

NHIA and Allied Organizations Urge FDA, State Regulators to Investigate, Regulate Direct Access Infusion Businesses

The groups ask the regulators to assess the impact of these businesses on critical drug shortages and for states to regulate them appropriately

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/EINPresswire.com/ -- Contact: Jeannie Counce
Editorial Director
Jeannie.Counce@[NHIA](https://www.nhia.org).org
406-600-2649



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Unregulated businesses that promote IV services to the general public without a medical assessment or prescriber order are diverting scarce resources from patients who have legitimate medical needs.”

*Connie Sullivan, BSP Pharm,
NHIA's President and CEO*

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Alexandria, Va. (January 18, 2022) — [In a statement](#), the National Home Infusion Association (NHIA) and several allied organizations called on the U.S. Food and Drug Administration (FDA) and state regulatory agencies to investigate unregulated direct access infusion businesses, which provide individuals with intravenous solutions absent the recommendation of a licensed prescriber. The groups ask the regulators to 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.

These businesses promote IV services to the general public without a medical assessment or prescriber order. The situations being treated (i.e., hangovers, exercise recovery, elevation

sickness) can usually be resolved with oral medications or through other means—making IV treatment unnecessary. The result is the diversion of scarce resources—many of which appear on the FDA’s drug shortage list—from patients who have legitimate medical needs.

In addition, the clinics, which operate on a cash basis rather than through medical insurance plans, often escape licensure and other requirements that are prerequisites for traditional providers of pharmacy, home health nursing, and medical services. For example, licensed infusion pharmacies must achieve and maintain independent accreditation to ensure compliance with accepted standards of practice for personnel competency, sterile drug preparation and administration, infection control, record keeping, and more.

To ensure safety and address critical shortages of medical products, NHIA, American Society of Health-System Pharmacists ([ASHP](#)), National Association for Home Care and Hospice (NAHC), American Society for Parenteral and Enteral Nutrition (ASPEN), National Infusion Center Association (NICA), and Infusion Nurses Society (INS) recommend the following:

- 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.
- 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.
- 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 IV products that are not medically necessary.
- 4) Establish a licensure category for businesses that sell direct access infusions.

“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,” said Connie Sullivan, BSPHarm, NHIA’s President and CEO. “In addition, as health care professionals, we approach patient care with the imperative to first do no harm. Unlicensed and unregulated businesses administering medically unnecessary therapies with no adherence to industry and professional standards introduces unwarranted risks. We urge state regulatory agencies and the FDA to assess the impact of these operations and establish an appropriate licensing requirement.”

NHIA is a trade association that represents companies that provide infusion therapy to patients in their homes and companies that manufacture and supply infusion and specialty pharmacy products. Infusion therapy involves patient-specific compounded medications, supplies, and a range of pharmacy, nursing, and other clinical services for delivering care to patients in the home setting. For more information, visit www.nhia.org.

ASHP is the collective voice of pharmacists who serve as patient care providers in hospitals, health systems, ambulatory clinics, and other healthcare settings spanning the full spectrum of

medication use. The organization's more than 60,000 members include pharmacists, student pharmacists, and pharmacy technicians. For 80 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety. For more information about the wide array of ASHP activities and the many ways in which pharmacists advance healthcare, visit ASHP's website, ashp.org, or its consumer website, SafeMedication.com.

Since 1973, INS has continued its commitment to bringing innovative resources and learning opportunities to the wide range of health care professionals involved in the specialty practice of infusion therapy. INS is dedicated to advancing the delivery of quality infusion therapy to patients, enhancing the specialty through stringent standards of practice and professional ethics, and promoting research and education in the infusion nursing practice. In January 2021, INS published their 8th edition of Infusion Therapy Standards of Practice that provides the framework to define and develop infusion-based policies and procedures for all practice settings. To learn more, visit ins1.org.

National Infusion Center Association (NICA) is a nonprofit trade association and the nation's voice for non-hospital, community-based infusion providers that offer a safe, more affordable alternative to hospital care settings for provider-administered medications. To learn more, visit infusioncenter.org.

ASPEN is dedicated to improving patient care by advancing the science and practice of clinical nutrition and metabolism. Founded in 1976, ASPEN is an interdisciplinary organization whose members are involved in the provision of clinical nutrition therapies, including parenteral and enteral nutrition. With more than 6,000 members from around the world, ASPEN is a community of dietitians, nurses, pharmacists, physicians, scientists, students, and other health professionals from every facet of nutrition support clinical practice, research, and education. To learn more, visit nutritioncare.org.

The National Association for Home Care & Hospice (NAHC) is the voice of home care and hospice. NAHC represents the nation's 33,000 home care and hospice providers, along with the more than two million nurses, therapists, and aides they employ. These caregivers provide vital services to Americans who are aged, disabled, and ill. Some 12 million patients depend on home care and hospice providers, who depend on NAHC for the best in advocacy, education, and information. NAHC is a nonprofit organization that helps its members maintain the highest standards of care. To learn more, visit nahc.org.

Jeanne Counce
NHIA
+1 4066002649
jeannie.counce@nhia.org

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