IV Hydration Facilities

Panel discussion with Federation of State Medical Boards, National Association of Boards of Pharmacy, and National Council of State Boards of Nursing

July 26, 2023

John Mistler, PharmD, MBA, BCSCP

Regulatory Officer, Branch 4

Office of Compounding Quality and Compliance

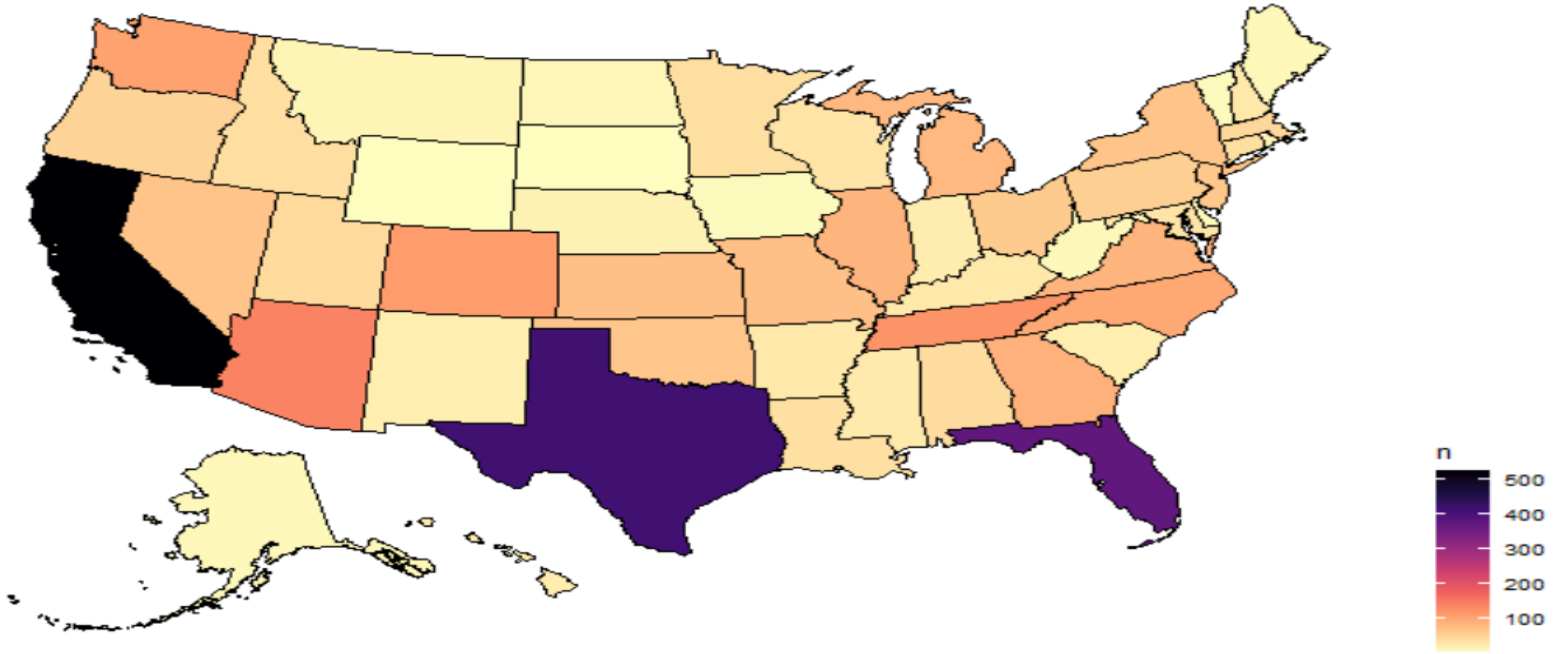
OBJECTIVES

- Provide a Brief Overview of IV Hydration Operations
- Describe the Current Landscape of IV Hydration Facilities
- Provide Examples of Uses
- Discuss State Oversight
- Discuss the Compounding Risk Alert
- Provide Case Examples

Businesses Offering IV Hydration Services

- Stand-alone retail & mobile facilities
- Medspas
- Holistic medicine & functional/integrative/ naturopathic medicine providers
- Urgent cares (non-hospital affiliated)
- Private Practice Facilities
- Chiropractors
- Physiotherapists and wellness gyms
- Tanning salons
- Other medical centers

Presence of Businesses Offering IV Hydration



Examples of Uses of IV Products from Websites

- “Just Feel Better”
- “Anti-aging Infusion”
- “Immunity Booster”
- “Covid rescue” “Covid Helper”
- “Long Haulers Drip”
- “Post Covid-19 Drip”
- “Glutathione Vitamin Glow”
- “Brain Boost”
- “Antioxidant Therapy”
- “Autoimmune Disease Helper”
- “Energy Boost”
- “Hangover Fix”
- “Slim Boost Infusion”
- “Beautify”
- “Sports Booster”
- “Asthma Help”

General Observations of State Oversight

- IV hydration facilities may not be registered/licensed with states (state licensing boards focus on licensure of the practitioner)
- State boards may be more reactive / complaint-driven
- Involvement of multiple disciplines may cause complexities with state oversight

October 2021 Compounding Risk Alert

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

- "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."

Case Example #1

Following notification of a 50 y/o female patient who was hospitalized for septic shock with multi-organ failure after receiving IV vitamin infusion from a medical clinic

- FDA collaborated with state regulators to conduct an inspection
- Observations of insanitary conditions found at the facility included:
  - Lack of a certified ISO 5 classified area for IV preparations
  - Peeling paint, stained work surfaces, visibly dirty equipment, and dusty air vents
  - Carpeting in the IV storage and mixing room
  - Standing water in a refrigerator used to store sterile vials
  - Use of expired APIs

Case Example #2

Following notification of concerns regarding insanitary conditions found at a medical clinic preparing IV hydration products

- FDA collaborated with state regulators to conduct an inspection
- Observations of insanitary conditions found at the facility included:
  - Ungloved hands preparing sterile syringes outside ISO 5
  - Personnel touching a trash bin and adjusting face masks during preparations of IV products
  - Discolored and damaged HEPA filters
  - Wood-like material workbench with a peeling top in the cleanroom
  - Use of expired APIs

Thank You

FTC Compliance Considerations

Joint Regulator IV Hydration Meeting
July 26, 2023

Christine DeLorme, Attorney
FTC Division of Advertising Practices

These views are my own and not those of the FTC or any Commissioner

FTC Jurisdiction Is Broad

- FTC Act
  - Section 5 (15 U.S.C. § 45) outlaws “unfair or deceptive acts or practices”
- We do not regulate the practice of medicine with individual patients

Same Legal Standards Apply to All Products, All Industries

- FDA regulatory status does not affect legal obligations under the FTC Act (and using the DSHEA disclaimer is not a safe harbor)
- All channels of advertising are covered, including traditional media (print, radio, television), online ads, websites, social media, email, product labeling, and point-of-sale displays

Enforcement Options

- Informal (*e.g.*, closing letter)
- More formal, but short of court filing (*e.g.*, warning letter)
- Formal enforcement action
  - Federal Court (since 1973)
  - Administrative Proceeding (since 1914)

Remedies

- Injunctions
- Redress/Disgorgement*
- In certain circumstances, civil penalties may be available (up to $50,120 per violation)

What Scientific Proof Do You Need for Health Claims?

- 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)

What About Claims of Clinical Proof?

- 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

In re A&O Enterprises dba iV Bars 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

iV Bars Consent Order

- Requires human clinical testing for disease claims
- Requires competent and reliable scientific evidence for other health claims
- iV Bars also agreed to send an email notice to consumers who had purchased the Myers Cocktail, informing them that scientific evidence has not shown the cocktail to be an effective treatment for any disease

COVID-19 Warning Letters

- The FTC has issued more than 450 warning letters to marketers promoting products and services to prevent, treat, or cure COVID-19
- About one-third of the letters were issued jointly with the FDA
- More than 70 letters have challenged various IV therapies (*e.g.*, Vitamins C and D, glutathione, Myers Cocktail)
- Many clinics offer IV therapies along with other alternative or compounded treatments (*e.g.*, vitamin injections, ozone, HBOT, stem cells, peptides)

Questions?

- www.ftc.gov
- www.ftc.gov/tips-advice/business-center
- https://www.ftc.gov/coronavirus

cdelorme@ftc.gov
202-326-2095

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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.

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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?

