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

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

Tony Evers, Governor
Dan Hereth, Secretary

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

1:00 P.M.

OPEN SESSION – CALL TO ORDER – ROLL CALL

A. Adoption of Agenda (1-2)

B. Welcome and Introductions
1. Welcome from Secretary Dan Hereth
2. Welcome from Assistant Deputy Secretary Jennifer Garrett
3. Introduction of Council Members and DSPS Staff

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) *Vacant* – Cosmetology Examining Board Representative
   f) *Vacant* – 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) *Vacant* – Cosmetology Examining Board Representative
   f) *Vacant* – Controlled Substances Board Representative

E. Open Meetings Law and Ethics Overview – Discussion and Consideration

F. 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 (3-50)

G. Resources on IV Hydration and Compounding – Discussion and Consideration (51-66)

H. Future Topics – Discussion and Consideration (67)
1. Compounding Semaglutides
2. Emerging Medi-Spa Practices

I. Future Meeting Dates and Availability – Discussion and Consideration

J) Public Comments

ADJOURNMENT

NEXT MEETING: TBD

****

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 disciplinary hearings may be changed by the examiner for the convenience of the parties. 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.

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request:	2) Date when request submitted:
Brad Wojciechowski, Executive Director	8/12/2024
	Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting

3) Name of Board, Committee, Council, Sections:

Choose an item. **Interdisciplinary Advisory Council**

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
8/22/2024	☐ Yes ☒ No	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

7) Place Item in:	8) Is an appearance before the Board being scheduled? *(If yes, please complete Appearance Request for Non-DSPS Staff)*	9) Name of Case Advisor(s), if applicable:
☒ Open Session ☐ Closed Session	☐ Yes <Appearance Name(s)> ☐ No	<Click Here to Add Case Advisor Name or N/A>

10) Describe the issue and action that should be addressed:

Dr. Phyllis Polk Johnson will discuss the Collaboration Compass between the Mississippi Board of Pharmacy, Mississippi Board of Nursing, and the Mississippi State Board of Medical Licensure as it relates to IV Hydration Therapy

11) Authorization

Signature of person making this request	Date: 8/12/2024
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.

NCSBN

APRN

ROUNDTABLE

Making an Impact on APRN Regulation:

Every Moment Matters

Tuesday, April 9, 2024 | Virtual

NCSBN

The Collaborative Compass:
Guiding IV Hydration Regulation for Improved Patient Outcomes in Mississippi

Dr. Phyllis Johnson, DNP, RN, FNP-BC

Executive Director, Mississippi Board of Nursing

Objectives

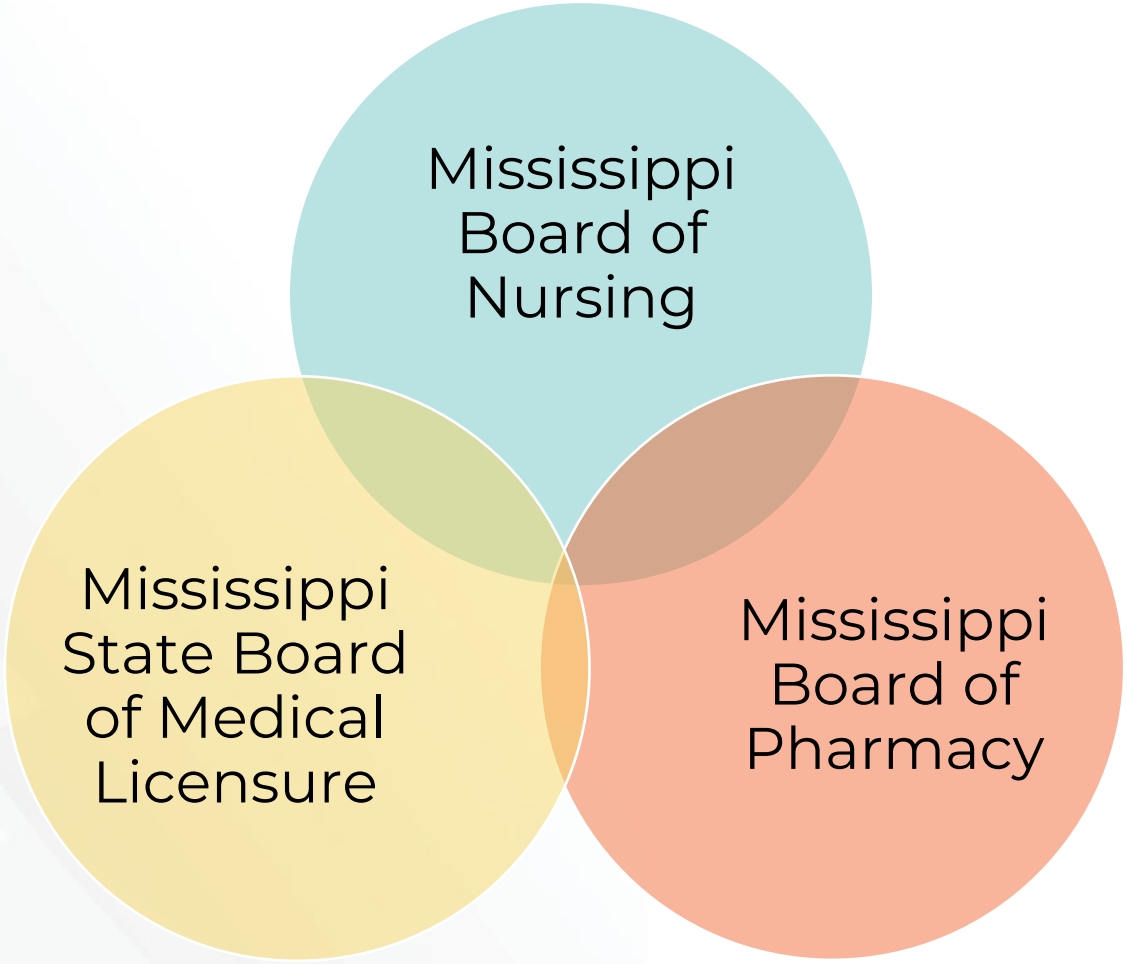
- Importance of Regulations
- Collaboration
- Common Indications for IV hydration
- Scope of Practice
- FDA
- FTC
- Case Studies

The Importance of Regulation

- Regulations represent legally mandated rules instituted by governmental agencies.

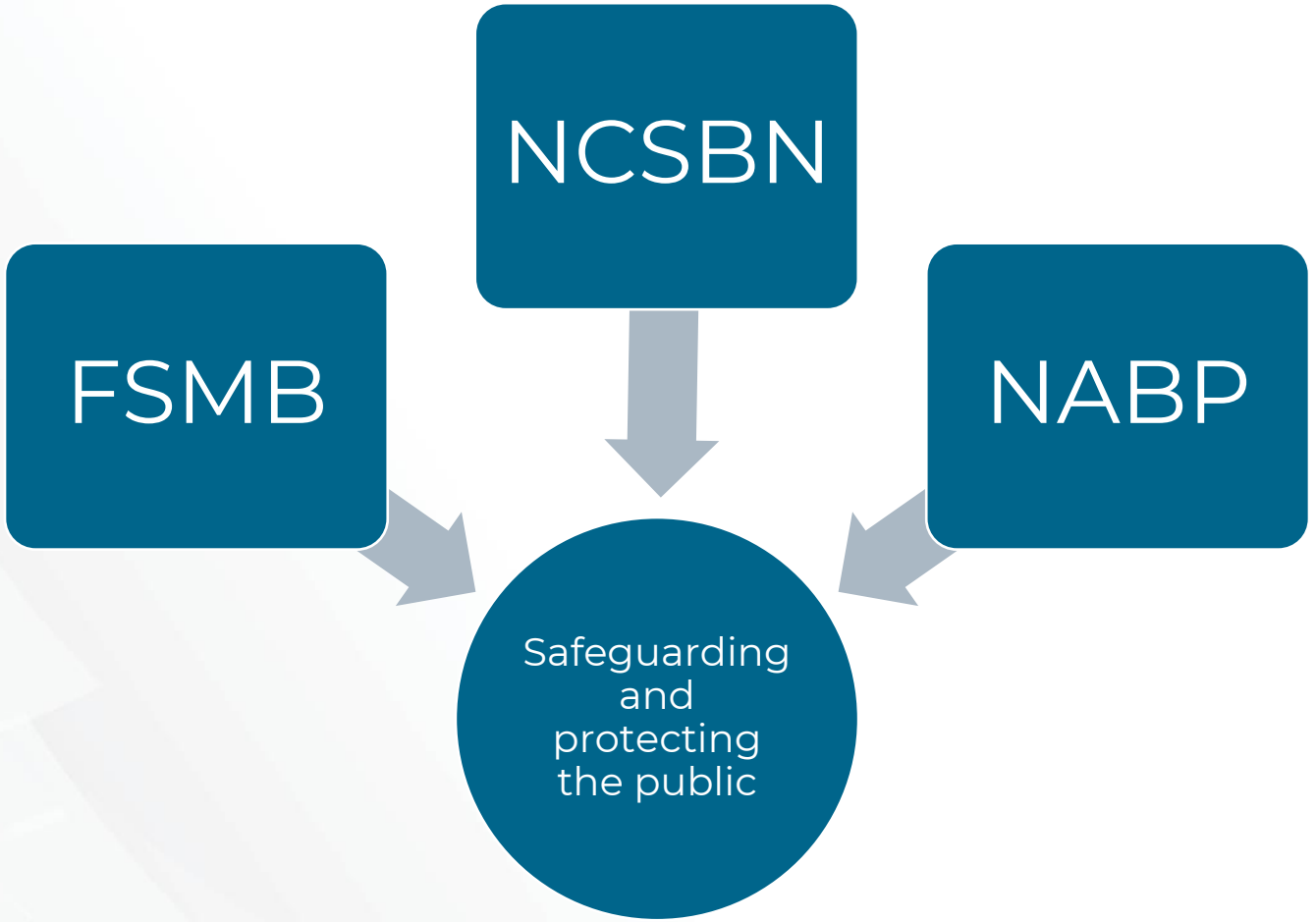
- Play a pivotal role in safeguarding the interests of citizens.

