# Investigating IV Hydration

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IV Hydration therapy is the practice of medicine

Common justification is treating dehydration

Medication order is required prior to initiating IV therapy



- IV fluids are prescription meds
  - A bag of IV saline is a prescription med ("RX Only"), requires medical license to buy
  - Vitamins and supplements are prescription meds when administered via IV, require medical license to buy
  - Combining three or more ingredients (bag of fluids counts as 1 of the 3, per FDA) is compounding and must be done in sterile conditions and in accordance with state and federal laws
  - FDA has warned of problems with compounding under unsanitary conditions

- Prior to administering a prescription medication, a complete H&P should be performed and documented.
- A medication order is required prior to initiating IV therapy
- Can't order a prescription med to be administered unless treating a condition or indication
- The person whose prescriptive authority is being used should be the one to do the H&P, document it, and order the medication

#### iDrip Therapy General Intake Form

Dec 10, 2022 1, Please enter your information. Gender: First Name: Last Name: Date of Birth: r State: Zip Code: Apt./Unit #: Street Address: City: Email: Mobile Phone: 2. Date/Time you would like us to come by: 12:00 3. Which IV Blend would you like? F ٢ E . Г Hangover Cure 4. Which Add-Ons would you like? Γ. F 5 Zofran/Nausea Relief Г F Toradol/Pain Relief 5. Are you pregnant or breastfeeding? r G NO if Yes, how far along are you? 6. Do you have high blood pressure/Hypertension? Compared and the second s a No 7. Do you have any heart, liver, or kidney conditions? C GNO If Yes, Please Explain: B, Have you been diagnosed Long QT Syndrome? C -@ NO 9. Do you have Diabetes (Type 1 or Type 2)? r GNO If Yes, what/when is your most recent blood sugar level?

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### **Business Model Part 1**

- Multi-state company formed (Company A)
- Recruits nurses, EMTs, paramedics to open and operate clinics, bars, or spas
- Recruits physicians to serve as "Medical Directors"
  - Physician/Medical Director gives Company A authority to use their credentials to order meds and supplies
  - Physician/Medical Director has limited communication with operators, if any



# **Business Model Part 2**

- Operators "order" fluids, meds, and supplements from Company A
- Company A uses Physician/Medical Director's credentials to order fluids, meds, and supplements from an out-of-state pharmacy
- Out-of-state pharmacy ships fluids, meds, and supplements directly to operators
- All Done Pursuant to Prescriptive Authority of "Medical Director"

#### IV/IM Consent Form

I consent to the insertion of a peripheral intravenous/intramuscular catheter/needie and to the infusion/injection of fluids, vitamins, mineral and/or compounded cofactor, and/or medications. I agree and acknowledge that no promises or guarantees were made regarding the efficacy of the infusion/injection. Further, I acknowledge that statements regarding vitamin and mineral infusions/injections have not been evaluated by the FDA and that the infusion/injection of such has no diagnostic value nor is the infusion a substitute, cure, therapy, or treatment for any disease or condition.

I understand that the infusion/injection is being carried out under the direction of and/or and/or (Medical Directors) and by a non-physician who is trained in the safe insertion, monitoring, stabilization, and removal of intravenous/intramuscular catheters/needles and infusions/injections. If at any time, a determination is made that the procedure or infusion is outside of the conditions of safety, it may be discontinued.

I understand the benefits of IV/IM infusions/injections may be limited if I am an active smoker, live a sedentary lifestyle, and/or have a diet that contains an excess of calories and/or a deficiency of nutrients. I understand that I may be asked to take oral supplements between treatments and a failure to take these supplements may reduce the benefits of the IV/IM therapy and may even create unwanted effects of the IV/IM therapy.

I understand that a series of infusions/injections may be anticipated. I understand that infusion(s)/injection(s) may need to be repeated in the future in order to maintain the benefits.

RISKS: I acknowledge that I am aware of the risks inherent in peripheral vascular catheterization and infusion that include but are not limited to: local irritation, pain, infection, phiebitis (irritation of the vein), venous thrombosis, shortness of breath, allergic reaction, fluid volume overload, medication interactions, and death. Despite these risks (and others) I consent to the procedure. I may withdraw my consent at any time.

PAYMENT: Payment is due at the time of service. There has been no representation that this procedure is covered under my insurance plan or that I can/should seek such reimbursement. I agree to pay the full cost of the service regardless if the infusion/injections cancelled or is stopped at any time prior to completion at the discretion of the technician/nurse/clinical assistant or myself.

I understand that I am responsible for the full cost of the procedure and agree to pay.

The procedure(s) and this consent form have been adequately explained to me. I certify that I am not intoxicated on alcohol or any illicit drugs. I authorize and consent to the performance of the procedure(s).