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

2024 APRN **ROUNDTABLE**

Objectives

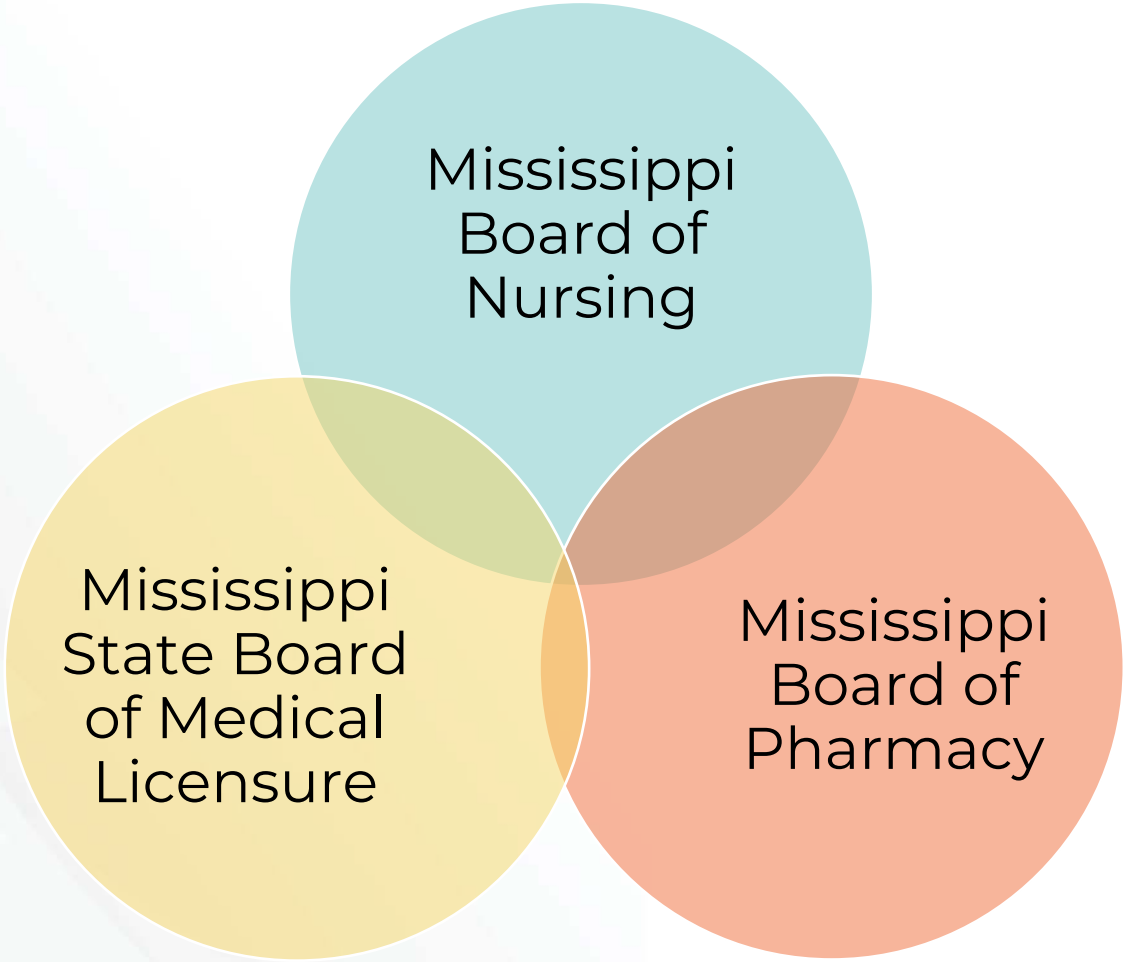
- Importance of Regulations
- Collaboration
- Common Indications for IV hydration
- Scope of Practice
- FDA
- FTC
- Case Studies

The Importance of Regulation

- Regulations represent legally mandated rules instituted by governmental agencies.

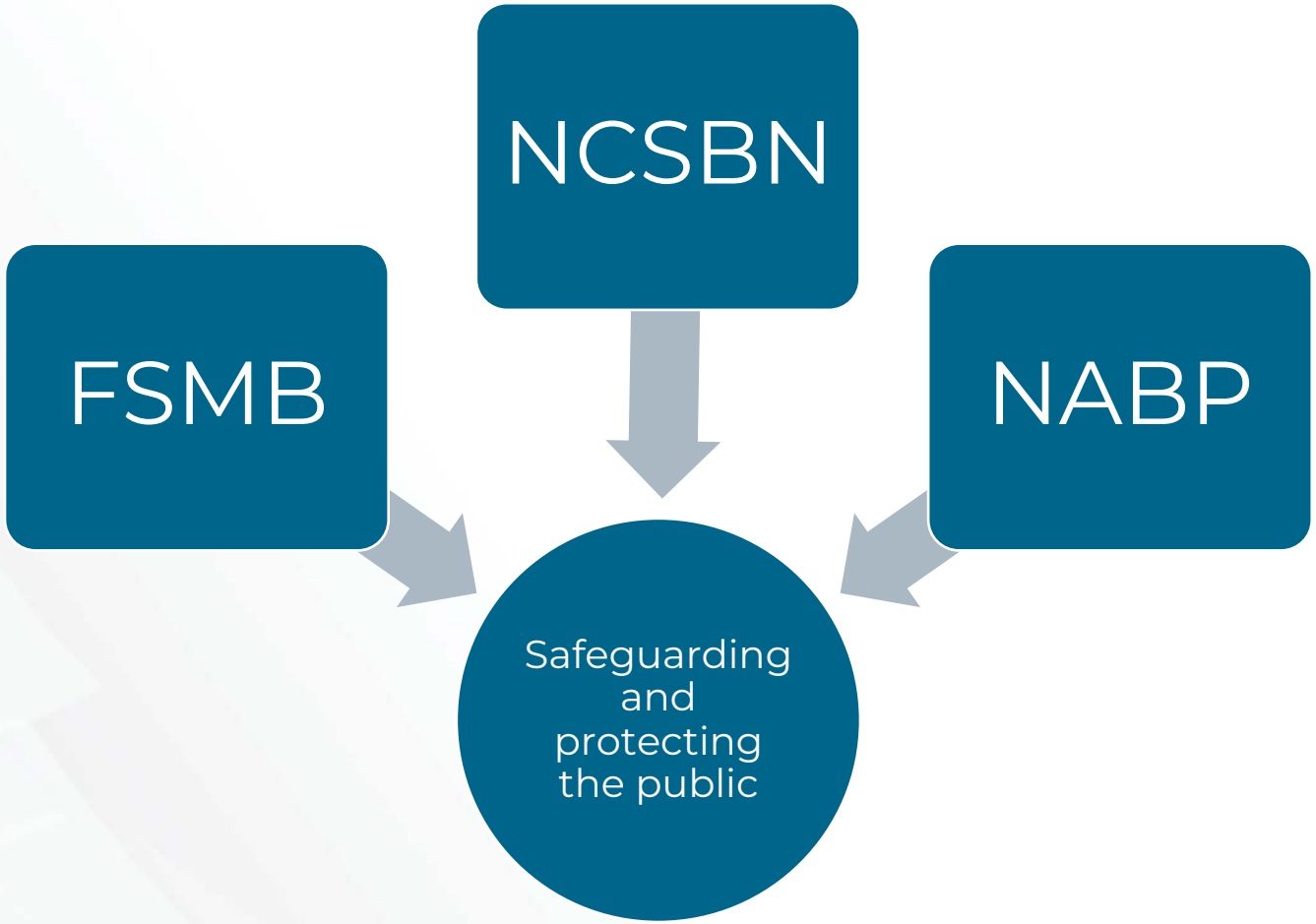
- Play a pivotal role in safeguarding the interests of citizens.

The Power of Triad Collaboration




ASSIST
TEAMWORK
SUPPORT
SUCCESS
COLLABORATION
SHARE
INSPIRATION
EXCHANGE
TRUST

National Perspective



Businesses Offering IV Hydration Services

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- Wellness Gyms and Physiotherapists
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FDA 7/26/23

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FDA

General Observations of State Oversight

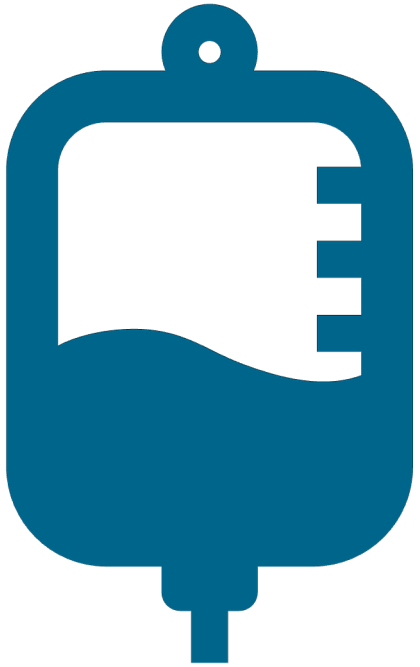
IV Hydration facilities may not be registered/licensed with states

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

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Mississippi Collaboration

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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.

