should be noted that emergency medical service practitioners (e.g., EMTS)[5], phlebotomists, licensed practical nurses, nursing assistants, medical assistants, dentists[6], podiatrists, chiropractors, veterinarians, naturopaths, and midwives are unable to provide services in these businesses as **it is outside of their scopes of practice** (i.e., diagnose, treat, prescribe, and/or administer IV fluids)**.**

In certain instances, an RN is the only licensed healthcare provider onsite at an IV therapy business. **The RN is operating outside of their scope of practice if they are diagnosing, prescribing, compounding, and/or treating the patient with IV hydration or therapy.**

While some IV therapy businesses have a physician, PA, and/or CNP owner, co-owner, investor, or associate, it may be that no practitioner evaluates the patient to make a diagnosis and prescribe a specific therapy to treat that diagnosis. Instead, the practitioner may be a "medical director," "consultant," "collaborator," "on staff," or "available" but only an RN assesses and treats the patient. This is insufficient to establish a valid practitioner-patient relationship that is required prior to the prescription and administration of drugs including IV therapies. Only licensed prescribers, namely physicians, PAs, and CNPs (only family practice CNPs or adult gerontology CNPs) can participate in an IV therapy business setting, evaluate the patient, make a diagnosis, and prescribe a treatment.

An appropriately licensed practitioner must first assess the patient (performing a history and physical exam) and document in a written medical record the assessment and plan (e.g., a diagnosis with a valid corresponding treatment regimen)[7]. Ideally, the exam is in person, as a complete medical assessment is difficult to conduct via telemedicine. For example, if a patient has signs of heart failure, listening to the heart and lungs with a stethoscope and looking for pitting edema in the lower extremities is critical, as such evidence would be a contraindication for additional fluids.

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[4] The term "practice of medicine," as used in this document, does *not* hold the same meaning as used in R.I. Gen. Laws § 5-37-1 or the rules and regulations for *Licensure and Discipline of Physicians* (216-RICR-40-05-1).
[5] While emergency medical practitioners can administer IVs, they cannot provide IVs in an IV therapy business as emergency medical service practitioners licensure is "solely in affiliation with an ambulance service currently licensed by RIDOH unless providing care as a Good Samaritan." From the rules and regulations for *Emergency Medical Services,* 216-RICR-20-10-2.
[6] Dentists can provide IV fluids in the normal course of their dental practice. They are prohibited from providing IV fluids in IV therapy businesses.
[7] This is required regardless of whether insurance will be billed for services.

A simple questionnaire without an appropriate clinical assessment (i.e., a history and physical examination) is prohibited and may be considered professional misconduct.

The practitioner must create a comprehensive medical record that complies with the standard of care in the same manner detailed above. IV therapy businesses with a practitioner available via telemedicine must still follow the above requirements for medical records and standard of care.

It is common that when a practitioner is only available via telemedicine, the IV therapy business will utilize the NPI number of a physician, PA, or CNP to acquire necessary supplies and then use standing orders directing the administration of IVs. **The issuance of standing orders for an RN to follow does not satisfy the standard of care by a physician, PA, or CNP; and the use of standing orders for this business model is considered unprofessional conduct and may result in disciplinary action against the licensed independent practitioner.**

IV treatments need to be individualized for patients and prescribed in the same manner as an urgent care center, emergency department, or hospital.

An IV therapy business cannot remove the requirement for practitioner involvement by allowing the patient to direct their own care; and **the practitioner (or nurse) engages in unprofessional conduct by allowing the patient to select their own medications and/or IVs from a menu**.

Compounding

Generally, the operation of an IV therapy business involves walk-in patients being offered a menu of pre-selected mixtures of additives to basic IV fluids (e.g., saline). These mixtures may include amino acids, vitamins, minerals, nutrients, and some medications like famotidine, omeprazole, ibuprofen, or ondansetron. These mixtures are offered to patients, often with catchy names, for the treatment of dehydration, migraines, hangovers, nausea, athletic or postoperative recovery, appetite regulation, and/or inflammation support. In some instances, the IV therapy business may make a "custom" IV mix based on the patient's selection or examination results.

The addition of any drug(s)/medication(s), vitamin(s), mineral(s), amino acid(s,) or other substance to an IV bag is, by law, compounding. Pursuant to the rules and regulations for *Pharmacists, Pharmacies, and Manufacturers, Wholesalers, and Distributors* (216-RICR-40-15-1), compounding is defined as "[t]he act of combining two or more ingredients as a result of a practitioner's prescription or medication order occurring in the course of professional practice based upon the individual needs of a patient and a relationship between the practitioner, patient and pharmacists."

The Food and Drug Administration (FDA) defines compounding as "[t]he process of combining, mixing, or altering ingredients to create a medication tailored to the needs of an individual patient. Compounding includes the combining of two or more drugs."[8] Thus, compounding must

[8] *See*: Drug Compounding and Drug Shortages | FDA (fda.gov)

result from a valid practitioner's order in the course of professional practice and not from a patient-driven menu akin to ordering at a restaurant.

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 RIDOH as the enforceable standard. Furthermore, all compounding is also subject to the requirements outlined in the rules and regulations for *Pharmacists, Pharmacies, and Manufacturers, Wholesalers, and Distributors* (216-RICR-40-15-1).

The USP <797> applies to all persons who prepare compounded sterile preparations (CSPs) and all places where CSPs are prepared for human and animal patients. This includes, but is not limited to, pharmacists, technicians, nurses, physicians, veterinarians, dentists, naturopaths, and chiropractors in all places including, but not limited to, hospitals and other healthcare institutions, medical and surgical patient treatment sites, infusion facilities, pharmacies, and physicians' or veterinarians' practice sites.

Rhode Island law allows pharmacists to compound drugs and oversee trained personnel compounding drugs. Physicians are permitted to compound as well as delegate compounding to other healthcare professionals, provided the compounding occurs under a physician's supervision. Pursuant to the Rules and Regulations for *Licensure and Discipline of Physicians* (216-RICR-40-05-1), physicians are required to follow USP <797> and the rules and regulations for *Pharmacists, Pharmacies, and Manufacturers, Wholesalers and Distributors* (216-RICR-40-15-1) when compounding. **The regular storage, preparation, and compounding of drugs by anyone other than a licensed physician, pharmacist, or pharmacy is prohibited unless licensed by RIDOH in these professions.** IV therapy businesses that elect to compound must have a physician on-site for supervised compounding or have a licensed pharmacy on-site to prepare compounds under the supervision of a pharmacist. The physician or pharmacist supervising the compounding must be on-site; remote supervision of compounding is prohibited. An IV therapy business that does not prepare their own compounds may receive compounds from a licensed pharmacy or a federally registered outsourcing facility (i.e., 503B Outsourcing Facility).

The USP <797> "immediate use" provision governs the emergency preparation of a sterile drug product, and in certain circumstances, this provision allows for the preparation of a sterile product to be made outside of full USP compliance. In some cases, IV therapy businesses have been interpreting the concept of "immediate use" to allow the compounding of IVs to circumvent USP requirements, especially for sterility and training. The "immediate use" provision is not a workaround for the quality and safety standards that govern sterile product preparation. Walk-in or concierge IV therapy services do not fall under USP <797> "immediate use" definition.

Scope of Practice in Medical Spas and IV Therapy Businesses

Scope of practice for professions can be found in R.I. laws and regulations promulgated by RIDOH. With the development of new technologies and procedures, RIDOH relies heavily on the professional boards to advise on what new procedures fall within the scope of practice of each licensee.