The Power of Triad Collaboration




ASSIST
TEAMWORK
SUPPORT
SUCCESS
COLLABORATION
SHARE
INSPIRATION
EXCHANGE
TRUST

National Perspective



Businesses Offering IV Hydration Services

- Medspas
- Urgent Cares (Non-hospital affiliated)Stand-alone retail & mobile facilities
- Wellness Gyms and Physiotherapists
- Tanning salons
- Chiropractors
- Holistic medicine & functional/integrative/naturopathic providers

FDA 7/26/23

Uses of IV Products from Websites

- “Just Feel Better”
- “Anti-aging Infusion”
- “Immunity Booster”
- “Brain Booster”
- “Energy Boost”
- “Hangover Fix”
- “Slim Boost Infusion”
- “Antioxidant Therapy”
- “Post Covid-19 Drip”

FDA

General Observations of State Oversight

IV Hydration facilities may not be registered/licensed with states

State boards may be more reactive/complaint driven

Collaborative Compass of IV Hydration in Mississippi

IV hydration

- IV hydration, or intravenous hydration, refers to the administration of fluids directly into a person's bloodstream through a vein to address dehydration or maintain proper fluid balance.
- This method allows for a quick and effective delivery of fluids, electrolytes, and, if necessary, nutrients.
- IV hydration is often used in medical settings, such as hospitals or clinics, when oral rehydration may not be sufficient or feasible.

Common Indications for IV Hydration

Severe Dehydration

Surgery and Medical Procedures

Nausea and Vomiting

Electrolyte Imbalances

STATE OF MISSISSIPPI
MISSISSIPPI BOARD OF PHARMACY

Mississippi Board of Pharmacy: Checklist for Compliance

Infusion Clinics (hydration, other medications)

1. Maintaining the drug storage area
    a. Are drugs stored per manufacturer's guidelines?
    b. Is the drug storage area clean and free of dust and clutter?
    c. No expired drugs in stock.
    d. The label of the container has the drug name, strength, manufacturer's lot number and expiration date.
    e. All medication is received with packaging intact, and the integrity of the medication has not been compromised.
2. Who supplies the clinic's medications?
3. Is the supplier permitted with the MS Board of Pharmacy?
4. Is the supplier an outsourcer or 503A pharmacy?
5. Are drugs shipped patient specific and only used for that patient?
    a. Are the patient specific medications single dose or multi-dose packages?
    b. When were the patient specific medications received?
    c. When is the patient scheduled to receive the medications?
    d. Does the beyond use date appear to be appropriate?
    e. For single dose vials, verify that remainder is discarded and not used for additional patients.
6. Are drugs shipped in bulk packages for specific patients or for clinic stock?
    a. Are these bulk packages multi-dose packages/vials?
7. Who created the account with the supplier/s?
8. Which provider credentials are drugs being ordered under?
9. Are any infusions prepared on-site or do they come premixed from the supplier?
10. Are infusions prepared on-site prepared according to manufacturer's guidelines?
11. Obtain copies of patient orders (proof of valid orders)
12. Obtain copies of invoices/purchases for the past 6 months
13. How are drugs labeled (patient specific, take home, etc)
14. How did the facility find their supplier?
15. Take pictures and get copies of any documentation that would be helpful.

Mississippi Collaboration

BOARD OF MEDICAL LICENSURE

BOARD OF NURSING

Investigative Questionnaire MSBML and MBON

Is there a physical exam performed prior to administering hydration therapy?

If yes, who performs the physical examination? (Should be done by practitioner with prescriptive authority)

What type of physical exam is performed? (In-person, telemedicine, hybrid)

Is there a medical indication to receive hydration therapy? (Dehydration, unable to tolerate po)

Is there a reason someone might be denied hydration therapy? (CHF, CKD, HTN, hyponatremia, hypernatremia, etc.)

IS there an order to administer IVF?

Who administers the hydration therapy? (MD, APRN, RN, LPN, EMT, unlicensed person)

Whose authority was the IV fluid ordered? (has to be a person with prescriptive authority) And any documentation? (Invoices)

If an APRN ordered, who is the collaborating physician?

Mississippi Collaboration

Scope of Practice

The activity or intervention is authorized by a valid order.

Standing orders cannot authorize the person carrying out the order to exercise independent medical judgement.

The patient's record is thoroughly reviewed, an appropriate nursing assessment of the patient is conducted, and no contraindications exist to the ordered treatment.

Administration and documentation of the intervention are accurate and complete in the patient's record, including the evaluation and documentation of the patient's response to the treatment.

The nurse is prepared and capable of instituting nursing interventions to resolve an untoward event/reaction that occurs as a result of the administration of IV therapies.

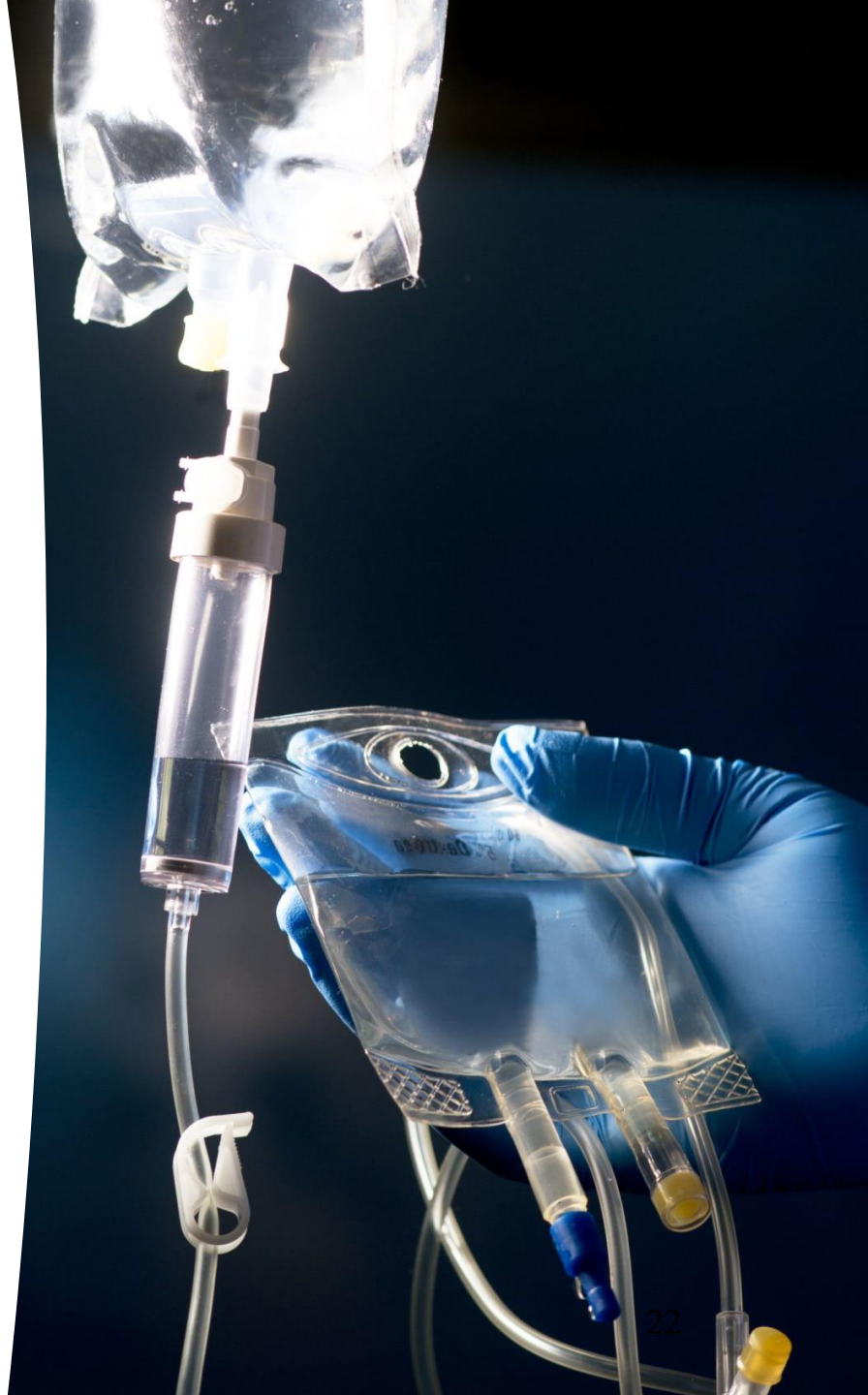
Implementation of measures to prevent exposure to infectious pathogens and communicable conditions.

