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Statement on the Need for State and FDA Review of Direct Access Intravenous Therapy Businesses

Recommendations from the National Home Infusion Association, American Society of Health-System Pharmacists, American Society for Parenteral and Enteral Nutrition, Infusion Nurses Society, National Association for Home Care and Hospice, and the National Infusion Center Association.

As organizations invested in the safe and effective administration of infused medications to patients with acute and chronic medical conditions, we are highly devoted to ensuring the availability of these products and their safe administration to patients with legitimate medical needs. However, considering the recent growth in unregulated "hangover clinics" serving patients absent the recommendation of a licensed physician, we share the concern that these entities are compromising both the availability of scarce medical resources and the reputational integrity of accredited medical providers.

The public health crisis and supply chain challenges caused by the COVID-19 pandemic are amplifying shortages of many critical parenteral products used by hospitals, physicians, and home infusion pharmacies to treat patients with serious medical conditions. Managing chronic shortages of drugs, sterile water for injection, normal and hypertonic saline, electrolytes, minerals and vitamins, and other components of parenteral nutrition is a significant burden for clinicians in these settings, taking time away from performing patient care activities. Additionally, the neonates, pediatric, and adult patients who rely on these life-sustaining therapies have few if any options for meeting their health care needs if there is a shortage of one or more critical component of parenteral nutrition. An emerging contributing factor is the sale of scarce parenteral products by a growing number of businesses that are offering direct access infusion treatments to the general public for a range of non-medical conditions, such as hangovers from excess alcohol ingestion, beauty enhancements, and recovery from exercise.

The **National Home Infusion Association (NHIA), American Society of Health-System Pharmacists (ASHP), American Society for Parenteral and Enteral Nutrition (ASPEN), Infusion Nurses Society (INS), National Association for Home Care and Hospice (NAHC), and National Infusion Center Association (NICA)** call on states and the Food and Drug Administration (FDA) to investigate and assess the impact of direct access infusion businesses on critical drug shortages and for states to regulate such businesses in a manner comparable to medical, pharmacy, and home health providers to reduce shortages of critical parenteral products, ensure safety, and protect the public.

For the purposes of this letter, direct access infusion is defined as a service being promoted and offered for purchase to the general public without an assessment to diagnose a medical condition

that is unable to be treated with oral medications or through other means, and/or not based on a prescriber order.

Recommendations:

1) **Investigate and assess the extent to which direct access infusion businesses are contributing to the ongoing national shortages of parenteral drugs, nutrition components, and diluents/solutions.**

   Hospitals, physicians, and infusion pharmacies rely on access to parenteral drugs, nutrition components, and solutions to treat patients with acute and chronic diseases that cannot be effectively managed by oral, or other routes of administration. Many parenteral products have regularly appeared on the FDA shortage list, requiring clinicians to modify treatment regimens or spend exceptional amounts of time and resources to procure and maintain inventories. State regulatory agencies and the FDA should collaborate to assess the impact the direct sale of intravenous infusions to the general public for non-medical uses has on drug shortages.

2) **Require all businesses that sell direct access infusion therapies to the general public to comply with licensure and regulations applicable to the services offered.**

   Hospitals, physicians, pharmacies, and home health agencies providing medically necessary infusion therapies in facilities or in patient homes are required to obtain state licensure and comply with rules and regulations to ensure safe and effective care. Additionally, most health care providers maintain independent accreditation to ensure compliance with accepted standards of practice for personnel competency, sterile drug compounding, safe administration, infection control, record keeping, and more.

   Businesses offering direct access intravenous (IV) infusions on a cash-basis to the general public escape such licensure requirements and regulations in most states. In October of 2021, the FDA published a statement outlining concerns regarding the compounding of sterile products under insanitary conditions in direct access infusion spas, clinics, and mobile IV units.[1] Physicians and pharmacists working in hospitals, clinics, and pharmacies adhere to sterile compounding standards by the FDA and the United States Pharmacopeia, thus ensuring compounded products are not contaminated, are chemically and physically stable, and maintain their integrity throughout storage. Additionally, we are concerned about businesses providing services in patients' homes without having obtained a home health license. We are calling on states to review direct access infusion business practices and ensure they comply with the same standards as medical practices, pharmacies, and home health providers.

[1] https://www.fda.gov/drugs/human-drug-compounding/fda-highlights-concerns-compounding-drug-products-medical-offices-and-clinics-under-insanitary

3) **Investigate claims of health benefit, treatment, or cure, and require businesses that sell direct access infusion therapies to disclose the lack of evidence and unique risks of administering compounded intravenous products that are not medically necessary.**

   Many of the compounded IV solutions being marketed for sale by these entities have no scientific evidence supporting their safety or use in healthy individuals, thus diverting scarce resources from patients who have legitimate medical needs and require these products to live. In particular, we worry that consumers are being misled about the benefits and risks associated with IV hydration and vitamin treatments from a growing number of direct access businesses. We ask the FDA and the states to investigate the claims being made by direct access infusion businesses, and at a minimum require such businesses to post disclaimers and provide written disclosures of the unique risks associated with the IV administration of such treatments.

4) **Establish a licensure category for businesses that sell direct access infusions.**

   Manufacturers and distributors of parenteral products intended for use by hospitals, physician offices, and pharmacies may not be aware that their products are being purchased by, or diverted to direct access infusion clinics, spas, or mobile services for sale to the public. States should establish a licensure category for such businesses to help manufacturers and distributors differentiate such entities from traditionally licensed health care providers and prioritize appropriately during product shortages.

Questions about these recommendations can be directed to Connie Sullivan, BSPharm, President and CEO, National Home Infusion Association at connie.sullivan@nhia.org.

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