The following chart is a visual of common procedures that are performed in medical spas and IV therapy businesses that RIDOH and the respective boards have determined are within each licensee's scope of practice, provided that such licensee has the requisite training and experience**. This list is not exhaustive and any questions about procedures not listed should be directed to the applicable board and/or to RIDOH.**

	Physician[1]	PA[1,2]	CNP[1,3]	Pharmacist	Dentist[1]	RN	LPN	Electrologist	Esthetician	Tattoo Artist	Permanent Makeup Artist
Body Sculpting	Yes	No	No	No	No	No	No	No	No	No	No
Chemical Peels	Yes	Yes	Yes	No	No	No	No	No	Yes[7]	No	No
Cryolipolysis (Cool Sculpting)	Yes	No	No	No	No	No	No	No	No	No	No
Dermal Filler	Yes	Yes	Yes	Yes[4]	Yes	No	No	No	No	No	No
Dermaplaning	Yes	Yes	Yes	No	No	No	No	No	No	No	No
Hair Transplant	Yes	Yes	No	No	No	No	No	No	No	No	No
Inkless Stretch Mark Revision	Yes	Yes	No	No	No	No	No	No	No	Yes	Yes
Intravenous Fluids	Yes	Yes	Yes	No	No[5]	Yes[1,4]	No	No	No	No	No
Laser Hair Removal	Yes	Yes	Yes	No	No	No	No	Yes[6]	No	No	No
Laser Tattoo Removal	Yes	Yes	No	No	No	No	No	No	No	No	No
Liposuction	Yes	No	No	No	No	No	No	No	No	No	No
Microblading	Yes	Yes	No	No	No	No	No	No	No	Yes	Yes
Micro Channeling	Yes	Yes	Yes	No	No	No	No	No	No	No	No
Microneedling	Yes	Yes	No	No	No	No	No	No	No	No	No
Neuromodulators (Botox)	Yes	Yes	Yes	Yes[4]	Yes	No	No	No	No	No	No
Oxygen Therapy	Yes	Yes	Yes	No	No[5]	Yes[1,4]	Yes[1,4]	No	No	No	No
Platelet-Rich Fibrin	Yes	No	No	No	No[5]	No	No	No	No	No	No
Platelet Rich Plasma	Yes	No	No	No	No[5]	No	No	No	No	No	No
Pulsed Intense Light	Yes	Yes	No	No	No	No	No	No	No	No	No
Radio Frequency	Yes	Yes	No	No	No	No	No	No	Yes	No	No
Saline Tattoo Removal	Yes	Yes	Yes	No	No	No	No	No	No	Yes	Yes

1. Must have appropriate training in these procedures.
2. In collaboration with a physician.
3. Family practice CNPs and adult gerontology CNPs only.
4. Must have a valid prescription by a physician, PA, or CNP.
5. Dentists can provide this procedure during the course of normal dental work; however, dentists cannot perform such procedure in a medical spa and/or IV therapy businesses.
6. Must meet training requirements in accordance with R.I. Gen. Laws 5-32-21
7. The acidity of the chemical peel cannot exceed 30%.

Ablative lasers or ablative energy devices are intended to excise or vaporize the outer layer of skin. These procedures should only be performed by a physician or delegated to an appropriately trained PA, with training and experience in the use of these devices. Examples of ablative lasers include carbon dioxide (CO_2) lasers and erbium lasers.

Body sculpting (also known as body contouring) is the use of non-invasive means to change the shape of an area of the body. This includes the use of very cold temperatures, heat, laser, red light or radiofrequency energy to destroy fat cells. This includes the use of Zerona®, truSculpt®, CoolSculpting®, ScupltSure®, EMSCULPT neo®, Morpheus8 Body, Vanquish RF and other devices.

Chemical Peels means a procedure in which a chemical solution is applied to the skin to remove the top layers. Chemical peels are used to treat wrinkles, discolored skin, and scars. They can be done at different depths from light to deep. Deeper chemical peels offer more dramatic results but also require a longer recovery period.

Cryolipolysis, also known as "CoolSculpting®" means the use of very cold temperature to break down fat cells.

Dermal Filler means injection of synthetic substances (e.g., hyaluronic acid, calcium hydroxyapatite, polymethylmethacrylate, Poly-L-lactic acid), collagen, or fat in order to increase the amount of collagen in a body area.

Dermaplaning is a treatment in which dead skin cells and peach fuzz are scraped off with a scalpel.

Hair Transplant means the surgical technique that removes hair follicles from one part of the body, called the "doner site", to a bald or balding part of the body known as the "recipient site."

Hyaluron pens are prohibited for use. They have not been approved by the Food and Drug Administration and are not for legal sale in the United States.

Inkless stretchmark revision means a procedure that involves injecting a serum and/or vitamins into the dermis layer of the skin using a tattoo needle, causing microabrasions. It is also known as dry tattooing, medical needling, inkless needling, and MCA needling.[9] This process may also be used to improve the appearance of scars.

Intravenous Fluids means injecting liquids to a person through a vein. This includes providing stock intravenous (IV) fluids (e.g., 0.9% normal saline, lactated Ringer's solutions) with or without the addition of vitamins, minerals, amino acids, medications, etc. Intravenous fluids are, by law, drugs that must be prescribed by a licensed independent practitioner (physician, physician assistant, or CNP) for a specific patient with a specific diagnosis for which the IV fluids are indicated.

[9] A tattoo is defined as inserting a colored ink into the skin through a needle to mark or color the skin by introduction of non-toxic dyes or pigments into the skin. From the rules and regulations for *Tattoo Artists and Tattoo Parlors*, 216-RICR-40-10-16.

Laser Hair Removal means using a non-ablative laser to perform hair removal or reduction. It differs from electrolysis, which is the use of an electric current to destroy hair follicles.

Laser tattoo removal means a procedure that uses laser light energy to break up tattoo pigment into small particles in which the body's immune system clears over time.

Liposuction means a cosmetic surgical procedure for removing excess fat from under the skin by suction.

Microblading means a semipermanent eyebrow tattooing procedure which uses a handheld tool with tiny needles to inject pigment into the skin.

Micro Channeling means the use of ultra-fine needles to inject customized serums (often containing dermal fillers, platelet rich plasma, and/or Botox) directly into the skin.

Microneedling means the use of thin needles to make tiny holes in the top layer of skin. The damage helps stimulate the skin's healing process, so it produces more collagen and elastin (proteins that keep skin firm and smooth).

Neuromodulators (Botox) means a wrinkle-relaxing injection of botulinum toxin, commercially known as Botox Cosmetic, Dysport, Xeomin, or Jeuveau – that are used to treat wrinkles, frown lines, and crow's feet.

Non-Ablative Lasers, light treatments and energy device treatments that do not excise or vaporize the outer layer of skin, may be provided by a physician or delegated to an appropriately trained CNP or PA with training and experience in these treatments. Laser hair removal uses a non-ablative laser. An electrologist who has completed training pursuant to R.I. Gen. Laws § 5-32-21 may perform laser hair removal without physician supervision.

Oxygen Therapy means the provision of supplemental oxygen.

Platelet Rich Fibrin (PRF) means the process of harvesting one's blood and mixing it with a protein matrix called fibrin. The mixture then is turned into a gel made up of a high concentration of white blood cells, fibrin, and stem cells (growth factors) and injected into other areas of the body.

Platelet Rich Plasma (PRP) means the process of harvesting one's blood, centrifuging it to separate platelets and plasma from other blood cells and injecting the platelets and plasma back into the body.

Pulsed Intense Light means the use of light energy of multiple wavelengths to remove pigmented skin areas including age spots, facial telangiectasia (broken blood vessels), freckles, and birthmarks by focusing the energy into the dermis.

Radio Frequency means a non-surgical skin tightening procedure involving an electromagnetic device that generates heat to stimulate the production of collagen, elastin, and new skin cells.

Saline tattoo removal means injecting saline into an existing tattoo in order to dissolve the ink. This procedure may only be performed by tattoo artists and permanent makeup artists.

Any license type not listed above, such as nursing assistants, emergency medical service practitioners (e.g., EMTs)[10], optometrists, veterinarians, or hairdressers cannot perform any of the above medical procedures as they are not within their scopes of practice.

Persons with no professional licensing are prohibited from performing any medical procedures. **A course certificate of completion for any of the above procedures does not constitute a license**. Performing any medical procedures without a license may subject an individual to fines and/or civil or criminal penalties.