Does Research Back its Benefits?


THRIVE
BEAUTY
THRIVE
ATHLETE
THRIVE
MIGRAINE
THRIVE
IMMUNITY
THRIVE
PARTY
THRIVE
HEALTH
THRIVE
JET LAG

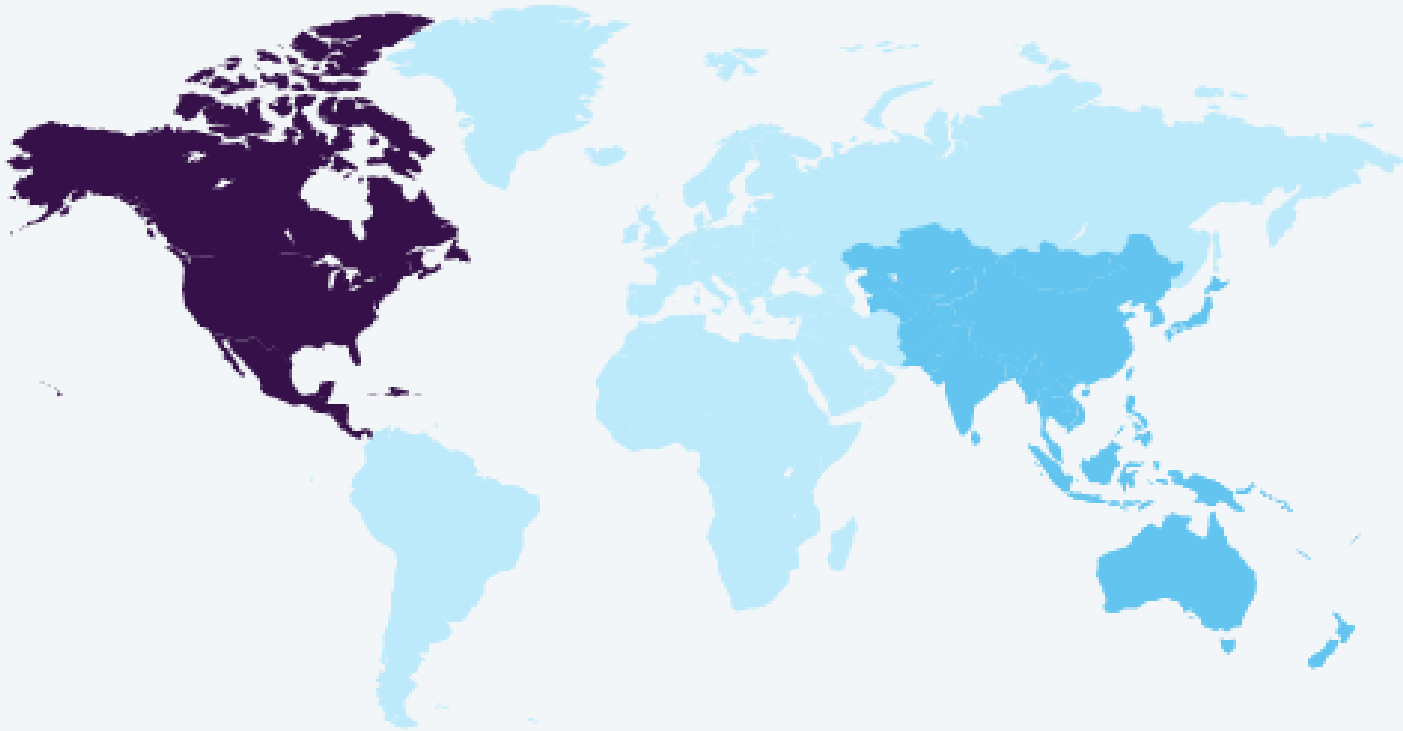
IV Hydration Advertisement

- “Fountain of Youth”
- “Revive”
- “Boost Immune System”
- “Ultimate Hangover Relief”
- “Beautification”
- “Stress Reducer”
- “Memory Enhancer”



Intravenous (IV) Hydration Therapy Market

Trends, by Region, 2023 - 2030



GRAND VIEW RESEARCH

46.8%

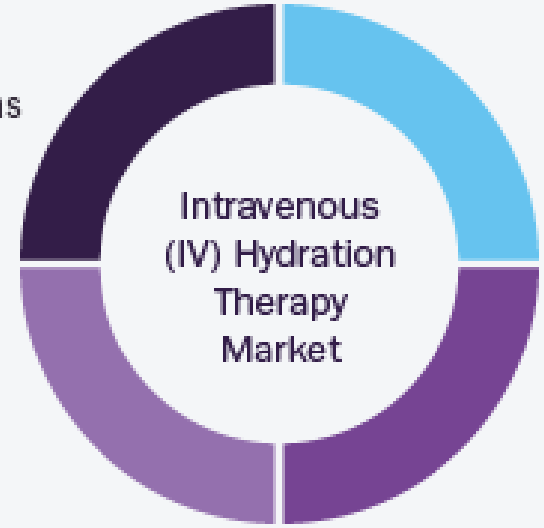
North America Market Revenue Share, 2022

Source: www.grandviewresearch.com

Global Intravenous (IV) Hydration Therapy Market

Report Segmentation

End-use Outlook
- Hospitals & Clinics
- Wellness Centers & Spas
- Home Healthcare
- Others



Service Outlook
- Immune Boosters
- Energy Boosters
- Skin Care
- Migraine
- Others

Regional Outlook
- North America
- Europe
- Asia Pacific
- Latin America
- Middle East & Africa

Component Outlook
- Medicated
- Non-medicated

GRAND VIEW RESEARCH

21+

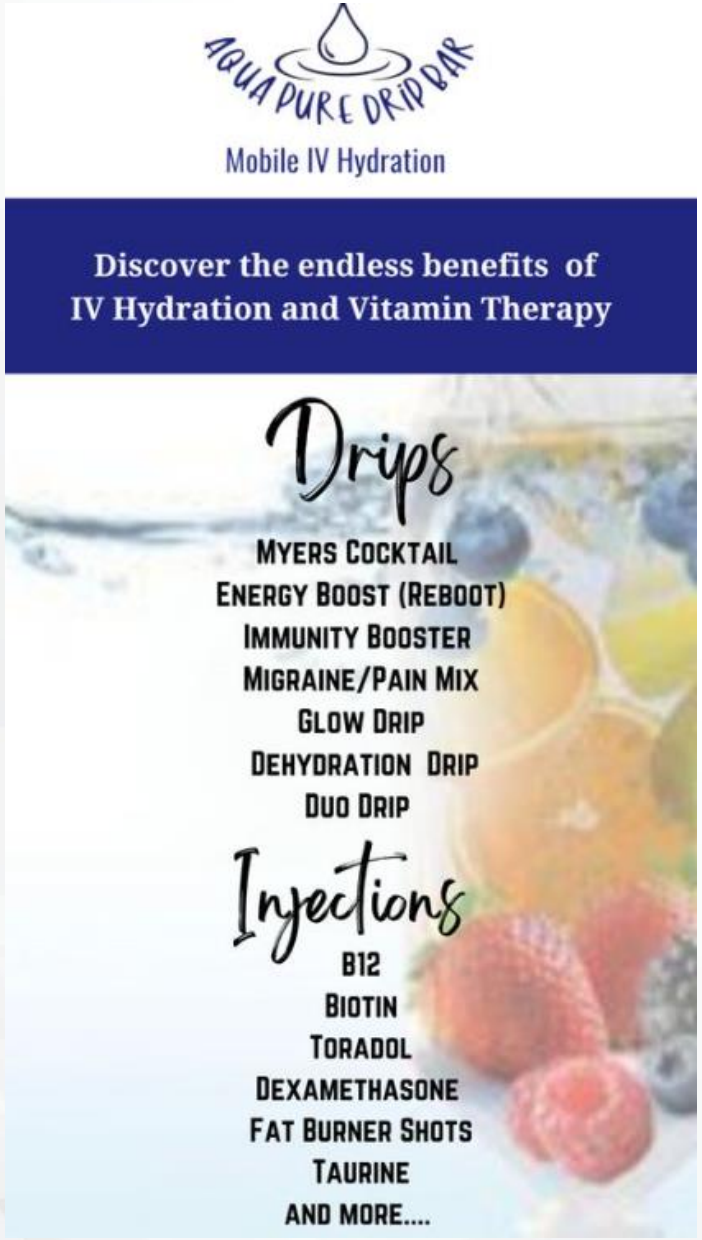
Number of Countries Covered in the Report

