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Tony Evers, Governor Dan Hereth, Secretary

VIRTUAL/TELECONFERENCE MEETING INTERDISCIPLINARY ADVISORY COUNCIL Virtual, 4822 Madison Yards Way, Madison Contact: Brad Wojciechowski (608) 266-2112 October 22, 2024

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

9:00 A.M.

OPEN SESSION – CALL TO ORDER – ROLL CALL

A. Adoption of Agenda (1-2)

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

C. Conflicts of Interest, Scheduling Concerns

D. Administrative Matters – Discussion and Consideration

- 1. Department, Staff and Council Updates
- 2. Election of Officers
- 3. Section Members Term Expiration Dates
 - a) Ferguson, Kris 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
- 4. Alternates
 - a) Chou, Clarence P. 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) Vacant Controlled Substances Board Representative

E. Rules, Regulations and Guidance related to IV Hydration Clinics in Other States – Discussion and Consideration (5-33)

F. Future Topics – Discussion and Consideration

G) Public Comments

ADJOURNMENT

NEXT MEETING: To Be Determined (2025)

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

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

VIRTUAL/TELECONFERENCE INTERDISCIPLINARY ADVISORY COUNCIL MEETING MINUTES AUGUST 22, 2024

PRESENT: Clarence Chou, Amanda Kane, Tara Streit, John Weitekamp

- **ABSENT:** 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 1:00 p.m. A quorum of four (4) members was confirmed.

ADOPTION OF AGENDA

MOTION: Clarence Chou moved, seconded by Tara Streit, to adopt the Agenda as published. Motion carried unanimously.

WELCOME AND INTRODUCTIONS

Welcome from Secretary Dan Hereth

MOTION: Tara Streit moved, seconded by John Weitekamp, to acknowledge and thank Dan Hereth, DSPS Secretary for his appearance and presentation to the Interdisciplinary Advisory Council. Motion carried unanimously.

Welcome from Assistant Deputy Secretary Jennifer Garrett

MOTION: Amanda Kane moved, seconded by Clarence Chou, to acknowledge and thank Jennifer Garrett, DSPS Assistant Deputy Secretary for her appearance and presentation to the Interdisciplinary Advisory Council. Motion carried unanimously.

PRESENTATION: PUBLIC SAFETY AND TRI-REGULATORY COLLABORATION AS IT RELATES TO IV HYDRATION CLINICS – PHYLLIS POLK JOHNSON, DNP, RN, FNP-BC, EXECUTIVE DIRECTOR, MISSISSIPPI BOARD OF NURSING

MOTION: Tara Streit moved, seconded by Clarence Chou, to acknowledge and thank Phyllis Polk Johnson, DNP, RN, FNP-BC, Executive Director, Mississippi Board of Nursing for her appearance and presentation to the Interdisciplinary Advisory Council. Motion carried unanimously.

ADJOURNMENT

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

The meeting adjourned at 2:53 p.m.

Interdisciplinary Advisory Council Meeting Minutes August 22, 2024 Page 2 of 2

State of Wisconsin Department of Safety & Professional Services

1) Name and title of person submitting the request:				2) Date when request submitted:		
Whitney DeVoe, Board Counsel				10/10/24		
				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 Council						
4) Meeting Date: 5) Attachments: 10/22/2024 ☑ Yes		6) How should the item be titled on the agenda page?				
		-	Rules, Regulations and Guidance related to IV Hydration Clinics in Other			
				ate – Discussion and Consideration		
7) Place Item in:			ce before the Board being		9) Name of Case Advisor(s), if applicable:	
☑ Open Session□ Closed Session		scheduled?				
		🖾 No				
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				10/10/24		
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						
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.						
If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.						
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AGENDA REQUEST FORM

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

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: <u>https://llr.sc.gov/med/Policies/Joint-Position-Statement-Retail-IV-Therapy.pdf</u> 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





South Carolina Department of Labor, Licensing and Regulation



Henry D. McMaster Governor

> Emily H. Farr Director

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 preselected 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 APRN⁴ 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 <u>https://llr.sc.gov/med/Policies/MEPRESCRIBEFAM.aspx</u>.

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.

<u>Telemedicine</u>

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 nonnarcotic) may not be prescribed or administered via solely a telemedicine visit and require an inperson 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 <u>https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers</u>

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.

<u>LPNs</u>

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

<u>RNs</u>

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.

<u>APRNs</u>

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.

THE 2024 KENTUCKY NURSE LICENSE RENEWAL PERIOD IS SEPTEMBER 15 THROUGH MIDNIGHT OCTOBER 31, 2024 (EDT). Renewal Information (https://kbn.ky.gov/pages/renewal.aspx)

4 ALERT (SHOW)

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KENTUCKY BOARD OF (7 NURSING

RN IV Hydration Clinics

IV Hydration clinics, mobile or freestanding are not regulated in Kentucky. IV fluid administration, regardless of whether medications may or may not be added, is considered a treatment, and <u>may not</u> be administered without a qualified healthcare provider's order.