[10] While some of these procedures can be performed by emergency medical service practitioners, they cannot provide services in a medical spa setting, as emergency medical service practitioners licensure is "solely in affiliation with an ambulance service currently licensed by RIDOH unless providing care as a Good Samaritan." From the rules and regulations for *Emergency Medical Services*, 216-RICR-20-10-2.

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JOINT ADVISORY OPINION OF THE SOUTH CAROLINA STATE BOARDS OF MEDICAL EXAMINERS, PHARMACY, AND NURSING REGARDING RETAIL IV THERAPY BUSINESSES

The retail IV therapy business model is growing in South Carolina and across the country. Currently, there are no set rules or guidelines that specifically guide their operation, which often touches on areas of medicine, nursing, and pharmacy.[1] Because of the concern over the proliferation of IV therapy businesses, the lack of any industry-specific guidelines or laws regarding the operation of these businesses, and the potential harm to the residents of South Carolina, the South Carolina Board of Medical Examiners, the South Carolina Board of Pharmacy, and the South Carolina Board of Nursing (collectively the "Boards") put forth this advisory opinion. This advisory opinion is based upon the existing laws of South Carolina and sets forth the relevant laws and standards of care implicated by IV therapy businesses.[2]

At its core, the IV retail business model involves the offering to walk-in patients of a menu of pre-selected mixtures ("cocktails") of additives to basic IV saline. The cocktails may include amino acids, vitamins, minerals, and some prescription drugs like Pepcid, Toradol, and Zofran.[3] They are sometimes marketed with catchy names and are offered to patients for the treatment of conditions such as dehydration, migraines, hangovers, nausea, athletic recovery, appetite regulation, and inflammation support. Some basic health screening generally occurs prior to the selection and administration of the IV.

Additionally, there are reports that many of these IV therapy businesses are owned and/or operated by registered nurses, EMTS, or by business entities that are not owned by physicians, physician assistants, or nurse practitioners, certified nurse midwives, or clinical nurse specialists (collectively "APRNs").

Furthermore, there are reports that while a physician, PA, NP, or APRN[4] may be associated with the business, in many cases he or she is not on the premises; rather, in many instances, there is only an RN on the premises. In order to obtain their IV supplies and additives, retail IV therapy business are using a physician's National Practitioner Identification ("NPI") number to acquire the IV supplies and additives. A physician, PA, or APRN will then issue "standing orders" directing the administration of IVs. The actual patient encounter, evaluation, diagnosis, formulation of the

[1] The Boards acknowledge and appreciate the Alabama Board of Medical Examiners for addressing many of these issues in its excellent and well-reasoned Declaratory Ruling dated July 21, 2022. The Boards find the issues raised by the Alabama Board of Medical Examiners are also an accurate representation of current IV practice in South Carolina.
[2] This Joint Position Statement is not meant to modify, supplement, or overrule existing protocols and practices in licensed healthcare facilities.
[3] This list is not intended to be exhaustive, only illustrative, and has no bearing on the guidance offered herein.
[4] "APRN" is used throughout to refer to NPs, CNSs, and CNMs, but not CRNAs, as CRNAs do not have prescriptive authority in South Carolina. In an IV clinic, a CRNA can only function as an RN and must follow those rules applicable to RNs.

treatment plan, and administration of the IV may occur without input from the physician, PA, NP, or APRN. In many instances, the RN may be the only licensed health care professional interacting with the patient or present at the facility. **These scenarios are unacceptable and unlawful** and have led the Boards to become increasingly concerned about whether qualified individuals are administering these IVs based upon their statutorily-defined scopes of practice and are complying with all of the laws governing the practice medicine, nursing, and pharmacy.

South Carolina Board of Medical Examiners and the Medical Practice Act

The South Carolina Board of Medical Examiners ("SCBME") is concerned that the unlicensed practice of medicine may be occurring in these IV clinics or that practitioners are not in full compliance with the Medical Practice Act.

There is no question that the services being provided by IV retail clinics constitutes the practice of medicine. The practice of medicine in this State includes (1) offering or undertaking to prescribe, order, give, or administer any drug or medicine for the use of any other person, (2) offering or undertaking to prevent or to diagnose, correct or treat in any manner, or by any means, methods, or devices, disease, illness, pain, wound, fracture, infirmity, defect, or abnormal physical or mental condition of a person, and (3) rendering a determination of medical necessity or a decision affecting the diagnosis and/or treatment of a patient. S.C. Code Ann. § 40-47-20(36) (2011).

Only the following individuals may diagnose, treat, correct, advise, or prescribe intravenous medication to a person for any human disease, ailment, injury, infirmity, deformity, pain, or other condition: (1) a physician licensed under Title 40, Chapter 47; (2) a physician assistant, licensed under Title 40, Chapter 47, and practicing pursuant to approved scopes of practice and with a supervising physician; or (3) a nurse practitioner, certified nurse midwife, or clinical nurse specialist licensed pursuant to Title 40, Chapter 33, who has prescriptive authority, and who is practicing pursuant to a collaboration agreement with a licensed physician.

Any person who maintains an office or place of business for the purpose of diagnosing, treating, correcting, advising, or prescribing intravenous medication to a person for any human disease, ailment, injury, infirmity, deformity, pain, or other condition is engaged in the unlawful practice of medicine unless said person (1) employs a physician, a PA, or APRN working with a supervising/collaborating physician, and (2) the physician, PA, or APRN exercises exclusive authority to diagnose, treat, correct, advise, and/or prescribe intravenous medication to a person for any disease, ailment, injury, infirmity, deformity, pain, or other condition. These practitioners must have prescriptive authority that allows them to lawfully prescribe the medications being ordered.

In a common scenario, a patient enters the business and reviews a menu of treatment options. He or she completes a health questionnaire and is assessed by an RN.[5] This RN may use diagnostic tools to measure the patient's pulse oximetry, heart rate, and blood pressure. The RN evaluates the patient's answers to the health questionnaire, which is designed to elicit the patient's health history,

[5] The SCBME is also aware that in some IV hydration clinics, EMTs or paramedics are being used to perform these procedures. This is also outside the scope of an EMT or paramedic and also constitutes the unlicensed practice of medicine, nursing, and/or pharmacy.

current medications, and allergies. With this information in hand, the RN will discuss the patient's current symptoms and treatment goals and recommend an IV cocktail, along with any additives that may be indicated.

In some cases, the RN may make the recommendations with the assistance of standing orders prepared by a physician. In other cases, there may be no standing order at all. The RN mixes the IV bag according to the RN's recommendations and the patient's selection. The RN then administers the IV therapy. The RN remains with the patient to assess the patient's treatment and observe any complications. Once the IV therapy is complete, the RN removes the IV catheter and applies a dressing. The patient is then discharged. **In this scenario, the RN, or any other person who is not a licensed practitioner, is practicing medicine without a license, and is jeopardizing patient safety.**

First, the diagnosis of the patient's condition and the recommendation of IV therapy constitutes the practice of medicine. This act is outside the scope of practice for an RN. Only a physician, PA, or APRN has the statutory authority to diagnose a patient and to make the decision to provide medication, by injection or otherwise, to a patient. *See* S.C. Code Ann. § 40-47-20-(36)(c) (2011) (the practice of medicine means "offering to diagnose…any illness [or] infirmity…").

Second, the discussion with the patient and recommendation of an IV and additives thereto, including "cocktails" and prescription drugs, are also outside the scope of practice of an RN. Only a licensed physician, PA, or APRN may diagnose a patient, assess his or her symptoms, and recommend IV treatment for the patient's condition. *See* S.C. Code Ann. § 40-47-20(36)(b), (c), and (f) ("rendering a determination of medical necessity or a decision affecting the diagnosis and/or treatment of a patient" is the practice of medicine).

