

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

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John Mistler, PharmD, MBA, BCSCP

Regulatory Officer, Branch 4

Office of Compounding Quality and Compliance

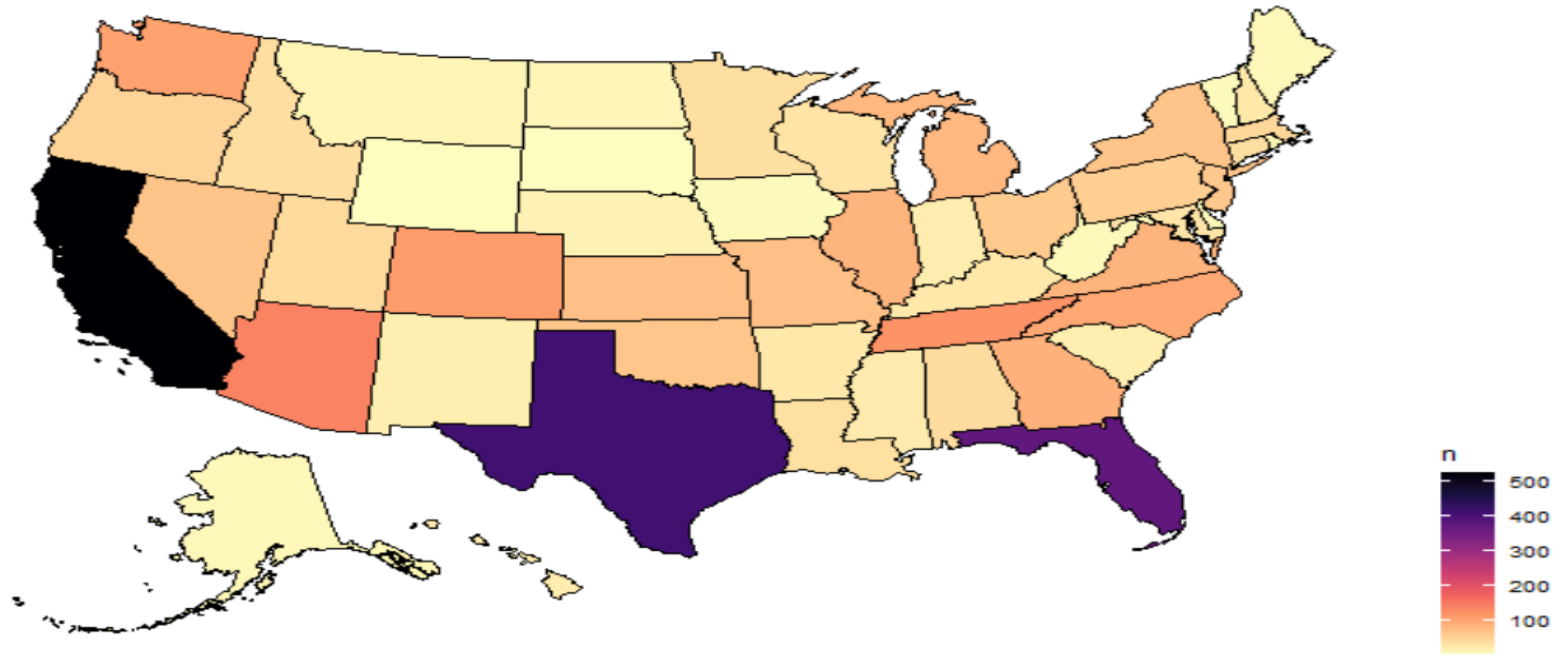
OBJECTIVES

- 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

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/NCA011.pdf>
- Wyoming Board of Nursing (2022). ADVISORY OPINION AESTHETIC & INFUSION THERAPY PROCEDURES. <https://drive.google.com/file/d/1sXCg2oJ1AuK9clfea-JW1S3-sxdarnTc/view>

MMB 04.10.23



STATE OF MISSISSIPPI
MISSISSIPPI BOARD OF PHARMACY

Mississippi Board of Pharmacy: Checklist for Compliance

Infusion Clinics (hydration, other medications)

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



BOARD OF MEDICAL LICENSURE



BOARD OF NURSING

Investigative Questionnaire MSBML and MBON

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

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

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

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

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

IS there an order to administer IVF?

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

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

If an APRN ordered, who is the collaborating physician?