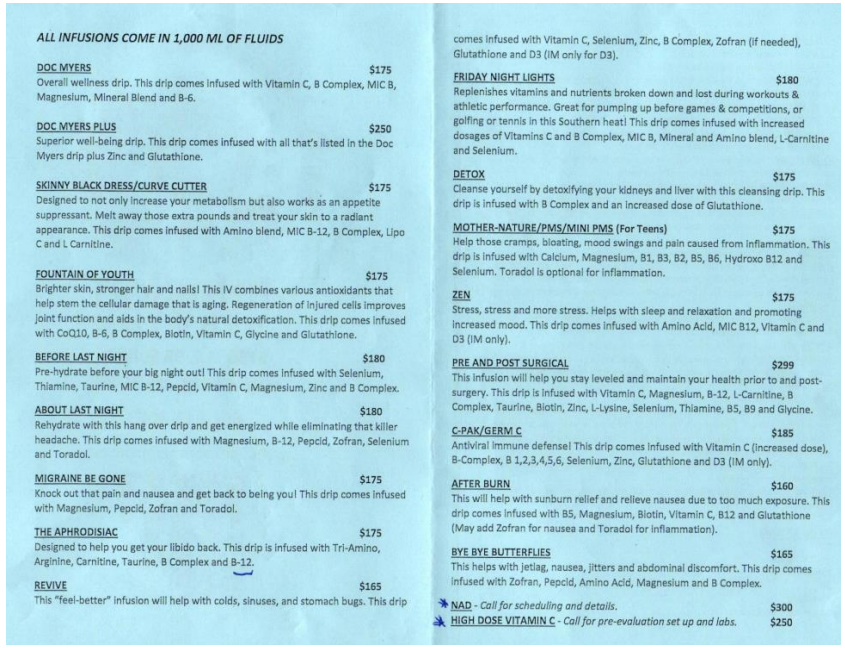
Source:
www.grandviewresearch.com

Evidence-based Research

- The “cocktails” that IV vitamin therapy clinics create and administer are not supported by scientific evidence.
- There have been no clinical studies to show vitamin injections of this type offer any health benefit or are necessary for good health.
- In situations where individuals find themselves too sick to meet their body's fluid requirements through regular oral intake, it is advisable to seek medical attention and consider placement in a healthcare facility where proper monitoring and care can be provided.

Mississippi IV Hydration Sites





ALL INFUSIONS COME IN 1,000 ML OF FLUIDS

DOC MYERS $175
Overall wellness drip. This drip comes infused with Vitamin C, B Complex, MIC B, Magnesium, Mineral Blend and B-6.

DOC MYERS PLUS $250
Superior well-being drip. This drip comes infused with all that's listed in the Doc Myers drip plus Zinc and Glutathione.

SKINNY BLACK DRESS/CURVE CUTTER $175
Designed to not only increase your metabolism but also works as an appetite suppressant. Melt away those extra pounds and treat your skin to a radiant appearance. This drip comes infused with Amino blend, MIC B-12, B Complex, Lipo C and L Carnitine.

FOUNTAIN OF YOUTH $175
Brighter skin, stronger hair and nails! This IV combines various antioxidants that help stem the cellular damage that is aging. Regeneration of injured cells improves joint function and aids in the body's natural detoxification. This drip comes infused with CoQ10, B-6, B Complex, Biotin, Vitamin C, Glycine and Glutathione.

BEFORE LAST NIGHT $180
Pre-hydrate before your big night out! This drip comes infused with Selenium, Thiamine, Taurine, MIC B-12, Pepcid, Vitamin C, Magnesium, Zinc and B Complex.

ABOUT LAST NIGHT $180
Rehydrate with this hang over drip and get energized while eliminating that killer headache. This drip comes infused with Magnesium, B-12, Pepcid, Zofran, Selenium and Toradol.

MIGRAINE BE GONE $175
Knock out that pain and nausea and get back to being you! This drip comes infused with Magnesium, Pepcid, Zofran and Toradol.

THE APHRODISIAC $175
Designed to help you get your libido back. This drip is infused with Tri-Amino, Arginine, Carnitine, Taurine, B Complex and B-12.

REVIVE $165
This "feel-better" infusion will help with colds, sinuses, and stomach bugs. This drip comes infused with Vitamin C, Selenium, Zinc, B Complex, Zofran (if needed), Glutathione and D3 (IM only for D3).

FRIDAY NIGHT LIGHTS $180
Replenishes vitamins and nutrients broken down and lost during workouts & athletic performance. Great for pumping up before games & competitions, or golfing or tennis in this Southern heat! This drip comes infused with increased dosages of Vitamins C and B Complex, MIC B, Mineral and Amino blend, L-Carnitine and Selenium.

DETOX $175
Cleanse yourself by detoxifying your kidneys and liver with this cleansing drip. This drip is infused with B Complex and an increased dose of Glutathione.

MOTHER-NATURE/PMS/MINI PMS (For Teens) $175
Help those cramps, bloating, mood swings and pain caused from inflammation. This drip is infused with Calcium, Magnesium, B1, B3, B2, B5, B6, Hydroxo B12 and Selenium. Toradol is optional for inflammation.

ZEN $175
Stress, stress and more stress. Helps with sleep and relaxation and promoting increased mood. This drip comes infused with Amino Acid, MIC B12, Vitamin C and D3 (IM only).

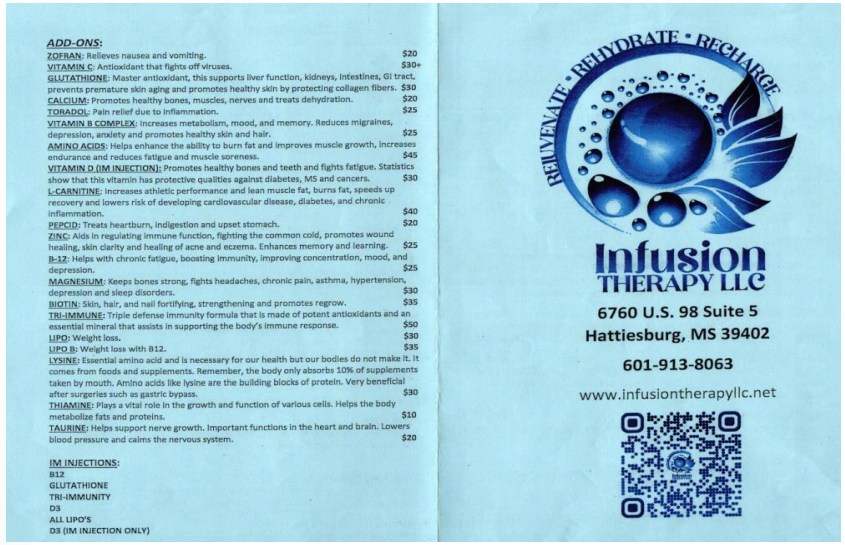
PRE AND POST SURGICAL $299
This infusion will help you stay leveled and maintain your health prior to and post-surgery. This drip is infused with Vitamin C, Magnesium, B-12, L-Carnitine, B Complex, Taurine, Biotin, Zinc, L-Lysine, Selenium, Thiamine, B5, B9 and Glycine.