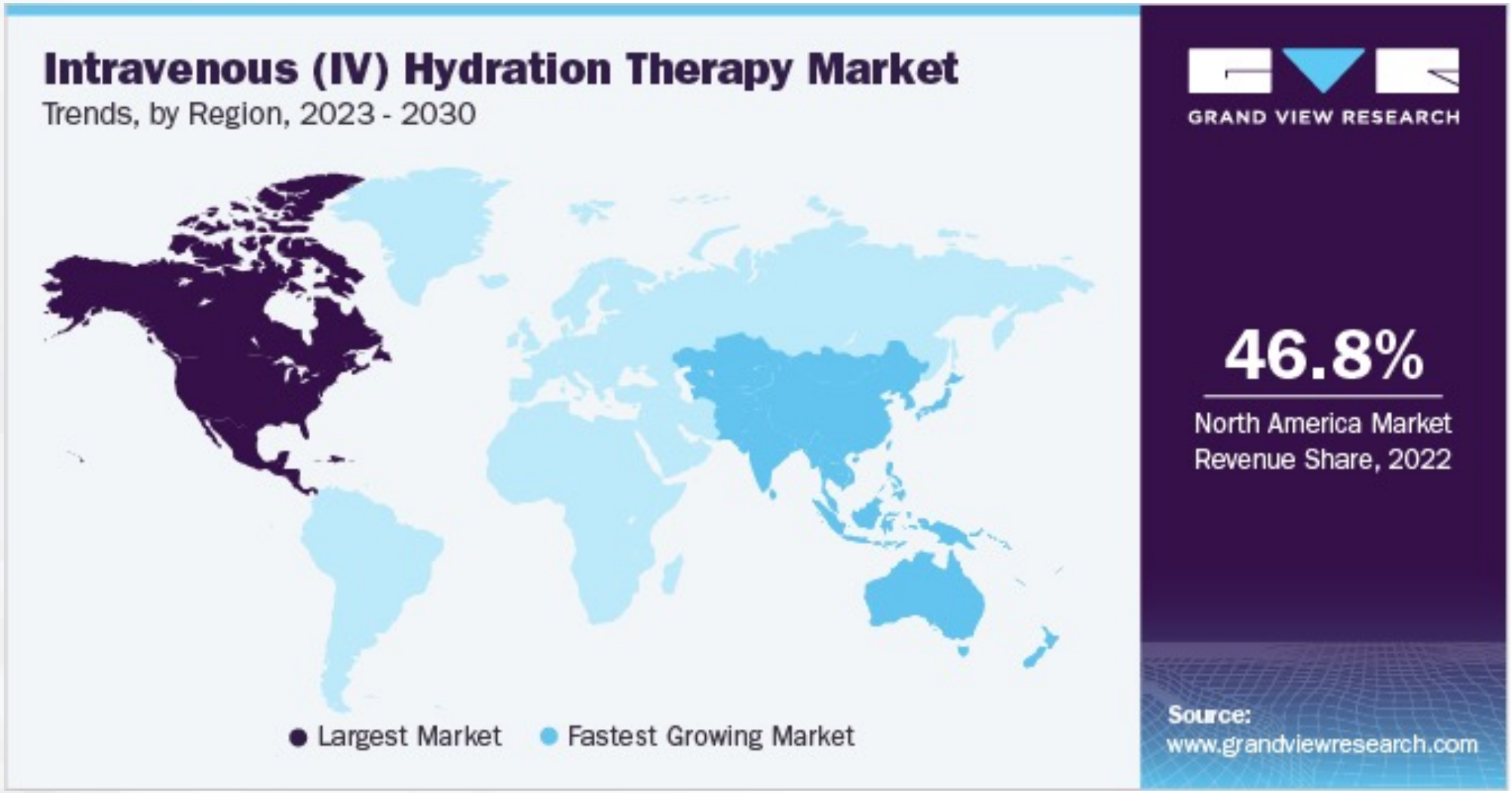
Implementation of measures to prevent exposure to infectious pathogens and communicable conditions.

Does Research Back its Benefits?


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

IV Hydration Advertisement

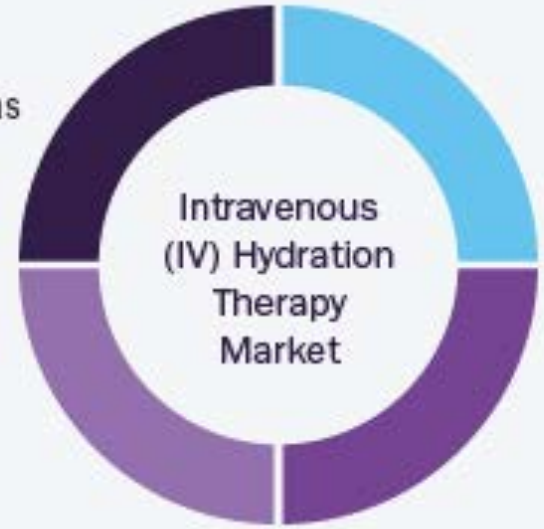
- “Fountain of Youth”
- “Revive”
- “Boost Immune System”
- “Ultimate Hangover Relief”
- “Beautification”
- “Stress Reducer”
- “Memory Enhancer”


Intravenous (IV) Hydration Therapy Market
Trends, by Region, 2023 - 2030
GRAND VIEW RESEARCH
46.8%
North America Market
Revenue Share, 2022
Largest Market
Fastest Growing Market
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+

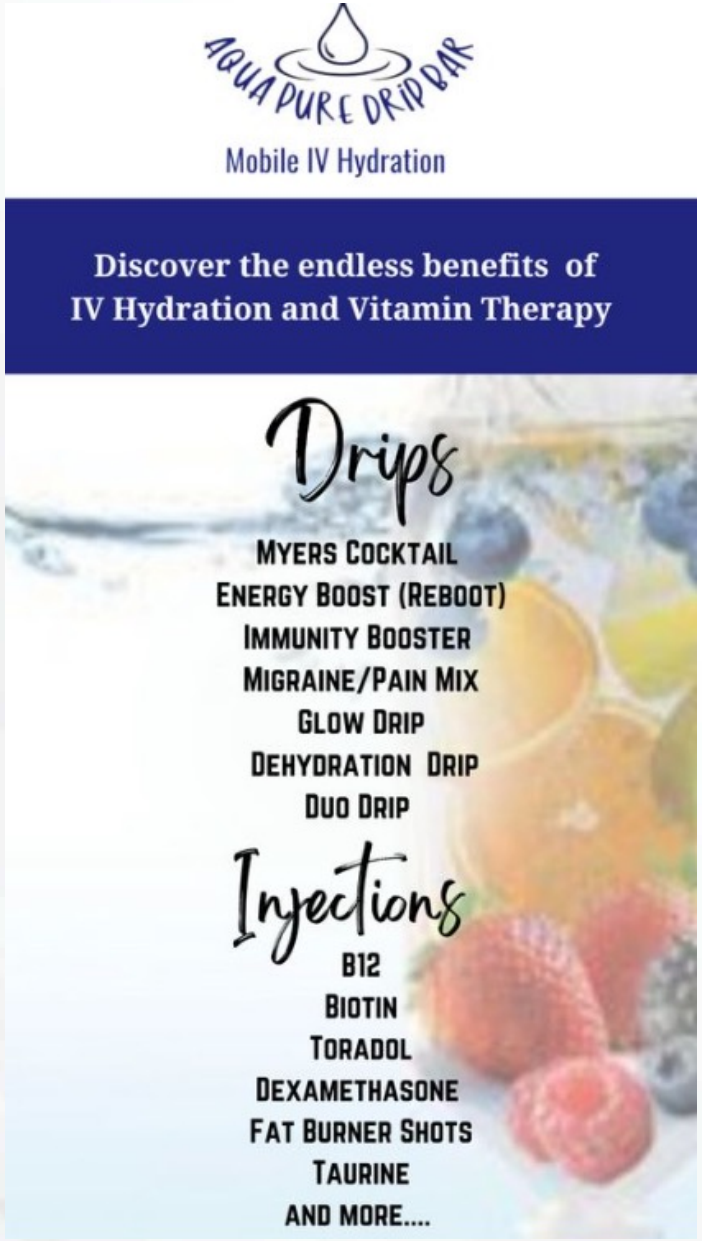
Number of Countries Covered in the Report

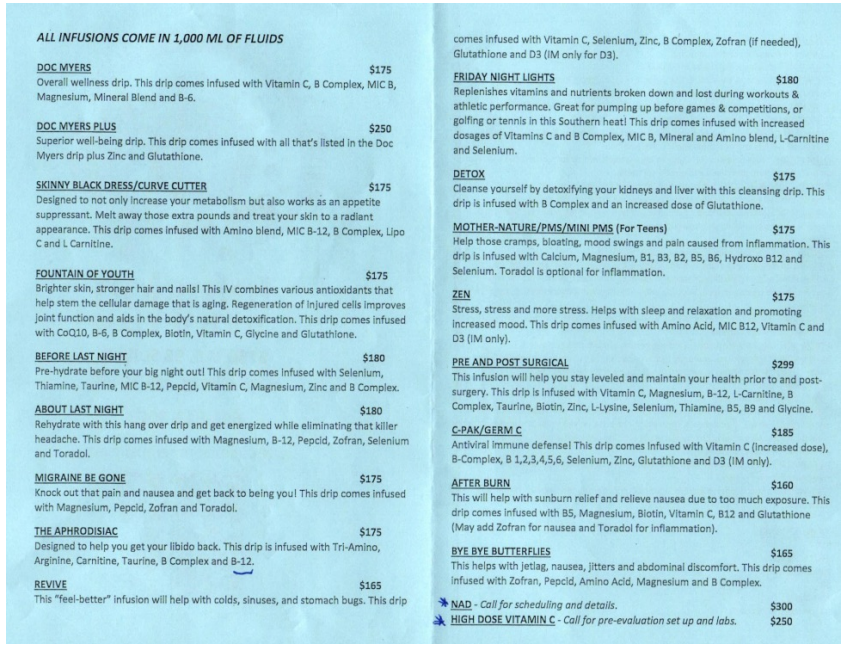
Source:
www.grandviewresearch.com

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).