While the RN may apply standing orders and protocols that have been prescribed, one of the most important elements in patient care is the medical relationship that exists between the provider and the patient. The relationship is termed the "practitioner-patient relationship" and is defined in KRS 218A.010 (18) & (41) (https://apps.legislature.ky.gov/law/statutes/statute.aspx? id=54047).

The performance of a documented initial assessment/evaluation and development of a treatment plan is a prerequisite for the implementation of any treatment or therapy by a qualified health care provider [MD, APRN, PA, Dentist – see KRS 314.011(6)].

• No more than three (3) medications may be added to a bag of IV fluids. Adding more than three (3) medications is considered compounding and is outside the scope of practice of the registered nurse.

Advisory Opinion Statements Pertinent to IV Hydration

- AOS #14 Roles of Nurses in the Implementation of Patient Care Orders (/KBN%20Documents/aos14-implementation-ofpatient-care-orders.pdf)
- AOS #16 Roles of Nurses in the Administration of Medication via Various Routes (/KBN%20Documents/aos16-meds-viaroutes.pdf)
- AOS #41 RN/LPN Scope of Practice Determination Guidelines (/KBN%20Documents/aos41-rn-lpn-scope-of-practicedetermination-guidelines.pdf)

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Kentucky Board of Nursing (https://kbn.ky.gov/) 312 Whittington Pkwy #300 Louisville, KY 40222 Get Directions (https://www.google.com/maps/place/Kentucky+Board+of+Nursing/@38.2423373,-85.5797414,17z/data=!4m15!1m8!3m7!1s0x88699f8 85.5797414!16s%2Fg%2F11bw3_pcff!3m5!1s0x88699f8d054eab15:0x8904641b9c2ddeec!8m2!3d38.2425007!4d-85.5796903!16s%2Fg%2F1v9t_ncw)

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Registered Nurse (/Registered-Nurse/Pages/default.aspx)

Licensed Practical Nurse (/licensed-practical-nurse/Pages/default.aspx)

Advanced Practice Registered Nurse (/advanced-practice-registered-nurse/Pages/default.aspx)

Sexual Assault Nurse Examiner (/sexual-assault-nurse-examiner/Pages/default.aspx)

State Registered Nurse Aide (/state-registered-nurse-aide/Pages/default.aspx)

Certified Medication Aide (/certified-medication-aide/Pages/default.aspx)

Dialysis Technician (/dialysis-technician/Pages/default.aspx)

Licensed Certified Professional Midwife (/licensed-certified-professional-midwife/Pages/default.aspx)

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SOUTH DAKOTA BOARD OF NURSING

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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;



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- 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.



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



ADMINISTRATION OF INTRAVENOUS FLUIDS (IV HYDRATION), NUTRIENT THERAPIES, AND MEDICATIONS FOR HYDRATION, HEALTH, AND WELLNESS

POSITION STATEMENT for RN, LPN, and APRN Practice

A Position Statement does not carry the force and effect of law and rules but is adopted by the Board as a means of providing direction to licensees who seek to engage in safe nursing practice. Board Position Statements address issues of concern to the Board relevant to protection of the public and are reviewed regularly for relevance and accuracy to current practice, the Nursing Practice Act, and Board Administrative Code Rules.

Issue:

Registered Nurses (RN), Licensed Practice Nurses (LPN), and Advanced Practice Registered Nurses (APRN) are accountable for the provision of safe competent nursing care in all practice settings. This includes but is not limited to various non-traditional practice settings that market wellness promotional services such as "walk-in" or mobile hydration clinics, drip bars, etc.

It is within the scope of practice for the RN and LPN to administer intravenous fluids (IV hydration), nutrient therapies, and medications as authorized by a valid order prescribed by a physician, nurse practitioner (NP), physician assistant (PA), or other licensed health care practitioner with prescriptive authority acting within the legal scope of practice.

RN Role:

The RN does not require the on-site presence of a physician, NP, PA, or other licensed health care practitioner to perform the prescribed/ordered IV hydration, nutrient therapies, and medication administration procedures.

LPN Role:

The LPN participates in the nursing process as assigned and requires supervision by an RN, physician, NP, PA, or other licensed health care practitioner with prescriptive authority. Under appropriate supervision, an LPN may provide nursing services, including the administration of prescribed/ordered IV hydration, nutrient therapies, and medications.

Both RN and LPN Role:

- 1. The nurse must have an individualized prescription/order for the procedure written by a physician, NP, PA, or other licensed health care practitioner with prescriptive authority acting within their legal scope of practice and have completed a client evaluation/assessment for procedure appropriateness.
- 2. Nurses must have the knowledge, skill, and competency necessary to carry out the administration procedures and client monitoring in a safe manner.
- 3. Agencies/businesses shall establish and maintain policies and procedures on-site for the administration of IV hydration, nutrient therapies, medications, and emergency interventions.