While some retail IV therapy businesses have a physician owner, co-owner, investor, or associate, it has been reported that the physician or another licensed practitioner may not actually evaluate the patient. Instead, a physician, PA, or APRN may be "a medical director," "on staff," or "available," but only the RN treats the patient, aside from the patient's specific request for medications. This is insufficient to establish a valid practitioner-patient relationship, which is required before the administration of prescribed drugs.[6] *See* S.C. Code Ann. § 40-47-113 (2011).[7]

Without an evaluation by a physician or practitioner to create a physician-patient relationship, the RN is dispensing medical supplies and medications to a person who is not the physician's patient. Failure of a physician, PA, or APRN to comply with section 40-47-113 constitutes unprofessional conduct and can subject the practitioners to disciplinary action. Moreover, an RN undertaking these steps in diagnosing and prescribing medications is outside the scope of the practice for an RN, and can subject an RN to disciplinary action by the SCBME for practicing medicine without

[6] This scenario also implicates, and potentially violates, multiple provisions of the Pharmacy Act.

[7] South Carolina Code § 40-47-113 states: "It is unprofessional conduct for a licensee initially to prescribe drugs to an individual without first establishing a proper physician-patient relationship. A proper relationship, at a minimum, requires that the licensee make an informed medical judgment based on the circumstances of the situation and on the licensee's training and experience and that the licensee: (1) personally perform and document an appropriate history and physical examination, make a diagnosis, and formulate a therapeutic plan; (2) discuss with the patient the diagnosis and the evidence for it, and the risks and benefits of various treatment options; and (3) ensure the availability of the licensee or coverage for the patient for appropriate follow-up care."

a license, or disciplinary action by the Board of Nursing for performing acts outside the scope of an RN.

Some IV retail facilities attempt to get around the requirement that a patient be seen by a physician, PA, or APRN, and receive an assessment, diagnosis, and prescription through the use of "standing orders." The issuance of standing orders in this scenario by a practitioner for the RN to follow does not satisfy the physician's legal duties to the patient. Nor does it satisfy a PA's or APRN's duty to the patient. The use of standing orders in what is supposed to be an individualized assessment, diagnosis, and treatment of patients at a retail IV therapy business creates a situation in which the physician is aiding and abetting the unlawful practice of medicine by the RN, in violation of S.C. Code Ann. § 40-47-200.[8] This practice of using standing orders and dispensing of medications by an RN also implicates the Pharmacy Act, as discussed below.

The SCBME further finds that the participation of the patient in the selection of the IV additives does not change the analysis. A patient is not licensed to practice medicine. A patient cannot enter a doctor's office or hospital and demand an IV any more than a patient can direct his or her own appendectomy. Even physicians are prohibited from treating themselves except in emergency situations. *See* S.C. Code Ann. § 40-47-630(6) (violating code of ethics is grounds for disciplinary action); *see also* AMA Code of Medical Ethics Opinion 1.2.1.[9] A retail IV therapy business cannot obviate the need for practitioner involvement by letting the patient direct their own care, and the practitioner is abandoning his or her obligations to the patient by allowing the patient to select their own medications.

To comply with the South Carolina Medical Practice Act, retail IV therapy businesses must create a practitioner-patient relationship through the performance of an individualized evaluation by a physician, PA, or APRN working under the supervision of or in collaboration with a physician. The PA must have an appropriate supervising physician and must have an appropriate scope of practice on file with the SCBME. The APRN must have an appropriate collaborating physician and have a written practice agreement that allows these activities. The physician, PA, or APRN must have the appropriate prescriptive authority.

The physician, PA, or APRN must personally evaluate the patient, diagnose the patient, and make the treatment recommendations. The physician, PA, or APRN must further create a comprehensive medical record that complies with the standard of care. If the physician, PA, or APRN decides to prescribe IV therapy, he or she must issue a prescription, and only then may the IV therapy be administered. It is the obligation of the physician, PA, or APRN to exercise their medical judgment in determining that the treatment will actually benefit the patient. A licensed person other than the physician, PA, or APRN may administer the IV only if administration of IVs is within that licensee's scope of practice.

[8] "A person who practices or offers to practice medicine in this State in violation of this chapter…is guilty of a misdemeanor and, upon conviction, must be imprisoned not more than one year or fined not more than fifty thousand dollars. … The provisions of this chapter apply to a person or entity aiding and abetting in a violation of this chapter." S.C. Code Ann. § 40-47-200 (2011).

[9] The SCBME has steadfastly maintained that a physician cannot establish a physician-patient relationship with one's self based upon the law. *See* Position Statement found at https://llr.sc.gov/med/Policies/MEPRESCRIBEFAM.aspx.

In addition to creating a comprehensive medical record that complies with the standard of care, the practitioner must obtain informed consent and document it in the medical record prior to the delivery of care. It is important to recognize that obtaining informed consent is an educational process involving the patient in shared decision-making. In obtaining informed consent, the health care provider should assess the patient's ability to understand relevant medical information and the implications of treatment alternatives and to make an independent, voluntary decision and present relevant information accurately and sensitively, in keeping with the patient's preferences for receiving medical information. Information should include: (1) the diagnosis, (2) the nature and purpose of recommended interventions, (3) the burdens, risks, and expected benefits of all options, including forgoing treatment, (4) document the informed consent conversation, or written consent, and (5) the patient's decision in the medical record in some manner.

Pursuant to the South Carolina Physicians' Patient Records Act, medical records must be retained for at least ten years for adult patients and at least thirteen years for minors. These minimum recordkeeping periods begin to run from the last date of treatment. After these minimum recordkeeping periods, the records may be destroyed. S.C. Code Ann. § 44-115-120 (2018). Records must be maintained and destroyed in compliance with HIPAA.

Regardless of the corporate makeup of the IV therapy retailer, neither the business nor the business owner is permitted to exercise any control over the manner in which the physicians provide medical services and must not interfere in the independent exercise of the practitioners' medical judgment. Whether a business is illegally practicing medicine, or whether a practitioner is illegally aiding and abetting the unlicensed practice of medicine by the business, is a fact-intensive inquiry. However, due to the presence of business owners, franchisors and franchisees, and investors in the corporate makeup of retail IV therapy, physicians are cautioned to understand the SCBME's regulations and South Carolina law before entering employment or partnership with these and similar businesses.

Telemedicine

The relationship between a practitioner and patient may be established via telemedicine in accordance with South Carolina Code § 40-47-37. Pursuant to this section, a licensee who establishes a physician-patient relationship solely via telemedicine shall adhere to the same standard of care as a licensee employing more traditional in-person medical care and be evaluated according to the standard of care applicable to the licensee's area of specialty. A licensee shall not establish a practitioner-patient relationship by telemedicine for the purpose of prescribing medication when an in-person physical examination is necessary for diagnosis. The failure to conform to the appropriate standard of care is considered unprofessional conduct under South Carolina Code § 40-47-110(B)(9).

Under current South Carolina law, Schedule II or Schedule III medications (narcotic or non-narcotic) may not be prescribed or administered via solely a telemedicine visit and require an in-person visit by a licensed prescriber. S.C. Code Ann. § 40-47-(C)(6) (2011).

Establishing a practitioner-patient relationship solely via telemedicine does not relieve the practitioner of responsibility for generating and maintaining medical records for each patient using

such telemedicine services in compliance with any applicable state and federal laws, rules, and regulations.

A licensee who establishes a practitioner-patient relationship solely via telemedicine shall be responsible for providing an appropriate evaluation prior to diagnosing and/or treating the patient. The practitioner must employ technology sufficient to accurately diagnose and treat the patient in conformity with the applicable standard of care. A practitioner shall establish a diagnosis through the use of accepted medical practices, which may include patient history, mental status evaluation, physical examination, and appropriate diagnostic and laboratory testing in conformity with the applicable standard of care. Additionally, a practitioner must ensure the availability of appropriate follow-up care and maintain a complete medical record that is available to the patient and other treating health care practitioners.

A simple questionnaire without an appropriate evaluation is prohibited and considered misconduct. S.C. Code Ann. § 40-47-37(C)(2) (2011).