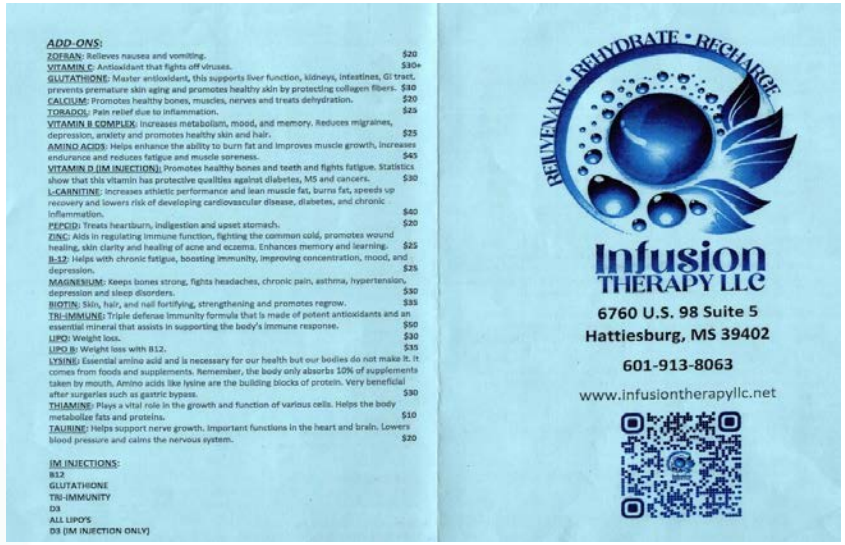
PRE AND POST SURGICAL $299
This infusion will help you stay leveled and maintain your health prior to and post-surgery. This drip is infused with Vitamin C, Magnesium, B-12, L-Carnitine, B Complex, Taurine, Biotin, Zinc, L-Lysine, Selenium, Thiamine, B5, B9 and Glycine.

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

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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.

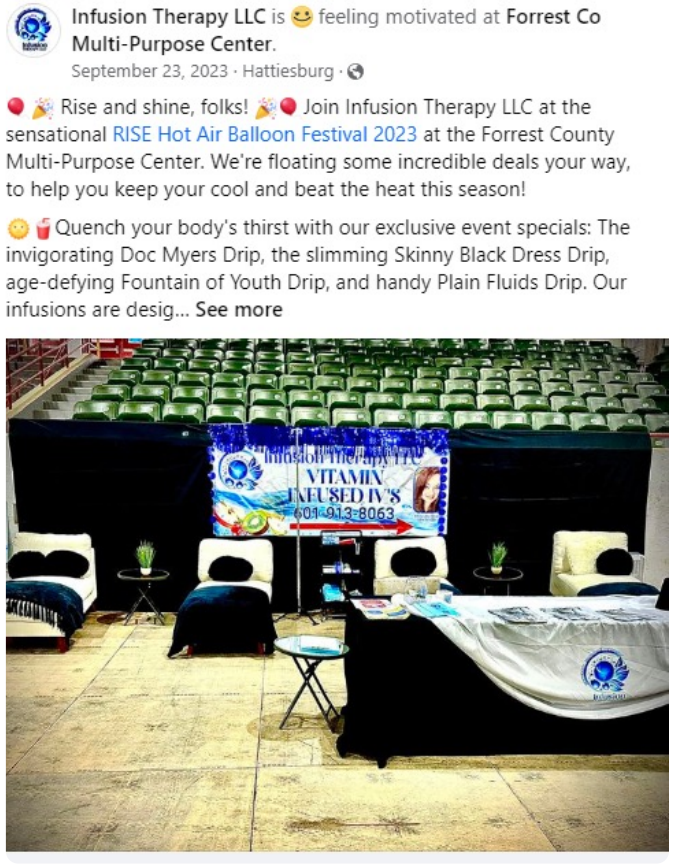
Hangover Cure:$149

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)

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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

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An advisory opinion adopted by AZBN is an interpretation of what the law requires. While an advisory opinion is not law, it is more than a recommendation. In other words, an advisory opinion is an official opinion of AZBN regarding the practice of nursing as it relates to the functions of nursing. Facility policies may restrict practice further in their setting and/or require additional expectations related to competency, validation, training, and supervision to assure the safety of their patient population and or decrease risk.

OPINION:INTRAVENOUS HYDRATION AND OTHER THERAPIES
DATE APPROVED: 9/23
REVISED DATE: 1/24, 5/24
ORIGINATING COMMITTEE:
SCOPE OF PRACTICE COMMITTEE

Within the Scope of Practice of _X_ RN _X_ LPN _X_ APRN

ADVISORY OPINION
INTRAVENOUS HYDRATION AND OTHER THERAPIES

STATEMENT OF SCOPE

It is within the Scope of Practice of the registered nurse (RN) and licensed practical nurse (LPN), and Advanced Practice Registered Nurse (APRN) who can demonstrate the necessary education, knowledge, judgment, skills, and licensure/certification, where applicable, to administer intravenous (IV) fluids hydration, nutrient therapies, and medications, as authorized by a valid order prescribed by a Licensed Provider (LP) with prescriptive authority and acting within their scope of practice. Orders need to be individualized, and based upon the patient-specific needs with a medical rationale for the order. The issuance of standing orders for elective IV therapies, including hydration, nutrients, or medications, by an APRN for a nurse or other healthcare staff member to follow is not consistent with the Arizona State Board of Nursing's 2017 Advisory Opinion regarding standing orders, and does not satisfy the APRN's duties to the patient.

It is not within the scope of practice for an RN or LPN to independently engage in acts that require independent medical judgment, medical diagnosis, or the ordering, compounding, or prescribing of IV fluids, IV medications, or IV therapeutic regimens. An LPN or RN must have a medical order to administer IV medication or IV therapy/hydration, including elective services marketed as wellness promotional services provided at the request of a patient in any setting, such as the home, mobile hydration clinic, drip bars, or other non-facility locations.

DEFINITIONS:

It is crucial for nurses and healthcare providers to understand the differences between compounding IVs and adding medication to an existing IV line. This explanation aims to clarify these concepts, ensuring that healthcare professionals can apply them safely and effectively.

Compounding: Drug compounding is often regarded as the process of combining, mixing, or altering ingredients to create a medication tailored to the needs of an individual patient. Compounding includes the combining of two or more drugs. Compounded drugs are not

FDA-approved (US Food and Drug Administration, 2022) Key points about IV compounding:

- Sterile Environment: Compounding IVs must be done in a sterile environment to prevent contamination and infection. This often happens in a pharmacy or a dedicated compounding facility within a health care setting, such as a hospital.
- Custom Formulations: Compounded IVs are often used when standard drug formulations are not suitable, such as when a patient needs a specific dosage, a different formulation to avoid an allergy, or a medication that is not commercially available.
- Regulations and Standards: Compounding must adhere to strict guidelines and standards, such as those set by the US Pharmacopeia (USP), particularly USP Chapter 797, which outlines the standards for sterile compounding.

Reconstituted Medications: Reconstituted medications include mixing, reconstituting medications approved by the FDA following the directions by the product's manufacturer and other manufacturer directions consistent with that labeling.

Adding Medication to an IV: Adding medication to an IV, often referred to as IV admixture, involves introducing a medication into an existing IV fluid bag or line. This is commonly done to administer drug doses at the point of care. The critical aspects of adding medications to IVs:

- Immediate Use: This process is typically performed to administer a dose of medication quickly and efficiently, often in response to changing patient needs or emergency situations.
- Standard Preparations: Unlike compounding, adding medication to an IV usually involves using commercially available, pre-prepared drugs that are added to IV bags of fluids like saline or dextrose.
- Technique: The technique is critical to ensure safety and efficacy. Nurses must use aseptic techniques to avoid contamination and check for compatibility and stability of the medication with the IV fluid. standards due to its complexity and risks.

APPLICABLE NURSING BOARD STATUTES AND RULES :
Scope of Practice as defined in ARS 32-1601 and 32-1634.05

Standards Related to RNP, CNM, and CNS Scope of Practice as defined in Arizona Administrative Code (AAC) R4-19-508

Prescribing and Dispensing Authority; Prohibited Acts as defined in AAC R4-19-511

Prescribing Drugs and Devices as defined in AAC R4-19-512

Dispensing Drugs and Devices as defined in AAC R4-19-513

APPLICABLE PHARMACY BOARD STATUTES:

ARS 32-1901 Definitions
11. "Compounding" means preparing, mixing, assembling, packaging or labeling a drug by a pharmacist or an intern or pharmacy technician under the pharmacist's supervision, for the purpose of dispensing to a patient based on a valid prescription order. Compounding includes preparing drugs in anticipation of prescription orders prepared on routine, regularly observed prescribing patterns and preparing drugs as an incident to research, teaching or chemical analysis or for administration by a medical practitioner to the medical practitioner's patient and not for sale or dispensing. Compounding does not include preparing commercially available products from bulk compounds or preparing drugs for sale to pharmacies, practitioners or entities for the purpose of dispensing or distribution.

ARS 32-1961. Limit on dispensing, compounding and sale of drugs
A. Except as otherwise provided in this chapter, it is unlawful for any person to compound, sell or dispense any drugs or to dispense or compound the prescription orders of a medical practitioner, unless that person is a pharmacist or a pharmacy intern acting under the direct supervision of a pharmacist. This subsection does not prevent a pharmacy technician or support personnel from assisting in the dispensing of drugs if this is done pursuant to rules adopted by the board and under the direct supervision of a licensed pharmacist or under remote supervision by a pharmacist.

