NHIA
National Home Infusion Association
Providing solutions for the infusion therapy community

July 6, 2015

The Honorable John Boehner
Speaker
Office of the Speaker
H-232 US Capitol
Washington, DC 20515

The Honorable Nancy Pelosi
Democratic Leader
Office of the Democratic Leader
H-204 US Capitol
Washington, DC 20515

Dear Speaker Boehner and Leader Pelosi:

The National Home Infusion Association (NHIA), representing the nation's providers of infusion therapy in home and alternate-site settings, strongly opposes Section 4004 of H.R. 6, The 21st Century Cures Act (Cures Act). This provision was added to the Cures Act last week. It would change the payment structure for infusion drugs under the Part B durable medical equipment (DME) benefit to an Average Sales Price (ASP) payment methodology. This provision is similar to a provision that was passed by the U.S. House of Representatives as part of H.R. 2570. We wrote to you about our opposition to that provision, and our reasoning applies with even greater force when that provision is tied to the Cures Act.

NHIA believes that Section 4004 in H.R. 6 is contrary to the stated goals of the Cures Act. It is astounding that this provision is included in legislation that is intended to bring new and innovative drugs to the market, when the current pipeline of drugs has a multitude of infusion drugs. As stated by the Energy & Commerce Committee, the Cures Act is supposed "to help modernize and personalize health care, encourage greater innovation, support research, and streamline the system." The ASP pricing provision is a step backward from this laudable goal. Infusion drugs require a number of professional services in order to be provided safely and effectively in the home setting. Section 4004 would effectively carve away payment for such services, which undoubtedly would create undue risk for beneficiaries. More than likely, this new policy would result in beneficiaries having to obtain access to these drugs in hospitals and other institutional settings, at a significantly higher cost to the Medicare program and at far greater inconvenience to the patients. We explain these concerns in greater detail below.

Currently, home infusion providers are able to provide Part B DME infusion drugs to beneficiaries only because the drug reimbursement is sufficient to cover the costs of the professional services. These professional services are currently not separately paid for, but have been captured by the drug reimbursement, thus making the drug therapies available to beneficiaries for several decades. Without reimbursement from Medicare for the services component of home infusion, the payment change for these drugs as set out in H.R. 6 will make it very difficult, if not impossible, for home infusion providers to provide these drugs and the necessary services to Medicare beneficiaries. Beneficiaries without access to home infusion would most likely need to receive their care in more expensive institutional settings.

The home infusion industry has been proposing a solution to this problem **since 2006**, which is currently reflected in the Medicare Home Infusion Site of Care Act, H.R. 605. It is disappointing, to say the least, that this change in drug payment represents a significant step backwards at a time when the industry itself has been proposing a solution to this problem for almost a decade. If H.R. 6 is passed in its current form, it would further fracture the already broken and illogical Medicare home infusion coverage structure.

100 Daingerfield Road • Alexandria, VA 22314 • *Phone:* 703.549.3740 • *Fax:* 703.683.1484 • www.nhia.org

NHIA is aware that the provisions included in H.R. 6 are carrying out the recommendations of a recent OIG follow up report on home infusion drug payments. We are greatly concerned with the methodology that the OIG used in its original and follow-up reports. The OIG's reports' recommendations do an injustice to a full and productive dialogue regarding Medicare's coverage of home infusion.

Specifically, both reports simply promote the "savings" that would result if Medicare reimbursed DME infusion drugs at the current ASP rates, instead of at the statutorily-mandated methodology of 95% of the average wholesale price as of October 1, 2003. The reports' recommendations are seriously flawed and may trigger policies that would result in Medicare beneficiaries having no choice but to obtain infusion drugs in hospitals, skilled nursing facilities or hospital outpatient facilities. Receiving infusions in these sites of care would be at a far greater cost to the Medicare program and at a significant impact to quality of life for this chronic patient population who require these drug therapies.

These two OIG analyses are, by design, very narrow, far too narrow to be the basis for new policy in this area. The analyses are **only** focused on the drug pricing methodology for Part B drugs, and do not reflect any attempt to assess the impact of a drastic reduction in drug reimbursement on an accredited Part B supplier's ability to provide all of the essential components of care for these extremely ill and vulnerable patients. Professional services (which include specialized pharmacy and nursing services) are critical to the safe and effective provision of these drugs and are not explicitly covered under the DME benefit. Simply imposing a significant payment reduction for the drugs, without a corresponding assessment on the overall clinical care provided to the patient, would be extremely unwise.

