Policy Statement Related to Risks to Patients Receiving Intravenous Hydration in Unlicensed Clinics or Locations

The California State Board of Pharmacy (Board) is aware of the retail intravenous (IV) therapy business model and its rapid growth both in California and nationally. Retail IV therapy, commonly referred to as "IV hydration," "IV nutrient therapy," or "vitamin infusion," is provided in a number of different types of businesses including med spas and IV therapy clinics. Through this policy statement, the Board seeks to educate Californians about the potential health risks of seeking IV hydration treatment at some of these businesses and actions you can take to protect yourself.

IV hydration is, as the name implies, administered directly to the patient's bloodstream, thereby bypassing many of the body's natural defenses. This can result in severe or life-threatening reactions if the IV mixture is compounded (mixed) or administered in an unsafe manner. IV hydration provided at a clinic is a medical treatment that requires an examination with an authorized prescriber before administration. The compounding (mixing) and administration of the IV mixture must be done under the supervision of an authorized prescriber and/or licensed healthcare professional.

Currently, IV hydration clinics are generally unregulated in California and as such, these businesses appear in large part to not comply with national standards in place to ensure safe compounding (mixing) and administration of IV hydration. Many of these clinics appear to offer patients a menu of preselected IV mixtures that include various additives or combinations of additives to basic IV solutions, such as multivitamins or electrolytes. Creating such IV mixtures is considered sterile compounding by national standards and by the Board, and, accordingly, must be done in a specific manner by individuals with specialized training to avoid contamination and harm to patients. There is a variety of IV mixtures offered, which are advertised as treating a variety of conditions including migraines, hangovers, nausea, athletic recovery, and jetlag. Depending on the IV mixture, there may be very little or no scientific evidence that these IV mixtures work as advertised. Treatments may be offered in an office, workplace, hotel, or gym, or in a private home. The Board is aware of incidents of harm to patients who have obtained IV hydration treatment at some of these businesses. Due to the largely unregulated nature of IV hydration clinics, there is very little recourse for patients who have been harmed by these products or their administration. The federal Food and Drug Administration (FDA) released a statement highlighting concerns with compounding of drug products by medical offices and clinics under insanitary conditions.

The Board encourages Californians to learn about businesses offering IV hydration therapy, their operations, and their oversight before receiving treatment. Below are some questions that may be appropriate to ask:

- 1. Did you speak with an authorized medical provider (e.g., physician or nurse practitioner) about your medical condition and medical history, and receive a diagnosis and prescription order for the IV hydration treatment?
- 2. Does the clinic purchase medications and supplies from an authorized and licensed entity? Are medications and supplies safely and correctly shipped and stored prior to use?
- 3. Is the medical director overseeing the clinic on site? If not, how often are they working at this location? How often does the medical director review patient's medical records or information to ensure the medication is appropriate for that patient?
- 4. Are licensed personnel compounding (mixing) and/or administering the IV hydration treatment?
- 5. Are the medications compounded (mixed) in a clean and well-maintained facility? How long are IV hydration products stored? Does this follow national standards for storage time and temperature?
- 6. Are there any licenses or permits posted in the facility? Are licenses from a California healthcare professional board? You can verify the status of licenses issued to medical providers and facilities authorized to provide medications here.

The Board's mission is to protect and promote the health and safety of Californians by pursuing the highest quality of pharmacist's care and the appropriate use of pharmaceuticals through education, communication, licensing, legislation, regulation, and enforcement.

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