I. GENERAL REQUIREMENTS

1. Advanced Practice Registered Nurse
    a. Must establish a patient relationship and assess the patient.
    b. Orders need to be individualized, and based upon the patient-specific needs with a medical rationale for the order. Issuing standing orders for elective IV therapies, including hydration, nutrients, or medications, by an APRN for a nurse or other healthcare staff member to follow contradicts the Arizona State Board of Nursing's 2017 Advisory Opinion regarding standing orders, and does not satisfy the APRN's duties to the patient.
    c. Follow state or federal requirements for the procurement of medications, IV solutions, or additives, including vitamins, minerals, or electrolytes.
2. Registered Nurse and Licensed Practical Nurse
    a. The nurse must have an order from a qualified LP who has established a patient relationship and completed an examination with the patient prior to the order;
    b. Must ensure that the LP has assessed the patient and ordered an individualized treatment/medication(s) for the patient;
    c. Follow state or federal requirements for the procurement of medications, IV solutions, or additives, including vitamins, minerals, or electrolytes.
    d. Follow state or federal requirements for the preparation and administration of medications, IV solutions, or additives, including vitamins, minerals, or electrolytes that meet United States Pharmacopeia (USP) Pharmaceutical Compounding-Sterile Preparations compounding standards;
    e. Because of the nature of infusion therapy and vascular access device (VAD) insertion and/or management, nurses engaged in any IV treatment must have competency with this role;
    f. The nurse must follow facility policy and procedures, be knowledgeable in vascular access procedures and complications;
    g. The nurse performing the infusion must have ongoing competency validation appropriate to the responsibilities, treatment provided and targeted patient population;
    h. The nurse must maintain standard nursing documentation including, but not limited to:
        i. Patient assessment and medical history data;
        ii. Education provided to the patient on the prescribed infusion and/or IV medication therapy;
        iii. Patient's informed consent for procedure(s);
        iv. Nurse's assessments/notes and orders;
        v. Specific procedures performed and patient's response to procedure.
    i. The nurse must provide continuous monitoring of the patient for adverse reactions and have emergency protocols in place.

II. RATIONALE

A nurse may perform nursing interventions in any setting, including the provision of IV therapies and IV medication administration as ordered by a qualified LP.

It is not within the RN or LPN scope to prescribe, order, or procure drugs or substances for IV medication administration or IV therapy/hydration without an authorized LP's order specific to the individual patient.

An LPN may assist and participate in the performance of IV therapy and IV medication administration as ordered by an LP under the supervision of an RN or LP who is readily available in person or by electronic communication.

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

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

Typical Retail IV Therapy Business Model

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

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

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

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

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

Licensees Scope of Practice

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

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

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

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

Medical Practice Act

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

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

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

Nurse Practice Act

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

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

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

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

Pharmacy Practice Act

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

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

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

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

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

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

Standards for Immediate-Use of Compounded Sterile Preparations

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

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

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

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

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

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

testing) that could potentially result in contamination or other adverse impact on CSP quality
        - Report any problems, deviations, failures, or errors to the designated person(s)
    - If the facility has only one person in the compounding operation, that person must document that they have obtained training and demonstrated competency, and they must comply with the other requirements of this chapter.
- The preparation is performed in accordance with evidence-based information for physical and chemical compatibility of the drugs (e.g. approved labeling, stability, and compatibility studies).
- The preparation involves not more than 3 different sterile products.
- Any unused starting component from a single-dose container must be discarded after preparation is complete. Single-dose containers must not be used for more than one patient.
    - A conventionally manufactured single-dose container is a container closure system that holds a sterile product for parenteral administration (injection or infusion) that is not required to meet the antimicrobial effectiveness testing requirements.
    - Single-dose containers: A container of sterile product for parenteral administration (e.g. injection or infusion) that is designed for use with a single patient as a single injection/infusion. A single-dose container usually does not contain a preservative. See <659>, *Injection Packaging Systems, Single-dose container.*
- Administration begins within 4 hours following the start of the preparation. If administration has not begun within 4 hours following the start of preparation, it must be promptly, appropriately, and safely discarded.
    - Administration: The direct application of a sterile product or preparation to a single patient by injecting, infusing, or otherwise providing a sterile product or preparation in its final form.
- Unless directly administered by the person who prepared it or administration witnessed by the preparer, the CSP must be labeled with the names and amounts of all active ingredients, the name or initials of the person who prepared the preparation, and the 4-hour time period within which administration must begin.

Acceptable and Prevailing Practices

Delegation

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

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

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

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

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

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

Purchasing Legend Drugs

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

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

Patient Choice of Drugs

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

Comprehensive Medical Record

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

Conclusion

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

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

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

POSITION STATEMENT
for RN, LPN, and APRN Practice

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

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

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

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

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

Both RN and LPN Role:
1. The nurse must have an individualized prescription/order for the procedure written by a physician, NP, PA, or other licensed health care practitioner with prescriptive authority acting within their legal scope of practice and have completed a client evaluation/assessment for procedure appropriateness.

2. Nurses must have the knowledge, skill, and competency necessary to carry out the administration procedures and client monitoring in a safe manner.

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3. Agencies/businesses shall establish and maintain policies and procedures on-site for the administration of IV hydration, nutrient therapies, medications, and emergency interventions.

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

Notes:

1. If working in a setting in which clients may independently present for IV hydration, nutrient therapies, or medication administration, the nurse is responsible for ensuring there is an individualized prescription/order from a duly authorized prescriber prior to the administration of any prescriptive or non-prescriptive medication or the implementation of a medical intervention/treatment. Authorized prescribers include physicians, NP, PA, or other licensed health care practitioner with prescriptive authority acting within their legal scope of practice.

2. The RN and LPN shall use the professional judgement required to implement treatments and pharmaceutical regimens prescribed by providers licensed and authorized by State law to prescribe such plans or regimens. The nurse who accepts responsibility for implementing the administration of IV hydration, nutrient therapies, and medications is accountable for:

    - recognizing side effects,
    - recognizing toxic effects,
    - recognizing allergic reactions,
    - recognizing immediate desired effects,
    - recognizing unusual and unexpected effects,
    - recognizing changes in a client's condition that contraindicates continued administration of the pharmaceutical or treatment regimen,
    - anticipating those effects that may rapidly endanger a client's life or well-being, and
    - making judgments and decisions concerning actions to take in the event such effects occur.

3. Standing orders allow for the facilitation of timely interventions for various client populations. Standing orders are not client driven but are signed instructions of a provider authorized by State law to prescribe the medical treatment and/or pharmaceutical regimen. Standing orders describe the parameters of specified situations under which the nurse may act to carry out specific orders for a client presenting with symptoms or needs addressed in the standing orders. The standing orders outline the assessment and interventions that the RN or LPN may perform or deliver. It is not within the RN or LPN scope of practice to make a medical diagnosis, identify medical problems, develop medical treatment plans, or declare someone "free" of illness. Standing orders must be in written form and signed and dated by the provider. The Position Statement, Standing Orders, provides additional guidance.

4. The RN and LPN shall practice in compliance with all federal laws and regulations, and all North Carolina (NC) laws and regulations including but not limited to, the NC Board of Nursing (NCBON), the NC Board of Pharmacy, and the NC Division of Health Service Regulation Home Care Licensure.

5. The RN planning to establish an independent professional nursing business, professional corporation (PC), or professional limited liability company (PLLC), for the purpose of providing nursing and related services, must assure they are compliant with all laws and rules applicable to the practice setting, procedures, and client population including a prescription/order by a physician, NP, PA, or other licensed health care practitioner with prescriptive authority acting within their legal scope of practice. The RN may refer to the NCBON website information, "Professional Corporations and Professional Limited Liability Companies," for more detail and are advised to seek legal advice if establishing a business.

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

Advanced Practice Registered Nurse (APRN) Role:

1. The client population must be within the scope of practice of the APRN.

2. The APRN with diagnostic and prescriptive authority shall meet the standard of care.

3. Documentation should demonstrate:

- Review of the medical record/history was conducted, and no contraindications exist.
- Initial evaluation including assessment of the client's status.
- Diagnosis including evidence-based indication for hydration and/or other prescribed regimens.
- Treatment plan with contingency for care beyond the ability of the current practice site.
- Client response to prescribed therapy.
- Informed consent including risk and benefit.
- Client education for pre-procedure, peri-procedure, after care, and follow up.

References:

General Statute (GS) 90-171.20 (7) (e-f) & (8) (c) – Nursing Practice Act
GS 90-178.2 Definitions
GS 90-178.3 Regulation of Midwifery
GS 55B-14 Types of Professional Services
21 NCAC 36.0221 (c) License Required
21 NCAC 36.0224 Component of Nursing Practice for the Registered Nurse
21 NCAC 36.0225 Components of Nursing Practice for the Licensed Practice Nurse
21 NCAC 36.0802 Scope of Practice
NCBON Position Statement - Practicing at Level Other Than Highest Licensure/ Approval/Recognition
NCBON Position Statement – Standing Orders

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IV Spa Hydration, Should I Be Doing This?
Nebraska Board of Nursing

PREAMBLE

The Board of Nursing has received inquiries about practice settings that market wellness promotion services, such as intravenous (IV) spa hydration, also sometimes referred to as "IV vitamin therapy" or "hydration therapy". In keeping with the Board's mission of public protection, this article aims to offer regulatory considerations nurses should be mindful of when deciding whether to practice in such a setting.

We also receive calls from concerned citizens regarding these IV hydration spas. DHHS cannot arbitrarily decide to regulate or require licensure for those facilities not named in statute, particular to these facilities the Health Care Facility Licensure Act linked below. These types of spas fall below the licensing threshold because they are considered health care practitioner facilities as defined by Nebraska Revised Statute 71-414 see definition below. These types of facilities do not require a facility license. Individuals in these facilities are operating under their own license to practice either independently or collaboratively as their scope of practice allows. Furthermore, Nebraska operates a complaint-based system where to investigate the practitioners providing these services a formal complaint must first be made to the Department. At that time the complaint process which is confidential begins. More information about the complaint process can be found on the DHHS website linked below.
Complaint website: https://dhhs.ne.gov/Pages/Investigations.aspx

Health Care Facility Licensure Act:
https://www.nebraskalegislature.gov/laws/display_html.php?begin_section=71-401&end_section=71-476

71-414. Health care practitioner facility, defined.
Health care practitioner facility means the residence, office, or clinic of a practitioner or group of practitioners credentialed under the Uniform Credentialing Act or any distinct part of such residence, office, or clinic.