South Carolina Board of Pharmacy and the Pharmacy Practice Act
IV Hydration and Compounding

As noted from the outset, the Boards involved in regulating IV therapy clinics have become increasingly concerned about whether qualified licensed individuals are administering IV medications based upon the statutorily-defined scopes of practice. The Board of Pharmacy has received numerous inquiries regarding IV hydration therapy by non-practitioners and is troubled about the safety of this practice.[10] These IV clinics implicate multiple areas of the Pharmacy Practice Act, including compounding, dispensing, storage, and administration of what is required to be sterile products. The compounding, dispensing, storing, and administration of sterile products is not a benign and risk-free activity as is often advertised.

"Practice of pharmacy" means, among other things, the responsibility for compounding and labeling of drugs and devices. *See* S.C. Code Ann. § 40-43-30(73) (2011). In addition, South Carolina Code § 40-43-30(67) defines a pharmacist as the individual health care provider licensed by this State to engage in the practice of pharmacy. The Board of Pharmacy has become aware of numerous individuals taking on this role who are not pharmacists and/or practitioners either licensed under the Pharmacy Practice Act or exempt from it.

Whether they realize it or not, by adding drugs or vitamins to the IV bag, these individuals at IV therapy clinics are performing compounding.[11] South Carolina law defines compounding as "…the preparation, mixing, assembling, packaging, or labeling of a drug or device as the result of a practitioner's prescription drug order or initiative based on the practitioner/patient/pharmacist relationship in the course of professional practice...." S.C. Code Ann. § 40-43-30(15) (2011). At the federal level, the Food and Drug Administration (FDA) defines compounding as "the process of combining, mixing, or altering ingredients to create a medication tailored to the needs of an

[10] *See* S.C. Code Ann. § 40-47-20(37) (2011) (defining practitioner).
[11] Sterile compounding does not include "mixing, reconstituting, or other such acts with nonhazardous agents that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer for immediate use." *Id*.

individual patient. Compounding includes the combining of two or more drugs."[12] Thus, compounding must result from a valid practitioner's order in the course of professional practice, and not from a patient-driven menu akin to a fast-food restaurant.

Compounding is the responsibility of a licensed pharmacist. Because of this requirement, a Board of Pharmacy permit is required for any entity that stores and/or administers any legend medications, including those administered at IV hydration clinics. The **only** exception to this permitting requirement is where an entity is 100% practitioner owned (MD, DO, APRN, PA); if the facility is 100% practitioner-owned, a pharmacy permit is not required. Non-practitioners, including but not limited to RNs, EMTs, and LPNs, may not possess and/or store legend medications of any type without a suitable permit for the respective facility (e.g., non-drug dispensing outlet permit). This prohibition includes overnight storage in any non-permitted location, including but not limited to a home or vehicle.

In relation to pharmaceutical compounding, USP (United States Pharmacopeia) is the recognized standard of care in relation to all things compounding, to include sterile compounding found in USP General Chapter <797>, and has been adopted by the FDA as the enforceable standard. Furthermore, all sterile compounding is subject to the requirements outlined in South Carolina Code § 40-43-88.

For purposes of General Chapter <797>, sterile compounding is defined as combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance to create a sterile medication. This chapter applies to all persons who prepare compounded sterile preparations (CSPs) and all places where CSPs are prepared for human and animal patients. This includes, but is not limited to, pharmacists, technicians, nurses, physicians, veterinarians, dentists, naturopaths, and chiropractors in all places including, but not limited to, hospitals and other healthcare institutions, medical and surgical patient treatment sites, infusion facilities, pharmacies, and physicians' or veterinarian practice sites.[13]

Also, of concern to the Board of Pharmacy is that the concept of "immediate use" is being interpreted to allow the compounding of IVs to circumvent USP requirements, especially for sterility and training. Current USP <797>'s "immediate use" provision governs the emergency preparation of a sterile drug product, and in certain circumstances, this provision allows for the preparation of a sterile product to be made outside of full USP compliance. This provision is not a workaround for the quality and safety standards that govern sterile product preparation. Walk-in or concierge intravenous therapy services do not fall into this provision.

South Carolina Board of Nursing and the Nurse Practice Act

The South Carolina Board of Nursing joins with the South Carolina Board of Medical Examiners and South Carolina Board of Pharmacy in their concern in the rise of retail IV therapy businesses and the perception that many participants are working outside the confines of the rules and regulations of the Boards. Specifically, the Board of Nursing is concerned that nursing licensees

[12] https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers
[13] https://www.usp.org/compounding/general-chapter-797

participating in retail IV therapy may be practicing beyond their scope and without the proper steps in place to ensure safe and legal administration.

IV therapy is a complex, learned skill. RNs and APRNs choosing to provide this therapy must ensure they are properly educated and fully compliant with all of requirements from the South Carolina Boards of Nursing, Medical Examiners and Pharmacy.

LPNs

It is outside the scope for LPNs to participate in retail IV hydration and vitamin infusion therapy.

RNs

An RN can only administer intravenous fluids, nutrient therapies, vitamin infusions, and medications after obtaining a valid prescription that was issued by a physician, PA, or APRN. The prescription or order must be part of a medically prescribed plan of care that includes a personal examination and a bona fide patient relationship. "Standing orders" are insufficient, as they are not client-specific and do not account for the individual health needs of patients. The Nurse Practice Act, South Carolina Code § 40-33-20(4) defines "administration of medications" as the acts of preparing and giving drugs in accordance with the orders of a licensed, authorized nurse practitioner, certified nurse-midwife, clinical nurse specialist, or a physician, dentist, or other authorized licensed provider as to drug, dosage, route, and frequency.[14] An RN cannot order IV hydration fluids and cannot determine the dosage, route or frequency.

As detailed above in the SCBME section, discussion with the patient and recommendation of an IV and/or the additives to the IV, including "cocktails" and prescription drugs, is considered to be the practice of medicine and is therefore outside the scope of practice of an RN. The "practice of Medicine" is defined as "…(b) offering or undertaking to prescribe, order, give, or administer any drug or medicine for the use of any other person; (c) offering or undertaking to prevent or to diagnose, correct or treat in any manner, or by any means, methods, or devices, disease, illness, pain, wound, fracture, infirmity, defect, or abnormal physical or mental condition of a person, including the management of pregnancy and parturition." S.C. Code Ann. § 40-47-20(36).

A RN does not require the on-site presence of a physician, PA, or NP to administer the prescribed/ordered IV hydration; however, the RN must have the knowledge, skill, and competency necessary to carry out the administration procedures and monitor the client in a safe manner. An RN should perform a nursing assessment of the patient to include vital signs. An RN should monitor the patient while the patient undergoes the IV administration. The RN should monitor the patient for such things as side effects, toxic effects, allergic reactions, unusual and unexpected effects, changes in a client's condition that contraindicate continued administration of the pharmaceutical or treatment regimen, those effects that may rapidly endanger a client's life or

[14] *See also* South Carolina Code § 40-33-20(48)(f), which states that the practice of registered nursing includes, but is not limited to administering and delivering medications and treatments prescribed by an authorized licensed provider. This section does not include diagnosing patients as being within the practice of nursing.

well-being, and must be prepared to make judgments and decisions concerning actions to take in the event such effects occur.

An RN is expected to document all nursing acts performed by the RN in carrying out the IV administration and noted during the monitoring of the patient during administration.

It is not within the scope of an RN to compound drugs, as noted by the Board of Pharmacy above. An RN owner/operator of an IV therapy clinic may not store any medications without a suitable permit from the Board of Pharmacy. A non-dispensing drug outlet permit is required, and the medications can only be stored at the permitted site. Storing these medications in a home or a vehicle is prohibited. Additionally, one of the statutory requirements of a non-dispensing drug outlet permit is the requirement to have a consultant pharmacist.

APRNs

APRNs are held to the same standard as a physician or PA working in a retail IV hydration environment. An APRN must have the appropriate prescriptive authority in order to prescribe medications under South Carolina law and in accordance with the standards set forth in this opinion.[15]

APRNs should carefully review the SCBME portion of this opinion to understand their obligations while working in an IV therapy clinic. An APRN must also include retail IV hydration as part of their collaborative agreement prior to undertaking this role.

