



December 16, 2019

Congresswoman Diana DeGette
2111 Rayburn House Office Building
Washington, DC 20515

Congressman Fred Upton
2183 Rayburn House Office Building
Washington, DC 20515

RE: "Cures 2.0" Request for Information

Dear Representatives DeGette and Upton:

The National Home Infusion Association (NHIA) appreciates the opportunity to provide comments to you in response to the request for information (RFI) as you initiate work on "*Cures 2.0*." NHIA is a trade association that represents companies that provide infusion therapy to patients in their homes, as well as companies that manufacture and supply infusion and specialty pharmacy products. As the leading voice for the home and specialty infusion industry, we write to share our recommendations for *Cures 2.0*. NHIA applauds you for seeking to build on the efforts of the *21st Century Cures Act*, which NHIA enthusiastically supported, and continue to modernize coverage and access to life-saving cures. Our comments are below.

Background

Home infusion therapy allows patients with serious infections, heart disease, pulmonary hypertension, immune deficiencies, certain cancers, and other conditions to access intravenous, infused drugs in the safety and comfort of their own homes. Until recently, Medicare did not reimburse for home infusion professional services. NHIA worked closely with Members of Congress for several years to establish a meaningful reimbursement system for home infusion therapy professional services provided to Medicare beneficiaries. Because of your leadership, this benefit ultimately was instituted under the *21st Century Cures Act* and *Bipartisan Budget Act of 2018 (BBA)*. The intent of the legislation was to give patients freedom to receive infusion therapy in the comfort of their homes as opposed to an institution or outpatient clinic, which may require frequent long-distance travel for patients in rural areas. Home infusion helps patients return home where they can resume their normal activities while receiving a necessary, life-sustaining treatment, and avoids exposure to opportunistic infections by resistant organisms.

The *21st Century Cures Act* changed the payment structure for infusion drugs under the Medicare Part B Durable Medical Equipment (DME) benefit from an Average Wholesale Price (AWP) methodology to an Average Sales Price (ASP) methodology, effective January 1, 2017. Congress understood that the differential between the drug acquisition price and AWP reimbursement was subsidizing the significant professional services required for patients to access these services in the home. Therefore, the *21st Century Cures Act* also established a reimbursement structure for the professional services associated with the Part B DME infusion drugs, which was scheduled to take effect in 2021. Congress recognized that this four-year gap between the implementation of ASP and the home infusion therapy services benefit



adversely affected access to home infusion therapy for Medicare beneficiaries so it enacted a temporary home infusion therapy services benefit beginning January 1, 2019.

The intent of the *21st Century Cures Act* was for the Centers for Medicare & Medicaid Services (CMS) to implement a home infusion therapy services benefit that would cover all professional services provided and coordinated by infusion pharmacies, including the nursing services, that are required to provide home infusions. Congress intended that all professional services, such as initial and ongoing assessment, drug preparation and delivery, clinical care planning, and care coordination would be covered under the benefit.

Unfortunately, in 2018, CMS implemented the transitional benefit in an extremely restrictive manner. It stated that home infusion therapy professional services would only be reimbursed when a nurse or other professional is physically present in the patient's home. In response to this interpretation, CMS received numerous letters from Members of Congress who were integral in establishing the home infusion therapy services benefit asking CMS to remove the physical presence requirement, which is inconsistent with both the intent of Congress and legislative history of the benefit. Notwithstanding these clear messages from Congress, CMS held to its flawed interpretation of "drug administration calendar day" in its final rule implementing the permanent benefit, essentially reducing or eliminating beneficiary access to the service.

In drafting the legislation, Congress worked to mirror the commercial private sector model for home infusion therapy reimbursement. Commercial home infusion benefits are generally structured as a pharmacy-coordinated service through which a home infusion pharmacy assumes responsibility for case-managing the therapy and providing oversight for all of the professional services. As such, commercial payers reimburse home infusion providers for each day the drug is infused. Importantly, no other payors for home infusion therapy – commercial, Medicare Advantage, the Veterans Administration – require a professional to be physically present in the home in order to reimburse for a patient's home infusion therapy services.