INTRODUCTION

Treatments provided to individuals without medical necessity and are offered for "wellness" on a cash basis are becoming increasingly more popular and sought-after solutions for improved wellness or recovery. The facilities offering these practices are not individually licensed and regulated in Nebraska at this time. The practices performed in these facilities when required should be performed by licensed health care providers as outlined in the Uniform Credentialing Act, the Uniform Controlled Substances Act and the various professional acts. The purpose of this article is to provide guidance document with references for the various elements of practice that are often the source of questions about IV spa hydration. This article contains excerpts from various statutes; for the most accurate information refer to the various acts linked below.

The Uniform Credentialing Act:
https://nebraskalegislature.gov/laws/search_range_statute.php?begin_section=38-101&end_section=38-1%2C147

The Uniform Controlled Substances Act:
https://nebraskalegislature.gov/laws/display_html.php?begin_section=28-401&end_section=28-476

The DHHS licensure webpage with links to the various practice acts:
https://dhhs.ne.gov/licensure/Pages/Professions-and-Occupations.aspx

IV therapy is a complex, learned skill and there are many considerations necessary to ensure the safe performance of this skill outside of a traditional facility setting.

Complex Interventions

IV spa hydration involves procedures that are complex nursing interventions (172 NAC 99-002) and may not be delegated by RNs/NPs/LPs to unlicensed persons. IV spa hydration is the practice of inserting an IV catheter into the client's vein to infuse fluid that has been compounded with vitamins or medications.

All nurses licensed to practice nursing in Nebraska must adhere to the Nursing Practice Act (NPA) and Board rules, as well as other regulations pertinent to the setting. Therefore, the performance of IV spa hydration in a non-traditional setting, such as a mobile unit or wellness spa, should be consistent with applicable regulations, prevailing standards of care, and current national nursing guidelines specific to IV therapy. When initiating IV therapy services, including the administration of medications, such as isotonic IV fluids, a valid provider order is required. (1)

IV spa hydration and vitamin infusion therapy are not medically necessary because this service is a client driven, on demand service. The "treatments" are done in a "spa" setting or may be done in a home, office, hotel room or another location. These areas, off-site, may not be clean or sanitary which may increase the possibility of infection. Before the IV infusion, the client is assessed by some type of exam, sometimes called a "good faith exam". I use the word "sometimes" because there are not regulatory standards of care for these services. There are several large companies offering franchises and each seems to have their own way of "assessing" the client, protocols for the service itself, etc, etc. Further, it is unclear if these businesses have record keeping standards that are HIPPA compliant. They may have, it's just not easy to find out. The healthcare worker (nurses or in come cases, an EMT) is relying on the client to provide accurate and true information without any validation from medical records. Lab values may or may not be performed. There is typically an informed consent for the client to read and sign. It can be quite lengthy and comprehensive, however may not be easy to understand which may be problematic for informed consent. (2, 3).

Decision-Making Framework
When evaluating whether you as a nurse or advanced practice nurse should be providing IV spa services a resource called the Decision-Making Framework is a powerful tool to help when trying to determine those answers. However, nurses, no matter their licensure, are responsible for their own practice and license protection. Nurses are encouraged to independently review the Decision-Making Framework and apply it based on his/her individual educational background, knowledge, and experience. (4)

From the DHHS Nebraska Nursing Website:

In an effort to ensure safe, competent nursing services to the public, as well as to educate and provide direction to nurses to facilitate clinical decision-making in determining legal scope of practice, the Nebraska Board of Nursing adopted a Decision-Making Model for Determining RN/LPN Scope of Practice on April 14, 2016. The model was designed to be utilized in conjunction with applicable Nebraska nursing laws and regulations in a given practice situation.

Recognizing the evolution of nursing practice and thought regarding scope of practice decisions, the APRN Board and Board of Nursing adopted a shared next generation model in 2017. The Scope of Nursing Practice Decision-Making Framework was developed by the Tri-Council for Nursing in collaboration with the National Council of the State Boards of Nursing (NCSBN). The framework was devised to include all licensed nurses at all experience levels in all practice settings practicing in a variety of roles.

The decision to provide any nursing care should be based upon self-assessment of competency, following an assessment of the client and environment. A licensed nurse is accountable to be competent for all nursing care that he/she provides. Competence means the ability of the nurse to apply interpersonal, technical and decision-making skills at the level of knowledge consistent with the prevailing standard for the nursing activity being applied. Accountability also includes acknowledgment of personal limitations in knowledge and skills and communication of the need for specialized instruction prior to providing any nursing activity.

ScopeOfPracticeFlo
wchart-decision mal

You will note that the second step in the DMF speaks to evidence-based practice. If what you are about to do, or you are considering doing, is not evidence based then you should stop. There is no work around or "what if". As a profession, we must adhere to protocols and standards that are in place to protect the patient or client and also protect the nurse from harm.

If you choose to move forward with the activity, even though it is not evidence based, nurses remain responsible for the following:

• The activity or intervention is authorized by a valid order. If there is any question about the accuracy or appropriateness of the order, the nurse must seek clarification

• The patient's record is thoroughly reviewed, an appropriate nursing assessment of the patient is conducted (related to the nurse's level of licensure), 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.

• That he/she 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. This includes use of the appropriate personal protective equipment (PPE) related to the patient's condition, in order to guarantee compliance with evidence-based practice guidelines from the Centers for Disease Control and Prevention (CDC) and the Nebraska Department of State Health Services

*If an LPN is performing the intervention, that appropriate clinical supervision is available by a RN (including APRN), physician assistant, physician.

• IV therapy nursing services are **consistent with current nursing evidence-based practice guidelines, and prevailing national nursing standards of care**, such as those published by the National Infusion Center Association (NICA) Minimum Standards for In-Office Infusions or the Infusion Nurse's Society (INS) recommendations.

The bolded words above are critical. Currently, the practice of IV spa hydration is not evidenced- based practice. This leaves the nursing license at risk, but it is much more than that. Engaging in practice that is not proven to be safe, effective and have evidence to prove this, puts the person/client/patient at risk as well. Protection of public health is not the job of the DHHS alone, it is the responsibility of each healthcare provider to critically think about how they are using their knowledge and skills. Keep asking the question, "Is this really nursing?"

Evidence

Currently, the practice of IV spa hydration is not evidence based. There is research regarding the components of the IV drip (vitamins, minerals) but not for this type of delivery. It is unknown if these short-term effects are lasting. The one research study that looked at treatment for fibromyalgia was inconclusive at best. The subjects reported improvement in both the treatment and placebo groups. So really what is meant by "evidence based practice"?

Research studies show that evidence-based practice (EBP) leads to higher quality care, improved patient outcomes, reduced costs, and greater nurse satisfaction than traditional approaches to care.[1-5] Despite these favorable findings, many nurses remain inconsistent in their implementation of evidence-based care. Moreover, some nurses, whose education

predates the inclusion of EBP in the nursing curriculum, still lack the computer and Internet search skills necessary to implement these practices. As a result, misconceptions about EBP—that it's too difficult or too time-consuming—continue to flourish.

Research evidence alone is not sufficient to justify a change in practice. Clinical expertise, based on patient assessments, laboratory data, and data from outcomes management programs, as well as patients' preferences and values are important components of EBP. There is no magic formula for how to weigh each of these elements; implementation of EBP is highly influenced by institutional and clinical variables (5)

Public Safety

Often, IV spa hydration products are not FDA approved. Once the components of an IV spa treatment are mixed in a way that does not guarantee the products are sterile and without contamination, they are listed as (503b) due to the sterility and safety of the components cannot be confirmed. A 503b is an "FDA outsourcing facility" The transport of these items for the mobile version of the IV spa has problems as well. It is uncertain if the meds are transported in a refrigerator or kept at a certain temperature. The mobile aspect of the clinic may also interfere with the components becoming unstable or de-natured. (References, 6,7,8)

In 2018, the Federal Trade Commission (FTC) filed charges against a marketer and seller of IV therapy products in Texas for making false and unsupported health claims (FTC, 2018). These claims advertised IV therapy products to treat serious diseases such as cancer, multiple sclerosis, diabetes, and congestive heart failure (FTC, 2018). The final FTC order prohibits the company from making such claims, unless they can be supported by competent and reliable scientific evidence (FTC, 2018). Joe Simmons, chairman of the FTC (2018), emphasized that, "This enforcement action should send a clear message to the burgeoning IV therapy industry and sellers of all healthcare products." Nurses should be mindful of practicing in a setting that makes false and unsupported health claims such as these. (9)

IV spa hydration procedures performed by nurses are subject to the same standards for nursing practice as those driven by medical necessity**.** The Nebraska Board of Nursing affirms this primary concern. IV spa hydration treatments and procedures are elective, and patients self-refer to a practitioner their choice for services. The lack of consistent standards for education and training in this service coupled with the rapid proliferation and ready availability of products and services that may or may not be regulated (Jones, et. al, 2018) (10) has resulted in confusion regarding nursing scope of practice and competency.