C-PAK/GERM C $185
Antiviral immune defense! This drip comes infused with Vitamin C (increased dose), B-Complex, B 1,2,3,4,5,6, Selenium, Zinc, Glutathione and D3 (IM only).

AFTER BURN $160
This will help with sunburn relief and relieve nausea due to too much exposure. This drip comes infused with B5, Magnesium, Biotin, Vitamin C, B12 and Glutathione (May add Zofran for nausea and Toradol for inflammation).

BYE BYE BUTTERFLIES $165
This helps with jetlag, nausea, jitters and abdominal discomfort. This drip comes infused with Zofran, Pepcid, Amino Acid, Magnesium and B Complex.

NAD - *Call for scheduling and details.* $300
HIGH DOSE VITAMIN C - *Call for pre-evaluation set up and labs.* $250



***ADD-ONS*:**
ZOFRAN: Relieves nausea and vomiting. $20
VITAMIN C: Antioxidant that fights off viruses. $30+
GLUTATHIONE: Master antioxidant, this supports liver function, kidneys, intestines, GI tract, prevents premature skin aging and promotes healthy skin by protecting collagen fibers. $30
CALCIUM: Promotes healthy bones, muscles, nerves and treats dehydration. $20
TORADOL: Pain relief due to inflammation. $25
VITAMIN B COMPLEX: Increases metabolism, mood, and memory. Reduces migraines, depression, anxiety and promotes healthy skin and hair. $25
AMINO ACIDS: Helps enhance the ability to burn fat and improves muscle growth, increases endurance and reduces fatigue and muscle soreness. $45
VITAMIN D (IM INJECTION): Promotes healthy bones and teeth and fights fatigue. Statistics show that this vitamin has protective qualities against diabetes, MS and cancers. $30
L-CARNITINE: Increases athletic performance and lean muscle fat, burns fat, speeds up recovery and lowers risk of developing cardiovascular disease, diabetes, and chronic inflammation. $40
PEPCID: Treats heartburn, indigestion and upset stomach. $20
ZINC: Aids in regulating immune function, fighting the common cold, promotes wound healing, skin clarity and healing of acne and eczema. Enhances memory and learning. $25
B-12: Helps with chronic fatigue, boosting immunity, improving concentration, mood, and depression. $25
MAGNESIUM: Keeps bones strong, fights headaches, chronic pain, asthma, hypertension, depression and sleep disorders. $30
BIOTIN: Skin, hair, and nail fortifying, strengthening and promotes regrow. $35
TRI-IMMUNE: Triple defense immunity formula that is made of potent antioxidants and an essential mineral that assists in supporting the body's immune response. $50
LIPO: Weight loss. $30
LIPO B: Weight loss with B12. $35
LYSINE: Essential amino acid and is necessary for our health but our bodies do not make it. It comes from foods and supplements. Remember, the body only absorbs 10% of supplements taken by mouth. Amino acids like lysine are the building blocks of protein. Very beneficial after surgeries such as gastric bypass. $30
THIAMINE: Plays a vital role in the growth and function of various cells. Helps the body metabolize fats and proteins. $10
TAURINE: Helps support nerve growth. Important functions in the heart and brain. Lowers blood pressure and calms the nervous system. $20

IM INJECTIONS:
B12
GLUTATHIONE
TRI-IMMUNITY
D3
ALL LIPO'S
D3 (IM INJECTION ONLY)

REJUVENATE • REHYDRATE • RECHARGE
Infusion THERAPY LLC
6760 U.S. 98 Suite 5
Hattiesburg, MS 39402
601-913-8063
www.infusiontherapyllc.net

IV HYDRATION 2 U

Making Wellness Easy

IV MENU

Myers Cocktail: $199

The Myers' Cocktail is named for the late John Myers, M.D., a Maryland physician who used intravenous injections of nutrients to treat many chronic conditions. Conditions that have responded positively to the Myers' cocktail treatment include asthma, migraines, chronic fatigue syndrome, fibromyalgia, muscle spasms, pain, allergies, and sinus and respiratory tract infections. The benefits of a Myer's Cocktail IV are well documented, especially its effective treatment of headaches, fatigue, mood disorders, and circulatory issues. The Myer's Cocktail contains electrolytes, B-Complex (Vitamins B1/2/3/5/6) B12, Magnesium, Vitamin C, and Glutathione.

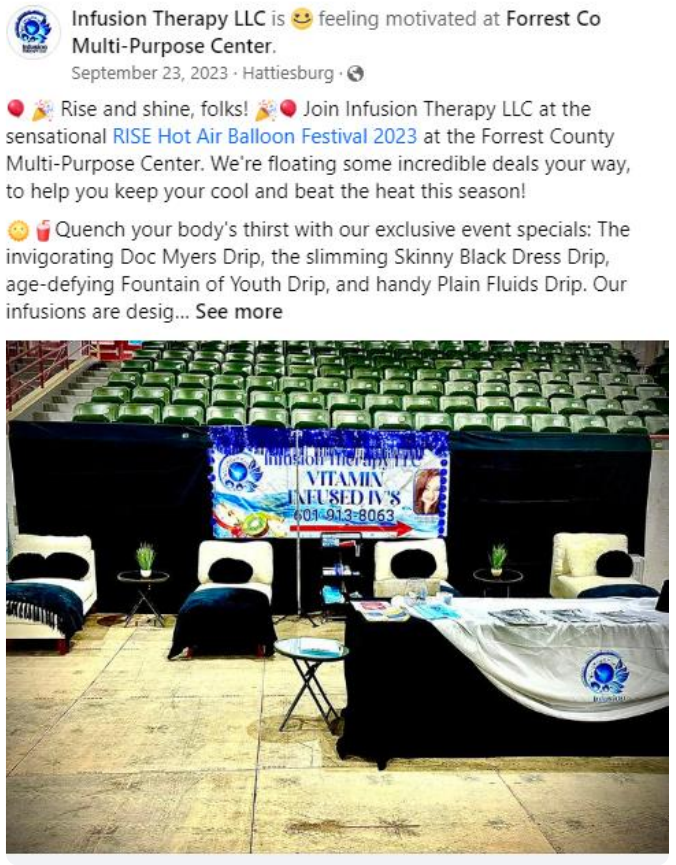
Hangover Cure:$149

Did you party a little too much last night? It's ok, it happens. There's no need to wait around and suffer with a crippling hangover for hours and hours when you can get rid of your symptoms much faster. The Hangover Cure will do just that. It works by rehydrating your body and replacing the vitamins and minerals that have been depleted from alcohol consumption. It also helps relieve symptoms by giving your body minerals like magnesium that reduce inflammation. The Hangover Cure contains Electrolytes, Vitamins B1/2/3/5/6, and Magnesium.

Energy+Performance: $165

This blend is perfect for anyone living a very active lifestyle as it was formulated to give you a huge boost of energy and allow your body to perform at the level that you need it to. It is perfect for athletes, runners, crossfitters, and everyone in between who demands more from their body. Whether you're training hard or have a long active day coming up, this blend will give you the boost you need to perform at your best. The Energy and Performance Blend contains electrolytes, Vitamins B1/2/3/5/6, and B12, Magnesium, a Tri-Amino blend of Arginine, Citrulline, and Ornithine.

Infusion Therapy LLC, Hattiesburg, MS



FDA: Compounded IV Therapies

The FDA is responsible for enforcing USP standards recognized by various provisions of the FD&C Act.

USP Chapter 797 provides standards for sterile compounding, including:

Supervision of compounding personnel;	Training of compounding personnel; and	Sanitary conditions for preparation of drug compounds.

IV Hydration clinic therapies must comply with both:

The legal conditions under Section 503A of the FD&C Act; and	The standards set forth under USP Chapter 797.

FTC - Federal Trade Commission

- Scientific Proof Needed for Health Claims (FTC)
- All health claims require competent and reliable scientific evidence
- Disease treatment or cure claims require human clinical studies (randomized, placebo controlled, double blind, measuring relevant endpoints or validated surrogate markers, with statistically significant results)

Scientific Proof Needed for Health Claims (FTC)

- All health claims require competent and reliable scientific evidence
- Disease treatment or cure claims require human clinical studies (randomized, placebo controlled, double blind, measuring relevant endpoints or validated surrogate markers, with statistically significant results)

Claims of Clinical Proof (FTC)

- An advertiser must have at least the level of proof claimed (e.g., reference to a clinical study or scientific research)
- Claims that a product is “clinically proven” or “scientifically proven” to work require evidence sufficient to satisfy the relevant scientific community of the claim’s truth

A&O Enterprises dba iVBars and Aaron K. Roberts

- Respondents operated a chain of IV clinics in Texas and Colorado
- FTC challenged false or unsubstantiated claims that the IV cocktails were:
  - Effective treatments for cancer, cardiovascular disease, MS, diabetes, fibromyalgia, etc.
  - Clinically proven to treat various diseases
  - Safe for all ages
  - Free of side effects

Legislation

- Florida – HB 227 and SB 672, which are companion bills.
  - Summary: This bill outlines the requirements that qualified healthcare providers, including APRNs, RNs, and PAs, must fulfill when administering intravenous vitamin treatment. Additionally, this bill directs the Board of Nursing and other relevant healthcare licensing boards to adopt rules establishing procedures to safely administer intravenous vitamin treatment as well as protocols to follow in the event of a health emergency.
  - Note: HB 227 was reported out of the House Health & Human Services Committee on January 16th.