CONCLUSION

Despite the proliferation of IV hydration clinics around the state, the diagnosis of a condition that results in the ordering of IV-delivered drugs, amino acids, or vitamins is unambiguously the practice of medicine. Likewise, the storage and administration of these medications constitutes both the practice of pharmacy and the practice of nursing. Failure to be licensed by the Boards as required is a violation of South Carolina law and can be punished by potentially up to a year in prison or a fifty thousand dollar fine.[16] Unlicensed practice may also be enjoined by the South Carolina Administrative Law Court, with future violations of an injunction potentially resulting in contempt proceedings that may include monetary sanctions and/or jail time. Meanwhile, failures by licensees to follow the laws governing their practice(s) could result in disciplinary proceedings and sanctions by their respective boards; by law, sanctions may include monetary fines, probation of a license, suspension of a license, or even revocation of a license, as set forth in each of the practice acts.

Most important, however, is the safety of the members of the public who seek IV treatment through these clinics. Public safety is the mission of each of the Boards, as charged by the Legislature.

[15] CRNAs, by law, lack prescriptive authority.

[16] "A person who practices or offers to practice a regulated profession or occupation in this State in violation of this article or who knowingly submits false information for the purpose of obtaining a license is guilty of a misdemeanor and, upon conviction, must be imprisoned not more than one year or fined not more than fifty thousand dollars." South Carolina Code Ann. § 40-1-200 (2011).

Patients must be evaluated by an appropriate practitioner. The IV medications must be compounded or stored in a safe and sterile environment. Administration of the IV must be done by those with the education, training, and skills to do so. Each of these roles in the process requires that the individual be licensed and requires them to carry out their obligations in the same manner that is required of them for any other task within their scope of practice. Each of the Boards is dedicated to ensuring the law in these areas of practice is followed, as that is how the public is best protected.

Est. 1917
South Dakota Board of Nursing
SDBON

SOUTH DAKOTA BOARD OF NURSING

4305 S. Louise Ave., Suite 201 **I** Sioux Falls, SD 57106-3115
605-362-2760 **I** **https://doh.sd.gov/boards/nursing/**

Elective IV Infusion and Medication Therapy Guidelines

The South Dakota Board of Nursing is authorized by the state of South Dakota, pursuant to SDCL 36-9-1.1, to safeguard life, health and the public welfare; and to protect citizens from unauthorized, unqualified and improper application of nursing practices.

The South Dakota Board of Nursing issues opinions as to what constitutes safe nursing practice. As such, an opinion is not a regulation of the Board and does not have the force and effect of law. An opinion is issued as a guideline to licensees who wish to engage in safe nursing practice, and to facilitate the delivery of safe, effective nursing care to the public.

Approval Date: November 9, 2022

The following guidelines are intended to promote safe care. Licensed nurses and institutions are encouraged to also refer to other national standards of practice and evidence-based literature to identify additional guidelines or considerations specific to a practice setting or patient population served.

Practice Statement:

The South Dakota Board of Nursing affirms that it is within the scope of practice of a licensed nurse to administer intravenous (IV) therapy/hydration and medications, including drugs, substances, or additives such as vitamins, minerals, or electrolytes, for medical or wellness reasons, commensurate with each nurse's licensure, scope, educational preparation, and experience, to "implement nursing care through the execution of regimens requested, ordered, or prescribed by an authorized health care provider", pursuant to SDCL 36-9-3, 36-9-4, and ARSD 20:48.

The registered nurse (RN) or licensed practical nurse (LPN) who initiates any form of order, including standing order, protocol, prescription, or regimen, must act within the scope of the Nurse Practice Act (NPA), SDCL chapters 36-9 and ARSD 20:48, and any other applicable local, state, or federal laws.

The NPA does not authorize an LPN or RN to engage in acts that require independent medical judgment, medical diagnosis, or the ordering or prescribing of medications or therapeutic regimens. An LPN or RN must have a medical order to administer medication or IV therapy/hydration, including elective services provided at the request of a client in a non-traditional setting.

The licensee is personally responsible for the actions that the licensee performs relating to the nursing care furnished to clients and cannot avoid this responsibility by accepting the orders or directions of another person.

Written Protocol or Standing Order Guidelines:

Protocols are written instructions or orders for procedures prepared by an authorized medical provider.

- The protocol provides authority and defines a plan of medical/wellness care for use with clients who have not been previously examined or evaluated by an authorized medical provider for that condition.
- The protocol should be developed and designed for a client population with a specific health disorder, set of symptoms, or wellness need.
- The protocol should provide clear instructions on procedures or interventions that the nurse can follow, without using medical judgment, to assure that the procedures are carried out correctly and safely.

Protocols or standing orders at a minimum, should:

1. Be in writing, dated, and signed by the authorized medical provider;
2. Specify which acts require a particular level of training or licensure and under what circumstances they are to be performed;
3. Specify any experience, training, and/or education requirements for those persons who shall perform the procedures;

4. Contain specific health history and assessment data to collect, the contraindications for treatment, and circumstances on when to consult with the medical provider;
5. State specific requirements which are to be followed by persons performing the procedures;
6. Be reviewed annually and updated according to accepted medical practice standards.

Healthcare Provider Guidelines:

A. Authorized Medical Provider Role:

A legally authorized medical provider, acting within their scope, is responsible to write an order for the administration of intravenous (IV) therapy/hydration and medications, including drugs, substances, or additives such as vitamins, minerals, or electrolytes, for medical or wellness reasons, for the RN or LPN to follow.

The medical provider is expected to:

1. Review the client's medical history and perform an assessment of the client's health status; or
2. Provide specific instructions within a written protocol that defines the review of the medical history and client assessment that must be performed by the nurse.
3. Develop a medical/wellness treatment plan that includes a specific order/prescription for IV and medication therapy.

B. RN Role:

An RN may perform nursing interventions including the provision of IV therapy and medication administration as ordered by a qualified medical prescriber.

It is not within the RN scope to prescribe, order, or procure drugs or substances for medication administration or IV therapy/hydration.

C. LPN Role:

An LPN may assist and participate in the performance of IV therapy and medication administration as ordered by a legally authorized medical prescriber in a stable nursing situation under the supervision of an RN, APRN, physician, or other authorized health care provider, who is readily available in person or by electronic communication.

The following tasks may be performed by an LPN:

- May perform peripheral venipuncture and administration of IV therapy for clients 12 years and older;
- Assemble and maintain equipment for gravity drip infusion and electronic controlling devices;
- Calculate and adjust infusion rates using standard formulas;
- Perform routine tubing set changes;
- Administer standard solutions, such as normal saline, at a defined flow rate, with or without admixtures that have been mixed and labeled by a pharmacist, RN, or physician;
- Administer vitamins, antibiotics, corticosteroids, and H2 antagonists by piggyback route, mixed and labeled by a pharmacist, RN, or physician; excluding the first dose which must be administered by an RN, or other authorized health care provider;
- Perform routine dressing changes;
- Perform routine saline and heparin flushes.

The following tasks may NOT be performed by an LPN:

- Administer medications by direct IV push or bolus routes.
- Prescribe or order drugs, substances, or IV therapy/hydration.

Practice Setting Guidelines:

1. Maintain written policies relating to the procedures that will be performed that are consistent with applicable standards of practice and evidence-based practice;
2. Maintain documentation on:
    a. Client assessments and medical history data;
    b. Education provided to the client on the prescribed infusion and/or medication therapy;
    c. Client's Informed consent for procedure(s);
    d. Specific procedures performed and client response to procedure;
3. Establish a method for initial and continuing evaluation of the competence of healthcare providers;
4. Have in place an emergency management plan that includes when to refer or consult with the authorized medical provider;
5. Have in place infection control measures that are consistent with applicable standards;
6. Follow state or federal requirements for the ordering and procurement of medications, IV solutions, or additives, including vitamins, minerals, or electrolytes. Substances must be obtained from a South Dakota licensed wholesale drug distributor or a South Dakota licensed 503B outsourcing facility; and
7. Follow state or federal requirements for the preparation and administration of medications, IV solutions, or additives, including vitamins, minerals, or electrolytes that meet United States Pharmacopeial (USP) <797> Pharmaceutical Compounding-Sterile Preparations compounding standards.