Compounding

What is compounding? Are nurses able to perform this activity with their scope of practice in Nebraska?
The combining of different products into a saline bag may be considered compounding which has to be done according to statute. The mixing of two or more drug products is considered compounding.

38-2811. Compounding, defined.

Compounding means the preparation of components into a drug product.

38-2867.01. Authority to compound; standards; labeling; prohibited acts.
(1) Any person authorized to compound shall compound in compliance with the standards of chapters 795 and 797 of The United States Pharmacopeia and The National Formulary, as such chapters existed on January 1, 2015, and shall compound **(a) as the result of a practitioner's medical order or initiative occurring in the course of practice based upon the relationship between the practitioner, patient, and pharmacist, (b) for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing, or (c) for office use only and not for resale**.

(2) Compounding in a hospital pharmacy may occur for any hospital which is part of the same health care system under common ownership or which is a member of or an affiliated member of a formal network or partnership agreement.

(3)(a) Any authorized person may **reconstitute** a commercially available drug product in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with labeling.

(b) Any authorized person using beyond-use dating must follow the approved product manufacturer's labeling or the standards of The United States Pharmacopeia and The National Formulary if the product manufacturer's labeling does not specify beyond-use dating.

(c) Any authorized person engaged in activities listed in this subsection is not engaged in compounding, except that any variance from the approved product manufacturer's labeling will result in the person being engaged in compounding.

(4) Any authorized person splitting a scored tablet along scored lines or adding flavoring to a commercially available drug product is not engaged in compounding.

(5) No person shall compound:

(a) A drug that has been identified by the federal Food and Drug Administration as withdrawn or removed from the market because the drug was found to be unsafe or ineffective;

(b) A drug that is essentially a copy of an approved drug unless there is a drug shortage as determined by the board or unless a patient has an allergic reaction to the approved drug; or

(c) A drug that has been identified by the federal Food and Drug Administration or the board as a product which may not be compounded.

When a client enters into an agreement with the healthcare provider to have an IV spa treatment, there are generally a menu of mixtures that can be purchased. Items like vitamins or medications are injected into the bag of normal saline and mixed. Then the bag is hung, a drip rate is set, and the client relaxes while the fluid infuses**. Introducing items into the bag of saline is compounding and that is not in nursing scope of practice.** To do the mixing properly, you need to have at least a pharmacy certificate. The mixing itself is required to be done under a hood with very specific readings all while in full protective gear. This all to ensure a clean and sterile environment and reduce the chance of contaminants being introduced into the mixture.

Once products are mixed, they cannot be advertised as FDA compliant or approved due to the risk of contamination. The safe selection of products must be done by a licensed provider. The client or RN does not have the knowledge or scope to perform this activity.

Are APRNs authorized to compound?

Any authorized person **may reconstitute** a commercially available drug product in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with labeling. **Mixing two drug products is compounding and is a pharmacy activity and is outside the scope of an APRN.**

United States Pharmacopeia **(USP) Chapter 797 on compounding**

To qualify for the immediate use criteria listed under USP Chapter 797, these compounded mixes need to be used for an emergency use and for immediate patient administration. The 503B products need to meet the requirements of the FDA; and the facilities they are compounded in need to be properly registered.

From USP Chapter 797:

The immediate-use provision is intended **only for those situations where there is a need for emergency or immediate patient administration of a Compounded Sterile Product or CSP**. Such situations may include cardiopulmonary resuscitation, emergency room treatment, preparation of diagnostic agents, or critical therapy where the preparation of the CSP under conditions described for *Low-Risk Level CSPs* subjects the patient to additional risk due to delays in therapy. Immediate-use CSPs are not intended for storage for anticipated needs or batch compounding**. Preparations that are medium-risk level and high-risk level CSPs shall not be prepared as immediate-use CSPs.** Immediate-use CSPs are exempt from the requirements described for *Low-Risk Level CSPs* only when all of the following criteria are met:
1. The compounding process involves simple transfer of not more than **three commercially *manufactured* packages** of sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers and not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device. For example, anti-neoplastics shall not be prepared as immediate-use CSPs because they are hazardous drugs.

2. Unless required for the preparation, the compounding procedure is a continuous process not to exceed 1 hour.
3. During preparation, aseptic technique is followed and, if not immediately administered, the finished CSP is under
continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter
or biological fluids, mix-ups with other CSPs, and direct contact of outside surfaces.
4. Administration begins not later than 1 hour following the start of the preparation of the CSP.
5. Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1-hour BUD and time.
6. If administration has not begun within 1 hour following the start of preparing the CSP, the CSP shall be promptly, properly, and safely discarded. Compounding in worse than ISO Class 5 (see *Table 1*) conditions increases the likelihood of microbial contamination, and administration durations of microbially contaminated CSPs exceeding a few hours increase the potential for clinically significant microbial colonization and thus for patient harm, especially in critically ill or immunocompromised patients.

Nursing Practice Alignment

Nursing Code of Ethics

There are 4 main principles that are part of the nursing code of ethics. They are,

1. Autonomy
2. Beneficence
3. Justice
4. Non-maleficence

These principles are ideally what every nurse should be aware of in their daily nursing practice. While ethical principles are sometimes confusing and often taught briefly during undergraduate nursing -- they should be constants in nursing practice in order to provide the best, safest, and most humane care to all patients.
Autonomy is recognizing each individual patient's right to self-determination and decision-making. As patient advocates, it is imperative that nurses ensure that patients receive all medical information, education, and options in order to choose the option that is best for them. This includes all potential risks, benefits, and complications to make well-informed decisions.

Beneficence is acting for the good and welfare of others and including such attributes as kindness and charity. The American Nurses Association defines this as "actions guided by compassion."

Justice is that there should be an element of fairness in all medical and nursing decisions and care. Nurses must care for all patients with the same level of fairness despite the individual's financial abilities, race, religion, gender, and/or sexual orientation.

Nonmaleficence is to do no harm. This is the most well-known of the main principles of nursing ethics. More specifically, it is selecting interventions and care that will cause the least amount of harm to achieve a beneficial outcome. (11)

With these 4 standards in mind, when a nurse evaluates their care and approach of using their skills and training, does it line up with an IV spa hydration setting? Is this nursing? Am I being taken advantage of because of my patient care training and complex skill training of IV insertion?

Nurses – Registered Nurses and Licensed Practical Nurses

The profession of nursing remains the most trusted profession by the general public. Even with recent events of the pandemic, mandates and court cases, this profession overall demonstrates compassion, intelligence and dignity of care. Conflict of interest is an inherent risk to ethical nursing practice in the provision of IV spa hydration. Licensed Practical Nurses function in the healthcare team in a directed role. Registered Nurses direct LPN practice and duties, however they cannot diagnose, write a prescription or treat or dispense.

Nurse Practitioners

Along with the above points of ethical practice, nurse practitioners as advanced practice registered nurses (APRNs) bear full accountability for practice that is aligned with graduate education, board certification and licensed practice role with one or more population foci.

38-2315. Nurse practitioner; functions; scope.
(1) A nurse practitioner may provide health care services within specialty areas. A nurse practitioner shall function by establishing collaborative, consultative, and referral networks as appropriate with other health care professionals. Patients who require care beyond the scope of practice of a nurse practitioner shall be referred to an appropriate health care provider.
(2) Nurse practitioner practice means health promotion, health supervision, illness prevention and diagnosis, treatment, and management of common health problems and chronic conditions, including: (a) Assessing patients, ordering diagnostic tests and therapeutic treatments, synthesizing and analyzing data, and applying advanced nursing principles; (b) Dispensing, incident to practice only, sample medications which are provided by the manufacturer and are provided at no charge to the patient; and (c) Prescribing therapeutic measures and medications relating to health conditions within the scope of practice. Any limitation on the prescribing authority of the nurse practitioner for controlled substances listed in Schedule II of section 28- 405 shall be recorded in the integrated practice agreement established pursuant to section 38-2310.
(3) A nurse practitioner who has proof of a current certification from an approved certification program in a psychiatric 33 or mental health specialty may manage the care of patients committed under the Nebraska Mental Health Commitment Act. Patients who require care beyond the scope of practice of a nurse practitioner who has proof of a current certification from an approved certification program in a psychiatric or mental health specialty shall be referred to an appropriate health care provider.

The fundamental premise of practice alignment is that the APRN has the knowledge to differentially diagnose and manage most conditions/potential adverse outcomes that will be encountered for a particular patient population (Buppert, 2017) (12). Advanced practice nurses have the added skills of diagnosing, treating, and prescriptive authority. This is a huge

advantage to providing increased access to care. It should also cause the APRN stop and ask these questions, “Is this how I want to use my skills?” “Is this nursing?” “Am I being taken advantage of because of my status as a licensed provider?” Is this within my scope of practice? Is this practice consistent with evidence-based nursing literature? Who is responsible for assessing the client? Who is responsible for the outcome?