- Mississippi – HB 648
  - Summary: This bill states that CNPs and RNs licensed by the Mississippi Board of Nursing shall be authorized to administer fluids containing vitamins for the purpose of improving a person's immune health through intravenous (IV) therapy in a clinical setting. The bill further states that there is no limit on the number of vitamins that may be administered through IV therapy by a CNP or RN at any one time.

Case Studies

Case Study

- RESPONDENT, who is a registered nurse rather than a nurse practitioner, has been engaging in practices beyond the typical scope of a registered nurse by administering IV hydration without specific orders.
- RESPONDENT enlisted with a company and operated within the framework of services provided by the franchise. Within this operational model, the administration of IVs was based on client preferences without any medical justification for the selected IV. Clients had the option to choose fluids and medications from a menu of services.
- RESPONDENT executed these procedures under standing orders from a physician located in another state who did not conduct a direct assessment of the clients involved.

Outcome

- Formal reprimand
- Fine
- Legal aspects of Nursing Course
- Ethics Course
- Scope of Practice Course
- Medication Administration Course

CRNA

- The Board of Nursing conducted an interview with Respondent, who is the owner of Anesthesia establishment. During the interview with Nurse, it was revealed that the establishment did not possess an approved practice site with the Mississippi Board of Nursing. At that time, Respondent was practicing in her home and through a mobile service, thereby violating 30 Miss. Admin. Code Pr. 2840, R. 1.1(N), and Pr. 2840, R. 1.2(D)(2).
- Respondent violated Miss. Code ANN. §73-15-20(7 (d): prescribing outside the scope of practice for a licensed CRNA with said scope of practice being limited to anesthesia and analgesia.

CRNA

- Respondent admitted to having no quality assurance/quality improvement plan or documentation in violation of Miss. code ANN. §73-15-20(7(f) and 30 Miss ADMIN. code pr. 2840, R. 1.4, D.
- Respondent did not have electronic medical records for the clients and admitted to performing no exams.
- Did submit a collaborative agreement dated 2019. However, standing orders were not signed until 2022. Respondent backdated documents submitted.

Outcome

- Formal reprimand
- Fine
- Legal aspects of Nursing Course
- Everyday Ethics Course
- Professional Accountability Course
- Documentation Course
- Social Media Course
- Scope of Practice Course

Case Study

- RESPONDENT is a registered nurse and not a nurse practitioner.
- RESPONDENT has a previous disciplinary action with another state Board of Nursing for practicing outside the scope of an RN. RESPONDENT has been practicing out of scope for a registered nurse by administering IV hydration without specific orders.

- RESPONDENT is the co-owner of an IV hydration business. IV's are administered based on a client's want and there is no medical justification for the selected lV. Clients selected fluids and medications from a menu of services.
- RESPONDENT administered the lV via standing orders from an MD located in another state who never assessed the client.
- The MD did not meet the physical practice requirement per Medical Licensure Code Part 2630. Chapter l.

Other Cases

Frisco Anesthesiologist

Radio Employee in Texas

MS death of a woman receiving IV therapy at home

References

Ali, A., Njike, V. Y., Northrup, V., Sabina, A. B., Williams, A. L., Liberti, L. S., ... & Katz, D. L. (2009). Intravenous micronutrient therapy (Myers' Cocktail) for fibromyalgia: a placebo-controlled pilot study. The Journal of Alternative and Complementary Medicine, 15(3), 247-257.

FDA highlights concerns with compounding of drug products by medical offices and clinics under insanitary conditions (2021). Retrieved from FDA highlights concerns with compounding of drug products by medical offices and clinics under insanitary conditions | FDA

FTC Brings First-ever Action Targeting “iV Cocktail” Therapy Marketer (2018). Retrieved from FTC Brings First-ever Action Targeting “iV Cocktail” Therapy Marketer | Federal Trade Commission

Gaby AR. Intravenous nutrient therapy: the "Myers' cocktail". Altern Med Rev. 2002 Oct;7(5):389-403. PMID: 12410623.

Gawronska, J., Koyanagi, A., López Sánchez, G. F., Veronese, N., Ilie, P. C., Carrie, A., ... & Soysal, P. (2022). The Prevalence and Indications of Intravenous Rehydration Therapy in Hospital Settings: A Systematic Review. Epidemiologia, 4(1), 18-32.

Intravenous fluid therapy in adults in hospital. London: National Institute for Health and Care Excellence (NICE); 2017 May. (NICE Clinical Guidelines, No. 174.) Available from: https://www.ncbi.nlm.nih.gov/books/NBK554180/

Liska, D., Mah, E., Brisbois, T., Barrios, P. L., Baker, L. B., & Spriet, L. L. (2019). Narrative review of hydration and selected health outcomes in the general population. *Nutrients*, *11* (1), 70.

NABP, FSMB, NCSBN join Federal Agencies in Educating Regulators and Practitioners on Risks of IV Hydration Clinics (2023). Retrieved from FSMB | NABP, FSMB, NCSBN Join Federal Agencies in Educating Regulators and Practitioners on Risks of IV Hydration Clinics

Padhi, S., Bullock, I., Li, L., & Stroud, M. (2013). Intravenous fluid therapy for adults in hospital: summary of NICE guidance. *Bmj*, *347*.

IV Hydration Guidelines

1. Establish clear guidelines: Develop comprehensive guidelines that outline the appropriate use of IV hydration in various healthcare settings, including hospitals, clinics, and other healthcare facilities. These guidelines should address indications for IV hydration, patient assessment criteria, dosing, monitoring, and documentation requirements.

2. Scope of practice: Define the scope of practice for different healthcare professionals involved in the administration of IV hydration, APRN , as registered nurses,& licensed practical nurses. Clearly outline their roles, responsibilities, and required competencies to ensure safe and effective delivery of IV hydration.

3. Education and training: identify educational programs and training initiatives to enhance the knowledge and skills of healthcare professionals regarding IV hydration. Research continuing education opportunities to keep nurses updated on the latest evidence-based practices, safety measures, and advancements in IV therapy.

4. Standardize protocols: Encourage the development and implementation of standardized protocols for IV hydration administration. These protocols should include guidelines for selecting appropriate IV fluids, calculating infusion rates, preventing and managing complications, and discontinuing therapy.

5. Quality assurance and monitoring: Establish mechanisms for monitoring and ensuring the quality of IV hydration practices in healthcare facilities. This can include regular audits, peer reviews, and incident reporting systems to identify and address any deviations from best practices.

6. Collaboration and interdisciplinary approach: Foster collaboration among healthcare professionals, including nurses, physicians, pharmacists, and other relevant stakeholders. Promote interdisciplinary discussions and decision-making processes to ensure optimal patient outcomes and safe administration of IV hydration.

7. Legal and regulatory considerations: Keep abreast of federal and state laws, regulations, and policies related to IV therapy and hydration. Ensure compliance with legal requirements, such as appropriate licensure, documentation, and informed consent processes.

8. Research and evidence-based practice: Encourage research initiatives to generate evidence on the effectiveness, safety, and cost-effectiveness of IV hydration. Promote the integration of research findings into clinical practice guidelines and educational programs.

9. Patient education: Develop educational materials and resources for patients and their families to enhance their understanding of IV hydration, including its purpose, potential benefits, and possible risks. Encourage healthcare professionals to provide adequate information and address any concerns or questions patients may have.

10. Continuous review and improvement: Establish a process for ongoing review and evaluation of IV hydration practices. Monitor outcomes, identify areas for improvement, and revise guidelines and protocols accordingly.

IV Hydration Notes

Recently, the Board has received numerous inquiries about practice settings that market wellness promotion services, such as intravenous (lV) hydration, often times referred to as "lV vitamin therapy" or "hydration therapy". ln keeping with the Board's mission of public protection, these notes aim to offer regulatory considerations nurses should be mindful of when deciding whether to practice in such a setting.

lV therapy is a learned skill practiced by many nurses. However, there are necessary considerations for the safe performance of this skill outside of a traditional facility setting.

