



APRN **ROUNDTABLE**

Making an Impact on
APRN Regulation:
Every Moment Matters

Tuesday, April 9, 2024 | Virtual





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

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Objectives

Importance of
Regulations

Collaboration

Common
Indications for
IV hydration

Scope of
Practice

FDA

FTC

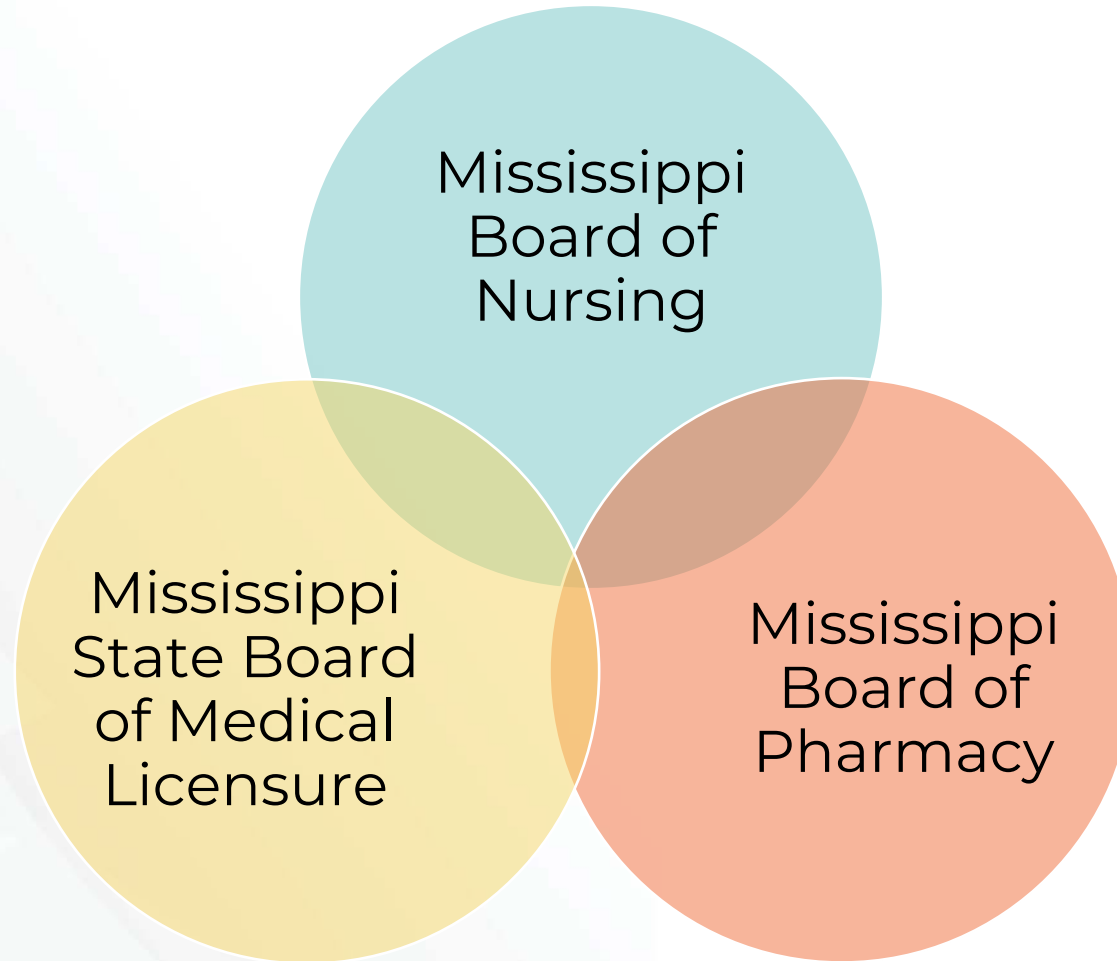
Case Studies

The Importance of Regulation

- Regulations represent legally mandated rules instituted by governmental agencies.
- Play a pivotal role in safeguarding the interests of citizens.

