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National Home Infusion Association Supports Drug Compounding Legislation Introduced to Preserve Patient Access to Lifesaving Medicines

Alexandria, VA. June 13, 2017— The National Home Infusion Association today applauded Congressmen Morgan Griffith (R-VA) and Henry Cuellar (D-TX) for introducing the *Preserving Patient Access to Compounded Medications Act* that will ensure patient access to lifesaving compounded medications dispensed to a patient from an out-of-state home infusion pharmacy. The bipartisan legislation clarifies congressional intent on several compounding provisions included in the *Drug Quality and Security Act (DQSA)* of 2013. Since passage of the DQSA, there has been a lack of understanding as to where federal regulatory oversight of traditional compounding pharmacies begins and ends. Specifically, there are questions regarding the dispensing of compounded products across state lines, inspection standards, and several other DQSA provisions.

It is important for home and specialty infusion providers to have clarification on application of a provision in the DQSA that calls for a Memorandum of Understanding (MOU)

between the U.S. Food and Drug Administration (FDA) and states, specifically regarding the distribution of compounded products across state lines. NHIA has long maintained that dispensing a compounded product to an individual patient pursuant to a prescription is not commonly considered distribution of the product under state or federal law. The FDA, in its draft MOU released in 2015, included dispensing as an act of distribution and imposed strict limits that could negatively affect access to medications for a patient whose provider is based in another state. This would have serious implications, since the common business practice of dispensing medications for administration in a patient's home can occur across a state line from the physical site where the drug is compounded.

"It is my hope that this legislation will bring clarification as to what the FDA should be doing within their regulatory authority to ensure patient safety, while leaving the regulation of the traditional practice of pharmacy to the states, as it has always been," said Representative Griffith. "Congress never intended for the FDA to assert regulatory authority over the traditional practice of pharmacy," he added.

"This legislation will address a long-standing problem with the Memorandum of Understanding which, over the past several years, NHIA has said needs clarification," stated NHIA President and CEO Tyler Wilson. "We believe Congress did not intend to have this provision halt the delivery of home infusion by a provider licensed in a patient's home state, but whose home infusion pharmacy is located in another state. This legislation will once and for all clarify the issue in statute and ensure patient access to home infusion therapy."

The National Home Infusion Association, based in Alexandria, Virginia, represents organizations that provide infusion and specialty pharmacy products and services to the entire

spectrum of home-based patients as well as the interests of Medicare patients unable to get home infusion therapy. For more information, visit the Association at www.nhia.org.