Implementation of the ASP methodology for home infusion drugs likely is behind the decreases in access to home infusion therapy that NHIA already is hearing about from its members. For example, we are aware that some home infusion therapy providers are no longer accepting new patients under the Medicare Part B benefit. The publicly available DME Utilization data shows that 20 percent fewer Medicare beneficiaries received DME infused drugs in 2017 compared to 2016, likely due to the drastic reduction in drug payments without an off-setting services reimbursement. CMS's problematic policies requiring a practitioner's physical presence are jeopardizing access to home infusion therapy, which is a safe, effective and less expensive service compared to other, acute and subacute sites of care. Reducing access to home infusion therapy services likely will lead to increased costs for the Medicare program as home infusion patients are forced to seek treatment in more expensive sites of care such as hospitals, skilled nursing facilities or other institutional settings. In addition, reducing access to home infusion therapy services may have negative quality of care implications for patients, as patients treated in a facility instead of at home are at greater risk of health care acquired infections.

Ensuring Access to Home Infusion Therapy Services

As you continue your work to modernize and enhance coverage, NHIA asks you to stem the damage that has been done to home infusion therapy reimbursement and help restore the original intent of the *21st Century Cures Act*. Specifically, NHIA asks you to support reforms that would ensure that Medicare reimburses for the full suite of professional services that are necessary for the safe and effective delivery of home infusion therapy by:

- Clarifying the definition of infusion drug administration calendar day to ensure that home infusion providers are reimbursed for each day the patient receives an infusion medication.
- Expounding upon the definition of professional services to capture pharmacy related services (including sterile compounding) and other services that are performed remotely.
- Assuring that providers have the requisite skills and licensures to safely and effectively deliver home infusion therapy, such as requirements around sterile compounding.
- Better coordinating care for patients who are eligible for both home infusion and home health.
- Clarifying that a self-administered drug that is routinely infused for 15 minutes or more is not excluded from the definition of “home infusion drug.”
- Providing that a plan of care can be signed by an “applicable provider,” not just a physician.

Other Reimbursement Recommendations

Medicare Part B currently only covers home infusion drugs that are necessary for the effective use of an external infusion pump. This requirement is not consistent with how physicians order drugs for home infusion. Home infusion drugs are ordered based on the totality of patient needs, not whether a pump is used. Again, using the commercial sector as a model, home infusion providers optimize newer technologies, such as elastomeric devices (disposable pumps) to facilitate the training of patients and their caregivers on self-administration. The use of mechanical pumps can often be avoided as they are the most challenging to learn and are more likely to interfere with daily activities and sleep. NHIA requests that you consider policies as part of “Cures 2.0” that would replace this current unnecessary limitation with a definition of a covered drug that meets the definition of being infused intravenously, or subcutaneously over 15 minutes or more. For drugs that require a pump, NHIA recommends a single home infusion therapy payment under Medicare Part B that bundles the pump and supplies with the professional services, consistent with reimbursement in the commercial sector. Reimbursement codes for home infusion utilized by the commercial sector already exist and could be utilized by CMS as its basis for defining the professional services payment.

Finally, NHIA notes that the *21st Century Cures Act* and *BBA* provide for reimbursement for home infusion therapy professional services, but that reimbursement only applies to the administration of Medicare Part B home infusion drugs. NHIA requests that the home infusion therapy professional services benefit also be applicable to Medicare Part D drugs.

NHIA thanks you for the opportunity to provide comments on these important issues and we welcome the opportunity to work with you and members of the Task Force. If you have questions or need additional information, please contact me at connie.sullivan@nhia.org.

Sincerely,



Connie Sullivan, B.S. Pharm
President and Chief Executive Officer