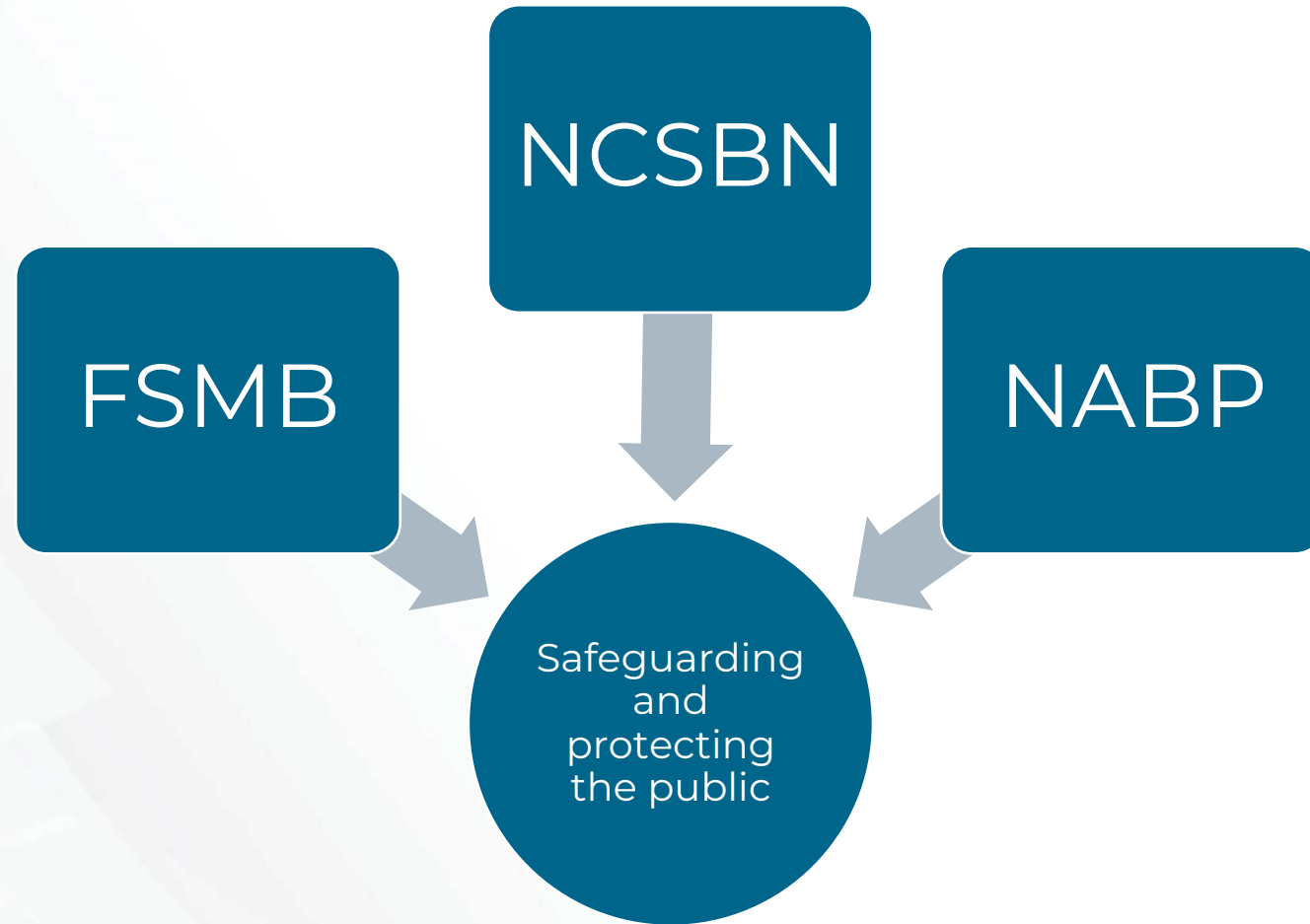


The Power of Triad Collaboration





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?