For example, the OIG studies are focused largely on a single drug—milrinone lactate—and states that subjecting the drug to the ASP payment methodology would have saved as much as $166 million from Q2 2013 to Q3 2014. This analysis falls far short of providing the full picture of what is involved to ensure patient safety and therapy success in the alternate-site setting for a drug with an extremely narrow therapeutic index.

Milrinone lactate is a type of inotropic medication that is indicated for patients suffering from end-stage heart failure.[1] These patients are either candidates for heart transplants, with inotropic therapy provided to sustain cardiac function and tissue perfusion until transplant occurs, or inotropic therapy is provided to maintain the highest quality of life possible in the final phase of their terminal condition. In both cases, care of these patients in the home setting requires a high degree of expertise, with intensive clinical monitoring needed to ensure patient safety. Inotropic therapy is life-sustaining.

Home infusion nurses and pharmacists prepare patients and their caregivers with comprehensive education regarding maintenance and use of the infusion pump that delivers the medication, as well as 24/7 access to clinical assistance should the need arise. Frequent clinical contact is essential to ensure optimal response to therapy, and to communicate changes in the patient's condition with the prescribing physician so that any needed adjustments to the patients overall medication regimen can be made. The goal in all cases is to maintain care of these end-stage heart failure patients at home, reducing or even eliminating emergency room visits and/or hospitalization whenever possible. Home infusion for patients receiving inotropic medication has been a great success story for our nation's health care system. It has reduced long stay hospitalizations, saved significant dollars for the Medicare program, and allowed patients the opportunity to receive life maintaining care in their own homes.

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[1] Hunt SA, Abraham WT, Chin MH, Feldman AM, Francis GS, Ganiats TG, Jessup M, Konstam MA, Mancini DM, Michl K, Oates JA, Rahko PS, Silver MA, Stevenson LW, Yancy CW. 2009 Focused update incorporated into the ACC/AHA 2005 guidelines for the diagnosis and management of heart failure in adults: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *Circulation.* 2009;119:e391– e479.

By its own admission in both the 2013 and follow-up reports, **the OIG "did not examine any infusion-related services (either covered or uncovered) that may have been provided to beneficiaries who received DME infusion drugs."** For this reason alone, we strongly believe the recommendations included in these reports should not be acted upon. However, there is a clear path towards sensible, cost-effective coverage of home infusion drugs—and that is for Congress to enact the Medicare Home Infusion Site of Care Act, HR 605.

As we continue to work toward a Medicare program that reflects the current needs of older and disabled Americans, it is important that we take an inclusive or holistic approach to home infusion policy issues and resolutions. Long ago, NHIA, along with numerous health policy professionals, identified the need for a comprehensive home infusion benefit to ensure that drug pricing methodologies are adequate and appropriate. We stand ready to work with you to find a realistic solution to ensure home infusion is a viable care option for seniors.

We urge you to remove the ASP pricing provision from H.R. 6 and instead take action to enact the Medicare Home Infusion Site of Care Act, H.R. 605. This legislation will resolve the Part B drug payment issue and also fix the fragmented Medicare coverage of home infusion.

Should you have questions for NHIA, please feel free to call me directly at (703) 838-2678, or contact our Vice President of Legislative Affairs, Kendall Van Pool, at (703) 838-2664. Thank you for considering our concerns on this pressing issue.

Sincerely,

Russell T. Bodoff
NHIA President & Chief Executive Officer

cc: Majority Leader Kevin McCarthy
Majority Whip Steve Scalise
Democratic Whip Steny Hoyer
Chairman Fred Upton, Energy and Commerce Committee
Ranking Member Frank Pallone, Energy and Commerce Committee
Subcommittee Chairman Joe Pitts, Energy and Commerce Subcommittee on Health
Subcommittee Ranking Member Gene Green, Energy and Commerce Subcommittee on Health
Chairman Paul Ryan, Ways and Means Committee
Ranking Member Sander Levin, Ways and Means Committee
Subcommittee Chairman Kevin Brady, Ways and Means Subcommittee on Health
Subcommittee Ranking Member Jim McDermott, Ways and Means Subcommittee on Health
Representative Diana DeGette
Representative Eliot Engel
Representative Pat Tiberi
Members of the US House of Representatives