- All nurses licensed to practice nursing in Mississippi (MS) must adhere to the Nursing Practice Act (NPA) and Board rules, as well as other regulations pertinent to the setting.

- The performance of lV hydration in a non-traditional setting, such as a mobile unit or wellness clinic, should be consistent with applicable regulations, prevailing standards of care, and current national nursing guidelines specific to lV therapy.

- When initiating lV therapy services, including the administration of medications, such as isotonic lV fluids, a valid provider order is required. **Some orders may come from a provider who has examined the patient. Other settings may utilize standing orders.**

- Nurses function under their own licenses and assume responsibility and accountability for the care they provide, as nurses do not practice "under a physician's license."

- Nurses must clarify any order or treatment regimen that the nurse has reason to believe is inaccurate, non-efficacious, or contraindicated by consulting with the appropriate licensed practitioner and notifying the ordering practitioner when the nurse makes the decision not to administer the medication or treatment.

Scope of Practice Decisions:

- **The activity or intervention is authorized by a valid order.**
- **Standing orders cannot authorize the person carrying out the order to exercise independent medical judgement.**
- **The patient's record is thoroughly reviewed, an appropriate nursing assessment of the patient is conducted, and no contraindications exist to the ordered treatment.**
- **Administration and documentation of the intervention are accurate and complete in the patient's record, including the evaluation and documentation of the patient's response to the treatment.**
- **The nurse is prepared and capable of instituting nursing interventions to resolve an untoward event/reaction that occurs as a result of the administration of lV therapies.**

- **Implementation of measures to prevent exposure to infectious pathogens and communicable conditions.**

Common Question:

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?
   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: a physician; APRN (NP/CNM); or PA. The diagnosis of the patient's condition and the recommendation of IV therapy constitutes the practice of medicine.

Note:

Full histories, examinations, diagnoses supported by medical justification, plan of care, and complete records must be maintained like any other medical condition. The patient may not select the product from a "menu." The hydration and/or supplements selected must be based on medical justification and clinical decision-making by the practitioner as a part of the assessment, diagnosis, and treatment plan. IV Hydration is a medical procedure with risks and should be conducted in the clinical setting as any other medical procedure.

NCSBN
Leading Regulatory Excellence

July 12, 2023

Board of Nursing Resources on IV Hydration and Compounding

Here are the board of nursing/pharmacy documents we are aware of related to IV hydration and compounding.

- Massachusetts Board of Nursing (2023). Advisory Ruling on Nursing Practice (92-04). Infusion Therapy. https://www.mass.gov/doc/ar-9204-infusion-therapy-pdf/download
- Morgan, L. (2022). Operating Under the Radar: IV Hydration Therapy and Risks to Patient Health. Innovations Magazine, Policy Perspectives, National Association of Boards of Pharmacy. (5) 2-3. https://www.nxtbook.com/nabp/innovations/innovations-magazine-nov-dec-2022/index.php?startid=5#/p/4
- NC Board of Nursing Position Statement (2022). ADMINISTRATION OF INTRAVENOUS FLUIDS (IV HYDRATION), NUTRIENT THERAPIES, AND MEDICATIONS FOR HYDRATION, HEALTH, AND WELLNESS POSITION STATEMENT for RN, LPN, and APRN Practice. iv-hydration-clinics.pdf (ncbon.com)
- NC Board of Pharmacy (2022). State and Federal Pharmacy Law Applicable to Walk-In IV Therapy Clinics. Microsoft Word - Final Draft Statement Clinics Offering Walk-in IV Therapies Oct 2022 (ncbop.org)
- Oregon Board of Nursing. Prescriptive and Dispensing Authority in Oregon for Advanced Practice Nurses. https://www.oregon.gov/osbn/Documents/Booklet_prescriptive_authority.pdf
- Rogers, G. (2022). IV Spa Hydration: Should I be Doing This? Nebraska Nursing News (74), 4-13. https://epubs.thinknurse.com/publication/?m=9518&i=770947&p=12&ver=html5
- South Dakota Board of Nursing (2022). Elective IV Infusion and Medication Therapy Guidelines. https://doh.sd.gov/documents/IV_Infusion_and_Medication_Guidelines.pdf
- Texas Board of Nursing Bulletin (2020). See pages 8-10. https://www.bon.texas.gov/pdfs/newsletter_pdfs/2020/July%202020%20Bulletin%20Web.pdf
- Washington Department of Health Nursing Care Quality Assurance Commission Advisory Opinion. Registered Nurse and Licensed Practical Nurse: Compounding and Reconstituting Medications. https://www.doh.wa.gov/Portals/1/Documents/6000/NCAO11.pdf
- Wyoming Board of Nursing (2022). ADVISORY OPINION AESTHETIC & INFUSION THERAPY PROCEDURES. https://drive.google.com/file/d/1sXCg2oJ1AuK9cIfea-JW1S3-sxdarnTc/view

MMB 04.10.23

STATE OF MISSISSIPPI
MISSISSIPPI BOARD OF PHARMACY

Mississippi Board of Pharmacy: Checklist for Compliance

Infusion Clinics (hydration, other medications)

1. Maintaining the drug storage area
    a. Are drugs stored per manufacturer's guidelines?
    b. Is the drug storage area clean and free of dust and clutter?
    c. No expired drugs in stock.
    d. The label of the container has the drug name, strength, manufacturer's lot number and expiration date.
    e. All medication is received with packaging intact, and the integrity of the medication has not been compromised.
2. Who supplies the clinic's medications?
3. Is the supplier permitted with the MS Board of Pharmacy?
4. Is the supplier an outsourcer or 503A pharmacy?
5. Are drugs shipped patient specific and only used for that patient?
    a. Are the patient specific medications single dose or multi-dose packages?
    b. When were the patient specific medications received?
    c. When is the patient scheduled to receive the medications?
    d. Does the beyond use date appear to be appropriate?
    e. For single dose vials, verify that remainder is discarded and not used for additional patients.
6. Are drugs shipped in bulk packages for specific patients or for clinic stock?
    a. Are these bulk packages multi-dose packages/vials?
7. Who created the account with the supplier/s?
8. Which provider credentials are drugs being ordered under?
9. Are any infusions prepared on-site or do they come premixed from the supplier?
10. Are infusions prepared on-site prepared according to manufacturer's guidelines?
11. Obtain copies of patient orders (proof of valid orders)
12. Obtain copies of invoices/purchases for the past 6 months
13. How are drugs labeled (patient specific, take home, etc)
14. How did the facility find their supplier?
15. Take pictures and get copies of any documentation that would be helpful.

BOARD OF MEDICAL LICENSURE **BOARD OF NURSING**

Investigative Questionnaire MSBML and MBON

Is there a physical exam performed prior to administering hydration therapy?

If yes, who performs the physical examination? (Should be done by practitioner with prescriptive authority)

What type of physical exam is performed? (In-person, telemedicine, hybrid)

Is there a medical indication to receive hydration therapy? (Dehydration, unable to tolerate po)

Is there a reason someone might be denied hydration therapy? (CHF, CKD, HTN, hyponatremia, hypernatremia, etc.)

IS there an order to administer IVF?

Who administers the hydration therapy? (MD, APRN, RN, LPN, EMT, unlicensed person)

Whose authority was the IV fluid ordered? (has to be a person with prescriptive authority) And any documentation? (Invoices)

If an APRN ordered, who is the collaborating physician?

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request: Brad Wojciechowski, Executive Director		**2) Date when request submitted:** 8/13/2024 **Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting**
3) Name of Board, Committee, Council, Sections: Choose an item. Interdisciplinary Advisory Council		
4) Meeting Date: 8/22/2024	**5) Attachments:** ☒ Yes ☐ No	**6) How should the item be titled on the agenda page?** Resources on IV Hydration and Compounding – Discussion and Consideration
7) Place Item in: ☒ Open Session ☐ Closed Session	**8) Is an appearance before the Board being scheduled?** *(If yes, please complete Appearance Request for Non-DSPS Staff)* ☐ Yes <Appearance Name(s)> ☐ No	**9) Name of Case Advisor(s), if applicable:** <Click Here to Add Case Advisor Name or N/A>
10) Describe the issue and action that should be addressed: <Click Here to Add Description>		
11) Authorization  **8/13/2024** **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.