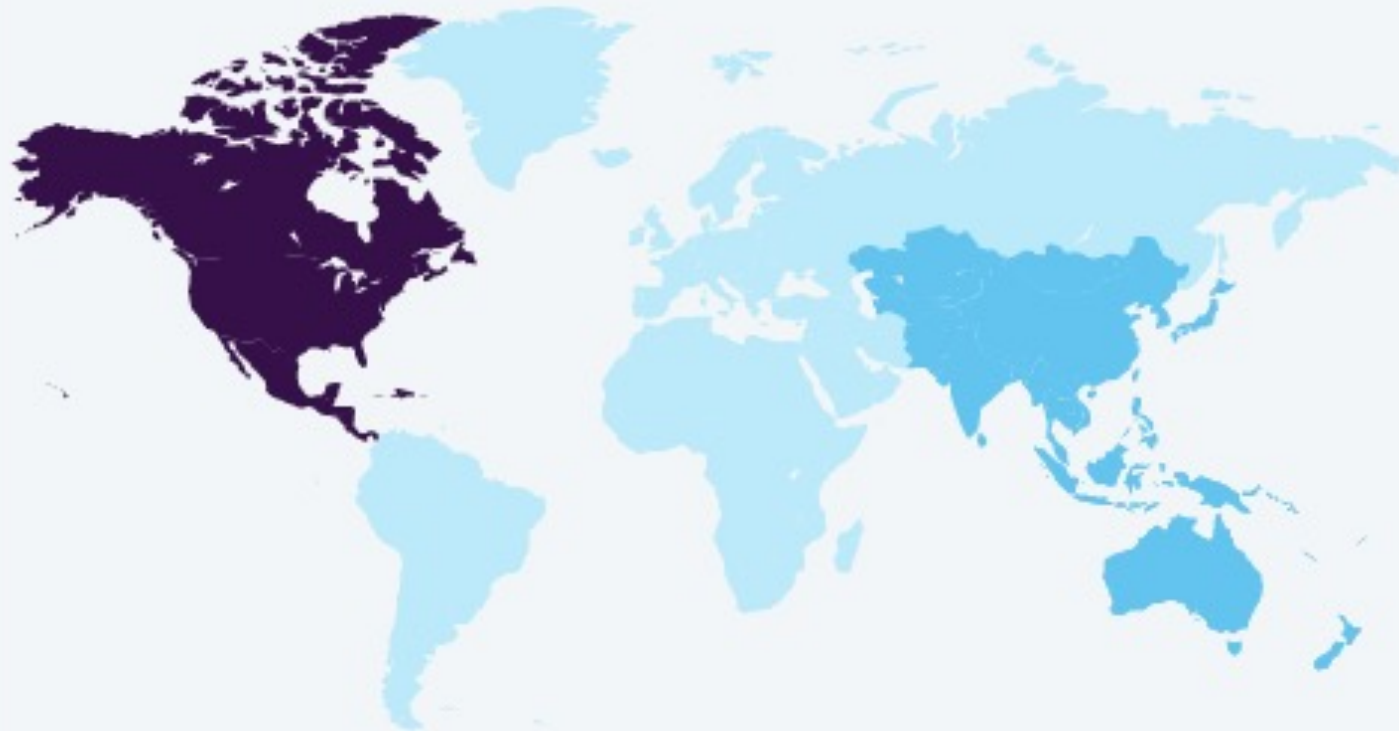
IV Hydration Advertisement

- “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



● Largest Market ● Fastest Growing Market



GRAND VIEW RESEARCH

46.8%

North America Market
Revenue Share, 2022

Source:
www.grandviewresearch.com

Global Intravenous (IV) Hydration Therapy Market

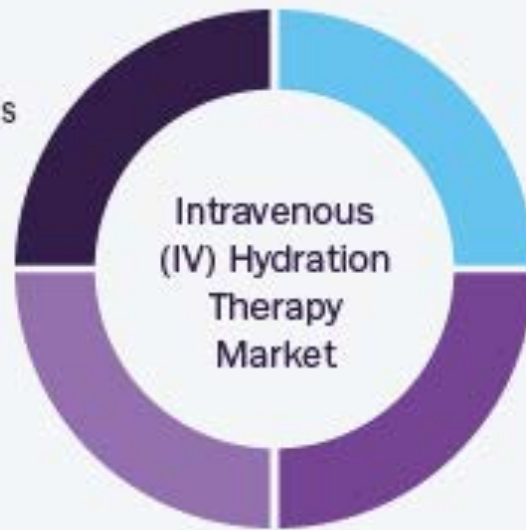
Report Segmentation

End-use Outlook

- Hospitals & Clinics
- Wellness Centers & Spas
- Home Healthcare
- Others

Regional Outlook

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



Service Outlook

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

Component Outlook

- Medicated
- Non-medicated



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.



Mobile IV Hydration

Discover the endless benefits of IV Hydration and Vitamin Therapy

Drips

- MYERS COCKTAIL
- ENERGY BOOST (REBOOT)
- IMMUNITY BOOSTER
- MIGRAINE/PAIN MIX
- GLOW DRIP
- DEHYDRATION DRIP
- DUO DRIP

Injections

- B12
- BIOTIN
- TORADOL
- DEXAMETHASONE
- FAT BURNER SHOTS
- TAURINE
- AND MORE....

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, Peppid, 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, Peppid, 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, Peppid, 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, sinus, and stomach bugs. This drip

comes infused with Vitamin C, Selenium, Zinc, B Complex, Zofran (if needed), Glutathione and D3 (M 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 (M 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 (M 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, Peppid, 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:**