Fragmentation of Care

What has been happening recently is the proliferation of small, solo, or “small single-specialty group practices have dominated the landscape, with unfortunate fallout: wide variation in practices and costs and relatively low accountability” Our practice as a profession must adhere to the ethical standards of individual patient care but also to the healthcare system as a team. Independent practice should not be at the cost of care coordination. The small and solo or concierge practices should integrate with the system as a whole. The risk otherwise may be patients/ clients engaging in what they see as wellness activity when, for that person, the activity may have a negative impact on their overall wellbeing. Individuals can choose obviously what they want to do, but as a profession we are obligated to teach and inform the individual and clarify risks and benefits. (13)

Patient-centered and population health focus. Patients have multiple points of entry to appropriate care and information. Provider’s respect and respond to individual patient preferences, needs, and values-this includes cultural competence (ie, knowledge of the patient's language and culture as relevant to health)-to inform all clinical decisions. Patients participate in those decisions. Resources and services are matched to the needs of and are directed toward improving the overall somatic and mental health of, the population/community served, including prevention initiatives.

Coordination. Care is coordinated and information shared across all settings and providers-inpatient, outpatient, physician's office, and home-to provide a seamless continuum of services. Care is delivered at the least invasive and most cost-effective appropriate setting. All or most of a patient's care remains within the system, enabling maximum efficiency and coordination. Transitions and handoffs between settings are explicitly and effectively managed to reduce costs by avoiding rehospitalizations and other complications.

Final Note

As new trends emerge in health care, nurses are called upon to deliver safe nursing care, and must realize their responsibility to stay aware of current evidence-based practice standards, along with all applicable laws and rules related to their area of nursing practice. Board Staff recommends that nurses exercise caution and critical thinking when considering practicing in a setting that offers elective IV spa hydration and vitamin therapy. This ensures that patients are receiving the safe, high quality health care they deserve.

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Scope of Nursing Practice Decision-making Framework

Approved by the Nebraska Board of Advanced Practice Registered Nurses on April 21, 2017
Approved by the Nebraska Board of Nursing on July 13, 2017

Identify, describe, or clarify the activity, intervention, or role under consideration.

Is the activity, intervention, or role prohibited by the NPA and rules/regulations or any other applicable laws, rules/regulations, or accreditation standards or professional nursing scope and standards?
YES → STOP

NO

Is performing the activity, intervention, or role consistent with evidence-based nursing and health care literature?
NO → STOP

YES

Are there practice setting policies and procedures in place to support performing the activity, intervention, or role?
NO → STOP

YES

Has the nurse completed the necessary education to safely perform the activity, intervention, or role?
NO → STOP

YES

Is there documented evidence of the nurse's current competence (knowledge, skills, abilities, and judgments) to safely perform the activity, intervention, or role?
NO → STOP

YES

Does the nurse have the appropriate resources to perform the activity, intervention, or role in the practice setting?
NO → STOP

YES

Would a reasonable and prudent nurse perform the activity, intervention, or role in this setting?
NO → STOP

YES

Is the nurse prepared to accept accountability for the activity, intervention, or role and for the related outcomes?
NO → STOP

YES

The nurse may perform the activity, intervention, or role to acceptable and prevailing standards of safe nursing care

Used with permission from the *Journal of Nursing Regulation*
Ballard, K., Haagenson, D., Christiansen, L., Damgaard, G., Halstead, J.A., Jason, R.R.,… Alexander, M. (2016). Scope of nursing practice decision-making framework. *Journal of Nursing Regulation* 7(3); 19-21.

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

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

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

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

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

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

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

South Carolina Board of Medical Examiners and the Medical Practice Act

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Telemedicine

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

South Carolina Board of Nursing and the Nurse Practice Act

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

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

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

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

LPNs

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

RNs

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

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

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

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

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

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

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

APRNs

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

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

CONCLUSION

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

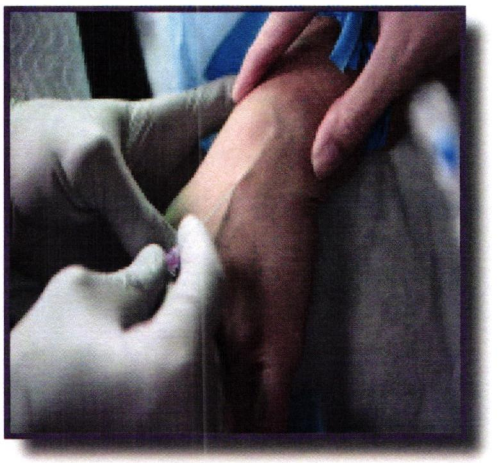
Most important, however, is the safety of the members of the public who seek IV treatment through these clinics. Public safety is the mission of each of the Boards, as charged by the Legislature.

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

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

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

IV Hydration: What Texas Nurses Need to Know



Nursing Consultants for Practice at the Texas Board of Nursing (Board) receive hundreds of calls and email inquiries pertaining to nursing practice regulation each month. Through this communication with nurses, employers, and other stakeholders, Board consultants remain apprised of developments in nursing practice as the health care industry evolves and new health trends gain public attention. Recently, the Board has received inquiries about practice settings that market wellness promotion services, such as intravenous (IV) hydration, also sometimes referred to as "IV vitamin therapy" or "hydration therapy".

In keeping with the Board's mission of public protection, this article aims to offer regulatory considerations nurses should be mindful of when deciding whether to practice in such a setting. In 2018, the Federal Trade Commission (FTC) filed charges against a marketer and seller of IV therapy products in Texas for making false and unsupported health claims (FTC, 2018). These claims advertised IV therapy products to treat serious diseases such as cancer, multiple sclerosis, diabetes, and congestive heart failure (FTC, 2018). The final FTC order prohibits the company from making such claims, unless they can be supported by competent and reliable scientific evidence (FTC, 2018). Joe Simmons, chairman of the FTC (2018), emphasized that, "This enforcement action should send a clear message to the burgeoning IV therapy industry and sellers of all healthcare products." Nurses should be mindful of practicing in a setting that makes false and unsupported health claims such as these.

National Insight

To learn more about IV hydration practice trends, Board Staff distributed a survey to members of the National Council of State Boards of Nursing (NCSBN). Of the 25 responding boards of nursing, 11 confirmed that IV hydration services are offered in their state. Among the boards that have seen this new practice setting, several responded that nurses are provided general scope of practice guidelines as the authorization for the treatment, and other states responded that nurses are implementing physician standing delegation orders. It was noted that additional regulations may or may not require a provider evaluation of the patient at some point during the encounter. A few of the survey responses reflected that boards recommend nurses use well-developed policies, procedures, and guidelines. Some boards of nursing responded that there are laws and rules relevant to nursing practice, such as rules applicable to pharmacy regulation, that place limitations on IV hydration outside of the hospital setting. Given there is variability among states in their regulation of nurses administering IV hydration therapy, it is essential that nurses adhere to all laws and rules that apply to the state in which they are providing nursing care.

Guidance for the Texas Nurse

IV therapy is a learned skill practiced by many Texas nurses. There are, however, necessary considerations for the safe performance of this skill outside of a traditional facility setting. All nurses licensed to practice nursing in Texas must adhere to the Nursing Practice Act (NPA) and Board rules, as well as other regulations pertinent to the setting. Therefore, the performance of IV 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 IV therapy.

When initiating IV therapy services, including the administration of medications, such as isotonic IV fluids, a valid provider order is required. Some orders may come from a provider who has examined the patient.

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KEY NOTES FOR TEXAS NURSES RELATED TO PHYSICIAN STANDING DELEGATION ORDERS:

- Intended to be used prior to examination and evaluation by a physician, based on pre-determined criteria;
- Cannot authorize the person carrying out the standing orders to exercise independent medical judgement; and
- Can only be authorized by a physician.

Other settings may utilize physician standing delegation orders. If the nurse intends to provide these services under a physician standing delegation order, he/she should review the rules from the Texas Medical Board (TMB) that define standing delegation orders, found in **Texas Administrative Code Chapter 193**, and **Board Position Statement 15.5 Nurses with Responsibility for Initiating Physician 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." Even if all criteria for initiating physician standing delegation orders are met, nurses are required to act in the best interest of their patients, and this duty supersedes any physician order or employer policy. Nurses are among the most trusted professionals in America (Reinhart, 2020); therefore, patients, in addition to the Board, expect that during their care, nurses will advocate in the patient's best interest.

In all practice settings, 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 [**Board Rule 217.11(1)(N)**].

Scope of Practice Decisions

A resource called the **Scope of Practice Decision-Making Model** (DMM), developed by Board Staff, is a useful tool available for nurses within all levels of licensure. Parts of the DMM that apply to these practice settings and interventions under consideration have been included for further guidance; however, each nurse is encouraged to independently review the DMM in its entirety and apply it based on his/her individual educational background, knowledge, and experience. After reviewing the activity or intervention and verifying that it is not prohibited by the Texas NPA and Board rules, guidelines, or position statements, or any federal, state, local law or rule affecting the nurse's current area of nursing practice [**Board Rule 217.11**(1)(A)],the Texas nurse must also ensure:

- That the activity or intervention is authorized by a valid order. If there is any question about the accuracy or appropriateness of the order, the nurse must seek clarification [**Board Rule 217.11**(1)(N)].
- The patient's record is thoroughly reviewed, an appropriate nursing assessment of the patient is conducted (related to the nurse's level of licensure), and no contraindications exist to the ordered treatment [**Board Rule 217.11**(1)(C)].
- 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 [**Board Rule 217.11**(1)(D)].
- That he/she 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 [**Board Rule 217.11**(1)(B)&(M)].
- Implementation of measures to prevent exposure to infectious pathogens and communicable conditions. This includes use of the appropriate personal protective equipment (PPE) related to the patient's condition, in order to guarantee compliance with evidence-based practice guidelines from the **Centers for Disease Control and Prevention (CDC)** and the **Texas Department of State Health Services (DSHS)**.

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