Client Signature



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# **Standing Orders**

- Not a legitimate use of standing orders
- Practitioner with prescriptive authority has no relationship to patients
- Examples of "Standing Orders":



### Mega-Immunity

### <u>Blend</u>

- 1 bag-Lactated Ringers
- 2ml-Zinc (20mg)
- 2ml Magnesium (400mg)
- 3ml-B Complex (300/6/300/6/6mg)
- 1ml-B12 (2mg

Hydroxocobalamin)

- 4ml-Vit C (2000mg Ascorbic Acid)
- 5ml-L Lysine
- 5ml-Glutathione

(1000mg) Extra: Vit D Inj

#### **Immunity Booster**

- 1 bag-Lactated Ringers
- 1.5 ml-Zinc (7.5 mg)
- 3ml-Vit C (Ascorbic Acid 1500mg)
- 2ml-Magnesium (400mg)
- 1ml-B12 (2mg

Hydroxocobalamin)

- 3ml-B Complex (300/6/300/6/6mg)
- 3ml-L Lysine (300mg)
- 3 ml-Glutathione (600mg) Extra: Vit D Inj

#### **Migraine Blend**

- 1 bag Lactated Ringers
- 1ml-Zinc (10 mg)
- 3ml-Magnesium

(600 mg)

- 1ml-Vit B12 (2mg Hydroxocobalamin)
- 2ml-Vit C (1000 mg Ascorbic Acid)
- 2ml-B Complex

(200/4/200/4/4mg)

3ml-Glutathione (600mg

Extra: Zofran 4mg, Toradol 15mg, Mag 200mg

### **Beauty Blend**

- 1 bag-Lactated Ringers
- 1ml-NAD+ (100mg)
- 1ml-Zinc (10mg)
- 2ml-Magnesium
  - (400mg)
- 3ml-Vit B Complex (300/6/300/6/6mg)
- 1ml-Biotin (10mg)
- 1ml-Vit B12 (2mg
  - Hydroxocobalamin)
- 3ml-Vit C (1500mg
  - Ascorbic Acid)
- 4ml-Glutathione (800mg)



#### Myer's Cocktail

- 1 bag-Lactated Ringers
- 1ml-Zinc (10mg)
- 2ml-Magnesium (400mg)
- 3ml- B Complex (300/6/300/6/6mg)
- 1ml-Vitamin B12 (2mg
- Hydroxocobalamin)
- 2ml-Vit C (Ascorbic Acid

1000mg)

• 3ml-Glutathione (600

mg)

### Energy +

### Weight LossBlend

- 1 bag-Lactated Ringers
- 1ml-Zinc (10mg)
- 1ml-Magnesium (200mg)
- 1ml-Vitamin B12 (2mg Hydroxocobalamin)
- 3ml-Tri-Amino Blend (300/300/300)
- 3ml-B-Complex

(300/6/600/6/6mg)

- 3ml-L-Carnitine
  - (1500mg)
  - 2ml-Taurine (100mg)

#### Hangover Cure

- 1 bag-Lactated Ringers
- 1ml-Zinc (10mg)
- 2ml-Magnesium (400mg)
- 3ml-B-complex
  (300/6/300/6/6mg)
- 1ml-Vitamin B12 (2mg Hydroxocobalamin)
- 1ml-Folic Acid (5mg)
- 2ml Glutathione (400mg) Extra-Zofran 4mg, Toradol 15mg, Pepcid 10mg

## Joint Investigations Are Crucial

- From the outside, difficult to determine what type of practitioner was the operator of the clinic and which agency should take lead role
- Directors of three state agencies agreed to conduct joint investigations:
  - Mississippi State Board of Medical Licensure
  - Mississippi Board of Pharmacy
  - Mississippi Board of Nursing

# **Pharmacy Records**

- Mississippi Board of Pharmacy has most wide-ranging inspection authority
- Performed administrative inspections of out-of-state pharmacies identified during investigations
- Required production of documentation re: orders shipped to Mississippi



### **Three Cases**

- Case One: nurse performed intake on IV patient and sent records to in-state physician. Physician reviewed and sent order for IV therapy. Nurse gave IVs. Physician never had contact with patient.
  - Outcome: Consent order. Three month stayed suspension. CMEs in professionalism and ethics.



- Case Two: Physician had ownership interest in clinic. Physician had personal involvement in operations, and supplies ordered using his credentials. Physician knew or should have known how IV hydration was conducted.
  - Outcome: Consent order. Twelve-month suspension, stayed after sixth month. Further reduced to four months for speaking engagements. Physician agreed to divest ownership interest in business and not to practice hydration therapy for life of practice.

- Case Three: Mississippi licensed, out-of-state physician hired as medical director by out-of-state company. Nurses and others hired by company as operators, and opened physical clinics or used IV vans. Medical director allowed company to use credentials to order meds from out-of-state pharmacy that shipped meds directly to physical clinics in Mississippi. Credentials also used by company for personal prescriptions for individuals who turned out to be the clinic operators. Medical Director had no contact with IV hydration "clients" and minimal contact with operators of clinics.
  - Outcome: Contested hearing. Licensee found guilty of administrative charges for prescribing, administering, or dispensing a legend drug without a good faith prior examination and medical indication; knowingly performing any act assisting an unlicensed person to practice medicine; and unprofessional conduct. Six-month suspension, immediately stayed. CMEs in ethics and professionalism.

#### Questions