- ZOFAN:** 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. \$35
 - 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
 - PEPID:** 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
 - TRIMMUNE:** Triple defense immunity formula that is made of potent antioxidants and an essential mineral that assists in supporting the body's immune response. \$50
 - LIPID:** Weight loss. \$30
 - LIPID 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
 - TRIMMUNE
 - D3
 - ALL LIPO'S
 - D3 (IM INJECTION ONLY)



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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



NOW ACCEPTING NEW CLIENTS!

INFUSION THERAPY LLC
WHERE EVERY CLIENT IS FAMILY AND YOUR WELLNESS IS OUR HOME!

WEIGHT LOSS
Once weekly
Injection
(\$250 / Month)

**When you pay the month in advance*
~This would normally be priced at \$75 per Injection.~
Transparent Pricing!
No Initial Assessment or Start-Up Fees!*



Our Menu

IV Drips
Doc Myers, Myers MD+, Fountain of Youth, C-Pack Immunity, Skinny Black Dress, Fit for Tux, Migraine-Be-Gone, The Aphrodisiac, Zenn-Stress-Relief, NAD+, High Dose Vitamin C, and more!

IM Injections
Lipo/L-Carnitine, Lipo B, B12, Tri-Immune, Biotin, Vitamin D3, and more!

Ask us about our Add-On's

601-913-8063
infusiontherapyllc.net
6760 US-90 E, Suite #5, Hattiesburg, MS 39402

 Infusion Therapy LLC is 😊 feeling motivated at Forrest Co Multi-Purpose Center.
September 23, 2023 · Hattiesburg · 🌐

🌅 Rise and shine, folks! 🌅🌈 Join Infusion Therapy LLC at the sensational **RISE Hot Air Balloon Festival 2023** at the Forrest County Multi-Purpose Center. We're floating some incredible deals your way, to help you keep your cool and beat the heat this season!