FDA highlights concerns with compounding of drug products by medical offices and clinics under insanitary conditions

October 25, 2021

Background

Human drug compounding is generally a practice in which ingredients of a drug are combined, mixed, or altered to create a medication tailored to the medical needs of an individual patient. Section 503A of the Federal Food, Drug and Cosmetic Act (FD&C Act) describes the conditions under which compounded human drug products are exempt from the following three sections of the FD&C Act:

- Section 505 concerning approval prior to marketing
- Section 501(a)(2)(B) concerning current good manufacturing practice (CGMP) requirements
- Section 502(f)(1) concerning labeling with adequate directions for use

One of the conditions to qualify for these exemptions is that the drug is compounded by a licensed pharmacist in a state-licensed pharmacy or federal facility, or by a licensed physician, based on the receipt of a valid patient-specific prescription. Compounded drugs that meet the conditions of section 503A are still subject to section 501(a)(2)(A) of the FD&C Act which states a drug is considered adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

FDA has become increasingly aware of drug products compounded at medical offices and clinics that were prepared under insanitary conditions. FDA has also become aware of business models, such as intravenous (IV) hydration clinics, medical spas, and mobile IV infusion services, that are compounding drugs that may not meet the conditions of section 503A of the FD&C Act or comply with state regulations. Contaminated, or otherwise poor quality, compounded drug products can lead to serious patient illnesses, including death.

Case Examples and Discussion of Risk

The extent to which compounding of drug products is occurring in medical offices is not fully known as compounders seeking to compound drugs under section 503A generally do not register with FDA. Adverse events associated with drug products compounded at medical offices under insanitary conditions have been reported, but it is likely that these events are underreported. The compounding case examples below illustrate some of the risks associated with drug products prepared, packed, or held under insanitary conditions.

Cases of drug product compounding at medical offices under insanitary conditions are well documented. In 2016, a series of fungal infections were linked to an oncology medical practice where 38 patients were exposed and 17 patients were infected with *Exophiala dermitides*, a thermophilic black yeast. FDA communicated with state regulators and conducted an inspection of the medical office where sterile compounding was occurring. Insanitary conditions observed at the medical office during the inspection included contamination in the form of brownish soiled material inside the bottom edges of the ISO-5 classified hood used for sterile drug compounding. FDA also observed that the cleanroom design was inadequate to prevent microbiological contamination of drug products intended to be sterile as the ISO-5 classified hood was located adjacent to a refrigerator and in close proximity to a sink without any air quality control of the surrounding area. ISO-classified areas that meet standardized levels of cleanliness[1] help ensure an appropriate environment for sterile drug compounding.

More recently, in July 2020, FDA was made aware of drug products intended to be sterile that were being compounded under insanitary conditions at Advanced Nutriceuticals, LLC dba The Guyer Institute of Molecular Medicine. The Guyer Institute of Molecular Medicine is a medical clinic operating under a physician's license and offering services such as platelet-rich plasma therapy, IV vitamin therapy, hormone replacement therapy, and laboratory testing. FDA worked with state regulators and conducted an inspection during which numerous deficiencies involving insanitary conditions were observed (/media/144544/download) including, but not limited to:

- Personnel in street clothes with ungloved hands filling drug products intended to be sterile into syringes outside of an ISO-5 classified area. These drug products were scheduled for shipment to patients across the country.
- Personnel performing sterile drug compounding within the ISO-5 classified area failed to sanitize or change gloves after contact with non-sterile items including a face mask and trash can.
- Personnel in the ISO-5 classified area moved rapidly and blocked first pass (clean) air in the vicinity of open sterile units, increasing risk of product contamination.

- High efficiency particulate air (HEPA) filters located in the ISO-5 classified area and cleanroom were discolored and/or damaged.
- The ISO-5 classified cleanroom workbench where sterile drug compounding occurs was constructed of laminated wood which was peeling.
- A heating vent located below the ISO-5 classified hood was visibly dirty and had no filtering device attached.
- Hazardous drugs were handled without providing adequate containment, segregation, or cleaning of work surfaces and utensils to prevent cross-contamination.
- Stock solutions intended to be sterile were exposed to lesser quality than ISO-5 classified air after the stopper had been punctured multiple times.
- Use of expired active pharmaceutical ingredients to prepare drug products intended to be sterile.

In addition, in February 2021, FDA was made aware of a 50-year-old female patient who was hospitalized and treated for suspected septic shock with multi-organ failure after receiving an IV-vitamin infusion in her home. The patient's blood cultures grew *Pseudomonas fluorescens,* a gram-negative bacterium. The IV-vitamin infusion was compounded by Age Management Institute Santa Barbara, a medical clinic providing services including IV therapies and vitamin injectables, sexual health products, hormone replacement therapy, weight loss/management products, and diagnostic laboratory assays. FDA collaborated with multiple state regulators and conducted an inspection of the firm during which several deficiencies involving insanitary conditions were observed (/media/152075/download) including, but not limited to:

- Lack of a certified ISO-5 classified area for sterile compounding.
- Contamination in compounding areas including peeling paint, stained work surfaces, visibly dirty equipment, and air vents with dust and grime.
- Difficult to clean equipment and surfaces such as carpeting in the IV storage and mixing room.
- Standing water in a refrigerated storage area used to store sterile vials.
- Use of expired active pharmaceutical ingredients to prepare drug products intended to be sterile.

Furthermore, FDA has become aware of sterile compounding activities, such as adding vitamins to IV infusion bags, being performed by business entities such as IV hydration clinics, medical spas, and mobile IV infusion companies. It is unknown if drug products are prepared, packed, or held under insanitary conditions by these entities and whether a licensed practitioner is on-site

to evaluate patients and write prescriptions for the drug products intended to be sterile being administered. It is also uncertain whether entities producing these sterile products are following state regulations. It is FDA's understanding that entities such as these can be found nationwide; however, the number of these entities and the compounding practices occurring at these entities are not fully understood given that compounders seeking to compound drugs under section 503A generally do not register with FDA.

The extent to which compounding of drug products is occurring at medical offices and business entities such as IV hydration clinics is not fully known; however, compounding, packing or holding drug products intended to be sterile under insanitary conditions at any facility significantly increases the risk of serious product quality concerns, such as product contamination. Compounding drug products intended to be sterile under insanitary conditions, including employing poor aseptic practices, using dirty equipment, or working in a facility not properly designed to maintain appropriate levels of cleanliness, as noted in the examples described above, increases the risk of product contamination. Use of contaminated drug products intended to be sterile has led to serious patient illnesses, hospitalization, and death.

Conclusion

The above examples of compounding performed at medical offices highlight the crucial need for compounding to be performed in accordance with best practices and not under insanitary conditions to ensure the public has access to quality compounded drugs. Patients can be significantly harmed when drugs are compounded in a way in which sterility or quality cannot be assured. In addition, sterile compounding activities being performed by business entities such as IV hydration clinics present risk and require continued evaluation.

FDA is committed to continued evaluation of these practices and collaboration with state regulatory authorities to address identified and emerging risks to public health and promote the quality of compounded drugs. FDA urges compounders, including physicians' offices and emerging compounding entities, to comply with all state and federal laws and regulations related to compounding and take necessary actions to protect patients who receive their compounded drug products. It is critical that any manipulation of medications, particularly those required to be sterile, occurs in accordance with conditions and practices designed to prevent contamination and other quality concerns.

FDA encourages consumers, patients, and health care professionals to report any adverse events or quality problems experienced with the use of compounded drug products to FDA's MedWatch Adverse Event Reporting program:

- Complete and submit the report online at www.fda.gov/medwatch/report.htm (http://www.fda.gov/medwatch/report.htm); or
- Download and complete the form, then submit it via fax at 1-800-FDA-0178.

References

1. International Organization for Standardization (2015). *Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness by particle concentration* (ISO Standard No. 14644-1:2015).

South Carolina
Department of Labor, Licensing and Regulation

110 Centerview Drive
Post Office Box 11329
Columbia, SC 29211-1329
(803) 896-4300

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 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.

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request:	2) Date when request submitted:
Brad Wojciechowski, Executive Director	8/13/2024
	Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting

3) Name of Board, Committee, Council, Sections:

Choose an item. **Interdisciplinary Advisory Council**

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
8/22/2024	☐ Yes ☒ No	Future Topics – Discussion and Consideration

7) Place Item in:	8) Is an appearance before the Board being scheduled? *(If yes, please complete Appearance Request for Non-DSPS Staff)*	9) Name of Case Advisor(s), if applicable:
☒ Open Session ☐ Closed Session	☐ Yes <Appearance Name(s)> ☒ No	<Click Here to Add Case Advisor Name or N/A>

10) Describe the issue and action that should be addressed:

Council discussion on potential future topics.

11) Authorization

8/13/2024

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.