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NORTH CAROLINA BOARD OF NURSING PO BOX 2129 – Raleigh, NC 27602 (919) 782-3211 – FAX (919) 781-9461 Nurse Aide II Registry (984) 238-7697 www.ncbon.com IDMINISTRATION OF INTRAVENOUS FLUIDS (IV HYDRATION), NUTRIENT THERAPIES, AND MEDICATIONS FOR HYDRATION, HEALTH, AND $23\,$ wellness position statement for RN and LPN Practice

4. Nurses shall practice within the scope of practice associated with their highest level of active licensure. Position Statement titled, "<u>Practicing at Level Other Than Highest Licensure/Approval/Recognition</u>" provides additional information for RN, LPN, and APRN practice.

Notes:

- If working in a setting in which clients may independently present for IV hydration, nutrient therapies, or medication administration, the nurse is responsible for ensuring there is an individualized prescription/order from a duly authorized prescriber prior to the administration of any prescriptive or non-prescriptive medication or the implementation of a medical intervention/treatment. Authorized prescribers include physicians, NP, PA, or other licensed health care practitioner with prescriptive authority acting within their legal scope of practice.
- 2. The RN and LPN shall use the professional judgement required to implement treatments and pharmaceutical regimens prescribed by providers licensed and authorized by State law to prescribe such plans or regimens. The nurse who accepts responsibility for implementing the administration of IV hydration, nutrient therapies, and medications is accountable for:
 - recognizing side effects,
 - recognizing toxic effects,
 - recognizing allergic reactions,
 - recognizing immediate desired effects,
 - recognizing unusual and unexpected effects,
 - recognizing changes in a client's condition that contraindicates continued administration of the pharmaceutical or treatment regimen,
 - anticipating those effects that may rapidly endanger a client's life or well-being, and
 - making judgments and decisions concerning actions to take in the event such effects occur.
- 3. Standing orders allow for the facilitation of timely interventions for various client populations. Standing orders are not client driven but are signed instructions of a provider authorized by State law to prescribe the medical treatment and/or pharmaceutical regimen. Standing orders describe the parameters of specified situations under which the nurse may act to carry out specific orders for a client presenting with symptoms or needs addressed in the standing orders. The standing orders outline the assessment and interventions that the RN or LPN may perform or deliver. It is not within the RN or LPN scope of practice to make a medical diagnosis, identify medical problems, develop medical treatment plans, or declare someone "free" of illness. Standing orders must be in written form and signed and dated by the provider. The Position Statement, <u>Standing Orders</u>, provides additional guidance.
- 4. The RN and LPN shall practice in compliance with all federal laws and regulations, and all North Carolina (NC) laws and regulations including but not limited to, the NC Board of Nursing (NCBON), the <u>NC Board of Pharmacy</u>, and the <u>NC Division of Health Service Regulation Home Care Licensure</u>.
- 5. The RN planning to establish an independent professional nursing business, professional corporation (PC), or professional limited liability company (PLLC), for the purpose of providing nursing and related

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services, must assure they are compliant with all laws and rules applicable to the practice setting, procedures, and client population including a prescription/order by a physician, NP, PA, or other licensed health care practitioner with prescriptive authority acting within their legal scope of practice. The RN may refer to the NCBON website information, "Professional Corporations and Professional Limited Liability Companies," for more detail and are advised to seek legal advice if establishing a business.

6. LPNs are not authorized to own professional nursing businesses, in full or in part, under NC law.

Advanced Practice Registered Nurse (APRN) Role:

- 1. The client population must be within the scope of practice of the APRN.
- 2. The APRN with diagnostic and prescriptive authority shall meet the standard of care.
- 3. Documentation should demonstrate:
 - Review of the medical record/history was conducted, and no contraindications exist.
 - Initial evaluation including assessment of the client's status.
 - Diagnosis including evidence-based indication for hydration and/or other prescribed regimens.
 - Treatment plan with contingency for care beyond the ability of the current practice site.
 - Client response to prescribed therapy.
 - Informed consent including risk and benefit.
 - Client education for pre-procedure, peri-procedure, after care, and follow up.

References:

General Statute (GS) 90-171.20 (7) (e-f) & (8) (c) – Nursing Practice Act GS 90-178.2 Definitions GS 90-178.3 Regulation of Midwifery GS 55B-14 Types of Professional Services 21 NCAC 36.0221 (c) License Required 21 NCAC 36.0224 Component of Nursing Practice for the Registered Nurse 21 NCAC 36.0225 Components of Nursing Practice for the Licensed Practice Nurse 21 NCAC 36.0802 Scope of Practice

NCBON Position Statement - Practicing at Level Other Than Highest Licensure/

Approval/Recognition

NCBON Position Statement – Standing Orders

Origin: 9/2022

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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?

2

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.

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Chairman Alabama State Board of Medical Examiners