Nursing Corporation:

Licensed nurses who own a business to provide nursing services and have a nursing corporation registered with the Secretary of State must register the nursing corporation with the SDBON as a professional corporation: Nursing Corporation Registration & Certificate of Registration for a Healthcare Professional Corporation.

References

1. Gorski LA, Hadaway L, Hagle ME, et al. *Infusion Therapy Standards of Practice, 8th Edition*. Journal of Infusion Nursing. 2021; 44 (suppl 1):S1-S224.
2. National Infusion Center Association. (2019). *Minimum standards for in-office infusion*. Retrieved from: https://infusioncenter.org/2019-06-19-nica-minimum -standards-for-in-office-infusion/.
3. North Carolina Board of Nursing (2022). Position Statement: Administration of Intravenous Fluids (IV Hydration), Nutrient Therapies, and Medications for Hydration, Health, and Wellness. Retrieved from https://www.ncbon.com/myfiles/downloads/position-statements-decision-trees/iv-hydration-clinics.pdf.
4. South Dakota Board of Nursing. *Scope of Nursing Practice Decision-Making Framework.* Retrieved from: https://doh.sd.gov/boards/nursing/PDF/ScopeofPractice3.pdf.
5. United States Pharmacopeial Convention. (2014). USP general chapter <797> Pharmaceutical Compounding-Sterile Preparations.

Applicable South Dakota Laws and Rules

1. 36-9-3. Practice of registered nurse
2. 36-9-4. Practice of licensed practical nurse
3. 36-9A-12. Practice of certified nurse practitioner
4. 34-52. Telehealth utilization by health care professionals
5. 20:48:01. Definitions
6. 20:48:04:01. Scope and standards of nursing practice
7. 20:48:04:06. Intravenous therapy functions which may be performed by licensed practical nurses
8. 20:48:04:07. Intravenous therapy functions which may not be performed by licensed practical nurses

DECLARATORY RULING OF
THE ALABAMA STATE BOARD OF MEDICAL EXAMINERS

On June 16, 2022, the Alabama State Board of Medical Examiners ("BME") considered an investigation concerning the operation of certain wellness clinics offering to administer intravenous ("IV") medications to persons for a fee. The BME issues this declaratory ruling pursuant to Ala. Code § 41-22-11 and Ala. Admin. Code R. 540-X-1-.10 to clarify what practices constitute the practice of medicine or osteopathy under Ala. Code § 34-24-50.

FACTS PRESENTED

On July 21, 2021, the BME began a state-wide investigation into businesses providing IV therapy ("retail IV therapy businesses"). On September 21, 2021, BME investigators visited ten (10) retail IV therapy businesses. These businesses were selected to provide geographic representation of the state. Each business was presented with a standard questionnaire for business personnel to answer in addition to a subpoena requiring the production of documents, to include the identity of any licensed healthcare personnel working for the business and medical records showing the provision of IV therapy to patients.

On June 16, 2022, the BME considered the information gained from this investigation. The retail IV therapy business model is growing in Alabama; however, no rules or regulations directly guide their operation. A business entity can own and operate a retail therapy business and often does. The core business is the offering to walk-in patients of a menu of pre-selected mixtures ("cocktails") of additives to basic IV saline. The cocktails include amino acids, vitamins, minerals, and some prescription drugs like Pepcid, Toradol, and Zofran. They are sometimes marketed with catchy names and are offered to patients for the treatment of conditions such as dehydration, migraine relief, hangover recovery, nausea relief, athletic recovery, appetite regulation, and

inflammation support. Basic health screening occurs prior to the selection and administration of the IV. While a physician may be associated with the business, he or she is usually not on the premises. Instead, a retail IV therapy business uses a physician's National Practitioner Identification ("NPI") number to acquire the IV supplies and additives, and the physician will issue "standing orders" directing the administration of IVs. The actual patient encounter, evaluation, diagnosis, formulation of the treatment plan, and administration of the IV occurs without the physician's input. In certain instances, a registered nurse ("RN") may be the only licensed health care professional interacting with the patient. In other instances, the BME found that chiropractors were involved with the diagnosis, recommendation, and administration of the IVs. The BME received records for one adverse event involving an individual who had suffered a stroke soon after the individual returned home from receiving an IV.

In a substantial number of cases, the retail therapy business was functioning and treating patients in such a manner wherein unqualified or underqualified individuals were operating the business. Representatives from several of the retail IV therapy businesses that were surveyed requested guidance from the BME to clarify the legality of the operations.

QUESTIONS PRESENTED

(1) May a person other than a licensed physician diagnose, treat, correct, advise, or prescribe intravenous fluid or medication to a person for any human disease, ailment, injury, infirmity, deformity, pain, or other condition, whether real or imaginary?

(2) May a person other than a licensed physician maintain an office or place of business for the purpose of diagnosing, treating, correcting, advising, or prescribing intravenous fluid or medication to a person for any human disease, ailment, injury, infirmity, deformity, pain, or other condition, whether real or imaginary?

ANSWER

Only the following individuals may diagnose, treat, correct, advise, or prescribe intravenous medication to a person for any human disease, ailment, injury, infirmity, deformity, pain, or other condition, whether real or imaginary: (1) a physician licensed under Article 3 of Chapter 24 of Title 34, (2) an assistant to physician ("PA") licensed under Article 7 of Chapter 24 of Title 34 and practicing pursuant to a registration agreement with a licensed physician, or (3) a certified registered nurse practitioner ("CRNP") or certified nurse midwife ("CNM") licensed under Article 2 of Chapter 21 of Title 34 practicing pursuant to a collaboration agreement with a licensed physician. Any person who maintains an office or place of business for the purpose of diagnosing, treating, correcting, advising, or prescribing intravenous medication to a person for any human disease, ailment, injury, infirmity, deformity, pain, or other condition, whether real or imaginary, is engaged in the unlawful practice of medicine unless said person (1) employs a physician or a physician and a PA, CRNP, or CNM working within a registration agreement or collaboration with that physician; and (2) the physician or his or her PA, CRNP, or CNM exercises in fact exclusive authority to diagnose, treat, correct, advise, or prescribe intravenous medication to a person for any human disease, ailment, injury, infirmity, deformity, pain, or other condition, whether real or imaginary.

DISCUSSION

The IV therapy retail business model varies in Alabama. Some models comply with Alabama law, but others do not. The BME has received inquiries from business owners who operate IV clinics requesting clarification. This ruling is intended to clarify the application of state laws and regulations to the administration of IV therapy within the context of a retail or "on-demand" business setting.

Retail businesses offering IV therapy were typically found to operate by offering patients a menu of pre-selected mixtures ("cocktails") of additives to basic IV saline, including amino acids, vitamins, minerals, and some prescription drugs like Pepcid, Toradol, and Zofran. These cocktails are sometimes marketed with catchy names and are offered to patients for the treatment of conditions such as dehydration, migraine relief, hangover recovery, nausea relief, athletic recovery, appetite regulation, and inflammation support. Commonly, a patient enters the business and reviews a menu of treatment options. He or she completes a health questionnaire and is evaluated by an RN.[1] This employee may use diagnostic tools to measure the patient's pulse oximetry, heart rate, and blood pressure. The RN evaluates the patient's answers to the health questionnaire, which is designed to elicit the patient's health history, current medications, and allergies. With this information in hand, the RN will discuss the patient's current symptoms and treatment goals and recommend an IV cocktail, along with any additives that may be indicated. The RN makes the recommendations with the assistance of standing orders prepared by a physician. The RN then mixes the IV bag according to his or her recommendations and the patient's selection and administers the IV therapy. The RN remains with the patient to assess the patient's treatment and observe any complications. Once the IV therapy is complete, the RN removes the IV catheter and applies a dressing. The patient is then discharged.