🥤🍹 Quench your body's thirst with our exclusive event specials: The invigorating Doc Myers Drip, the slimming Skinny Black Dress Drip, age-defying Fountain of Youth Drip, and handy Plain Fluids Drip. Our infusions are desig... [See more](#)



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)

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Claims of Clinical Proof (FTC)

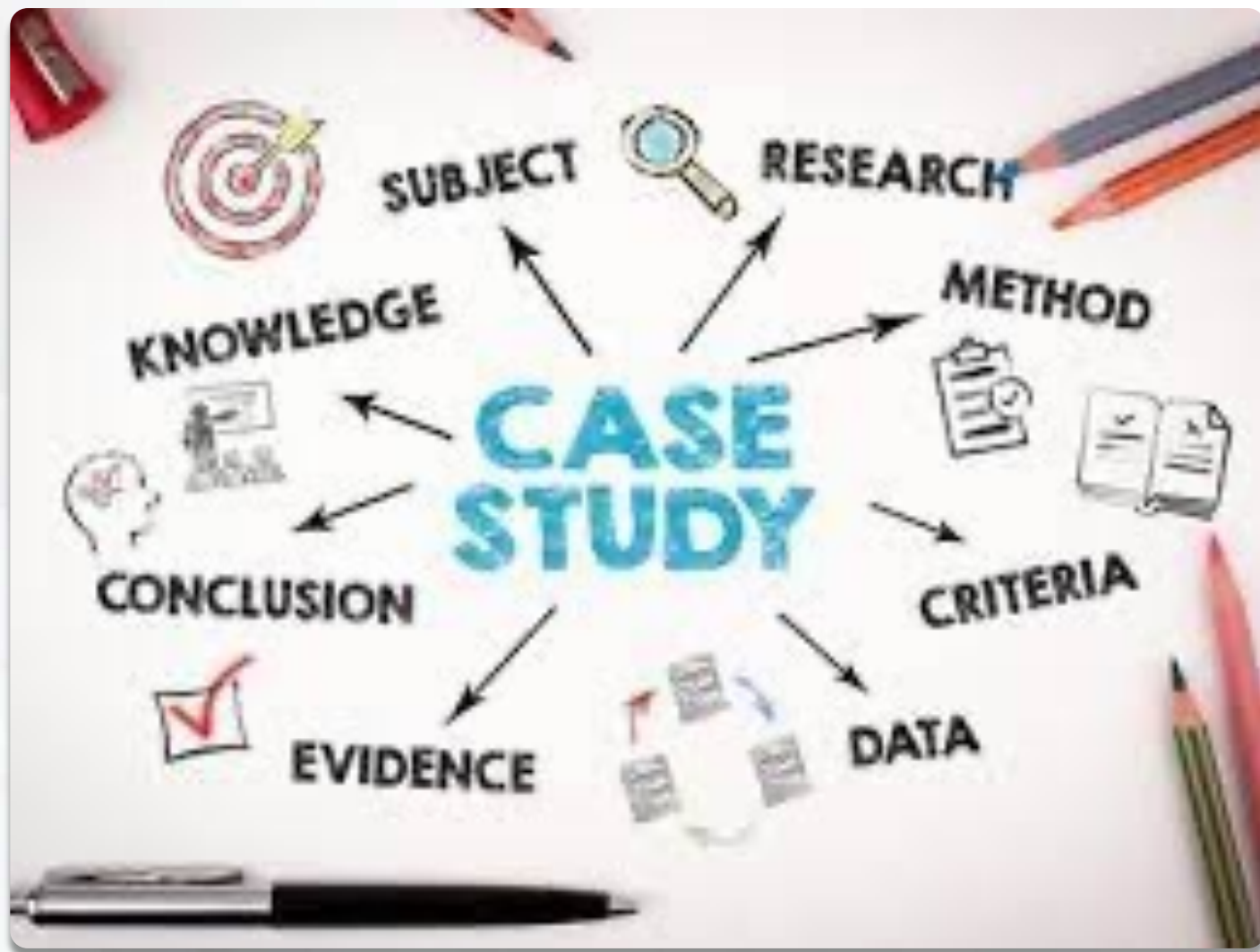
- An advertiser must have at least the level of proof claimed (e.g., reference to a clinical study or scientific research)
- Claims that a product is “clinically proven” or “scientifically proven” to work require evidence sufficient to satisfy the relevant scientific community of the claim’s truth

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. IVs are administered based on a client's want and there is no medical justification for the selected IV. Clients selected fluids and medications from a menu of services.
- RESPONDENT administered the IV 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 I.

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.