Under Ala. Code § 34-24-50, the "practice of medicine or osteopathy means (1) to diagnose, treat, correct, advise, or prescribe for any human disease, ailment, injury, infirmity, deformity, pain, or other condition, physical or mental, real or imaginary, by any means or instrumentality;" and (2) "to maintain an office or place of business for the purpose of doing acts described in subdivision (1), whether for compensation or not." It is a Class C felony for a person

[1] In some locations, a chiropractor was present and interacted with the patient. However, chiropractors are forbidden by state law from prescribing or administering medicine to patients. Ala. Code § 34-24-122.

to practice medicine or osteopathy without a certificate of qualification issued by the BME and without a license and certificate of registration issued by the Medical Licensure Commission of Alabama. *See* Ala. Code § 34-24-51. It is also violation of state law for a physician to aid or abet the unlicensed practice of medicine. *See* Ala. Code § 34-24-360(13). Each of these prohibitions is implicated by some of the practices observed by the BME's investigators.

First, the diagnosis of the patient's condition and the recommendation of IV therapy constitutes the practice of medicine. This act is outside the scope of practice for an RN. *See* Ala. St. Bd. of Med. Examiners Opinion 1-0399 March 23, 1999 ("only the physician has the authority to make the decision to provide medication, by injection or otherwise, to a patient"). The discussion with the patient and recommendation of an IV and the additives to the IV, including the "cocktails" and prescription drugs, are also outside the scope of practice of an RN. Only a licensed physician, or a PA, CRNP or CNM legally practicing with a physician, may diagnose a patient, assess his or her symptoms, and recommend an IV for the treatment of the patient's condition.

While some retail IV therapy businesses have a physician owner, co-owner, investor, or associate, the physician in most instances does not actually evaluate the patient. Instead, a physician or CRNP may be on staff or "available," but absent some affirmative action by the patient, the RN will treat the patient. The issuance of "standing orders" by the physician for the RN to follow does not satisfy the physician's legal duties to the patient. Instead, this "standing order" model creates a situation in which the physician is aiding and abetting the practice of medicine by the RN, in violation of Ala. Code § 34-24-360(13).[2]

[2] The participation of the patient in the selection of the IV cocktail and additives does not change the analysis. A patient is not licensed to practice medicine. A patient cannot enter a hospital and demand an IV or direct his or her own appendectomy. Even physicians are prohibited from treating themselves except in emergency situations. AMA Code of Medical Ethics Opinion 1.2.1.; Ala. Admin. Code R. 545-X-4-.06(12). A retail IV therapy business cannot obviate the need for physician involvement by letting the patient solely direct his or her own care.

Indeed, the "standing order" model not only violates Alabama law relating to the unauthorized practice of medicine, but it also implicates the Alabama Pharmacy Act. Physicians are generally authorized to dispense prescription medications. *See* Declaratory Ruling of the Ala. St. Bd. of Med. Examiners for the Jefferson County Department of Health (October 2020). Under Ala. Code § 34-23-11, nothing in the Alabama Pharmacy Practice Act "shall prevent any licensed practitioner of the healing arts from personally compounding, dispensing, administering, or supplying to his or her patients drugs and medicines for their use." (Emphasis added). This section "clearly exempts duly licensed physicians from the coverage of Chapter 23 . . . and furthermore expressly permits" the activities of dispensing, administering, or supplying drugs and medicines for the use of a physician's patients. *See* Ala. Op. Att'y. Gen. No. 83-00393 (July 18, 1983) (emphasis added). A "licensed practitioner of the healing arts" includes a physician licensed to practice medicine or osteopathy in Alabama. *See* Ala. Op. Att'y. Gen. No. 96-00263 (July 12, 1996) (concluding that "a licensed physician" is a "practitioner" exempted from the requirements of the Alabama Pharmacy Practice Act under Ala Code § 34-23-11). In the cases surveyed by the BME, the physician's NPI was typically used to order the medical supplies, medications, and additives. The retail IV therapy businesses are exploiting the exception to the Alabama Pharmacy Act by using the physician's NPI to obtain medical supplies from a pharmacy. In these instances, the physician is representing to the pharmacy that he or she is legally permitted to possess the supplies, and that he or she will dispense them to his or her patients. However, a physician's acquisition and dispensing authority is limited to medical supplies obtained and personally compounded and dispensed by the physician for the use of his or her patients. *See* Ala. Code § 34-23-11.

Nonetheless, this personal compounding, administering, or dispensing of medical supplies obtained by the physician to his or her patients is rarely happening. Instead, in instances where the RN alone sees the patient, there is no physician-patient relationship. BME rules generally require the examination of the patient by the physician prior to prescribing a drug or medication. *See* Ala. Admin. Code R. 540-X-9-.11(1). Without an evaluation by the physician to create a physician-patient relationship, the RN is dispensing medical supplies and medications to a person who is not the physician's patient. This violates both the physician's and the RN's legal authority to dispense or administer medications. *See* Ala. Code § 34-23-13.

To comply with Alabama law, retail IV therapy businesses must create a physician-patient relationship through the performance of an individualized evaluation by a physician or a PA, CRNP, or CNM working in a legal registration or collaboration with a physician. The physician, PA, CRNP, or CNM must personally evaluate the patient, diagnose the patient, and make the treatment recommendations. The evaluation and treatment of the patient may occur in person or utilizing telemedicine. *See* Ala. Code § 34-24-703(b). The physician, PA, CRNP, or CNM must further create a medical record that complies with the BME's regulations. If the physician, PA, CRNP, or CNM decides to prescribe IV therapy, he or she must issue a prescription, and only then may the IV therapy be administered. A licensed person other than the physician, PA, CRNP, or CNM may administer the IV if administration of IVs is within that licensee's scope of practice.

The BME notes that the involvement of business owners in the operation of retail IV therapy businesses may implicate the prohibition against unlicensed persons maintaining an office or place of business for the purpose of practicing medicine. *See* Ala. Code § 34-24-50. A business may employ a physician to provide medical services so long as the physician independently exercises his or her medical judgment when providing medical services to his or her patients. *See*

Declaratory Ruling of the Medical Licensure Commission 2-1195 (October 28, 1992). Neither the business nor the business owner is permitted to exercise "any control over the manner in which the physicians provide medical services or the independent exercise of the physicians' medical judgment." *Id.* Whether or not a business is illegally practicing medicine, or whether a physician is illegally aiding and abetting the unlicensed practice of medicine by the business, is a fact-intensive inquiry. However, due to the presence of business owners, franchisors and franchisees, and investors in the corporate makeup of retail IV therapy, physicians are cautioned to understand the BME's regulations and Alabama law before entering employment or partnership with these and similar businesses.

This ruling is based upon the precise facts presented and upon statutes and rules currently in existence. The BME offers no opinion or evaluation of the efficacy of IV therapy as offered by retail IV therapy businesses. This ruling assumes that when a physician, PA, CRNP, or CNM diagnoses a patient and prescribes, orders, or administers an IV, he or she has determined that the treatment will benefit the patient. Should any relevant statutes or rules be amended or repealed, this ruling may no longer be valid. This ruling is not meant to modify, supplement, or overrule existing protocols and practices in licensed healthcare facilities.

DONE this 21st day of July, 2022.

MARK H. LEQUIRE, M.D.
Chairman
Alabama State Board of Medical Examiners

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request: Whitney DeVoe, Board Counsel		**2) Date when request submitted:** 2/14/25 **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: Interdisciplinary Advisory Committee			
4) Meeting Date: 02/26/2025	**5) Attachments:** ☒ Yes ☐ No	**6) How should the item be titled on the agenda page?** Discussion and Consideration – Rough Draft IV Hydration Guidance Document	
7) Place Item in: ☒ Open Session ☐ Closed Session	**8) Is an appearance before the Board being scheduled?** ☐ Yes ☒ No	**9) Name of Case Advisor(s), if applicable:**	
10) Describe the issue and action that should be addressed: Discussion and consideration of the rough draft of the IV hydration guidance document.			
11) **Authorization**			
Whitney DeVoe		02/14/25	
Signature of person making this request		Date	
Supervisor (Only required for post agenda deadline items)		Date	
Executive Director signature (Indicates approval for post agenda deadline items)		Date	

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.