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

February 26, 2013

The Honorable Kathleen Sebelius
Secretary
Department of Health and Human Services
200 Independence Ave. SW
Washington, DC 20201

Dear Secretary Sebelius:

The National Home Infusion Association (NHIA), representing the nation's providers of home infusion therapy in home and alternate-site settings, is writing in regards to the recent Office of Inspector General Report entitled "*Part B Payments for Drugs Infused Through Durable Medical Equipment*," dated February 2013. We are greatly concerned that this report, which we believe is seriously flawed, may trigger policies that may result in Medicare beneficiaries being able to gain access to these infusion drugs only in hospitals or in long term care facilities—at a far greater cost to the Medicare program and at a significant impact to quality of life in this chronic patient population who require these drug therapies to sustain life.

The OIG analysis is, by design, very narrow. We believe it is far too narrow to be the basis for new policy in this area. The analysis is only focused on the drug pricing methodology for Part B drugs, and does 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. This is particularly important in this area where the professional services (which include specialized pharmacy and nursing services) that are critical to the safe and effective provision of these drugs are not explicitly covered under the DME benefit. Simply recommending a significant payment reduction for the drugs without a corresponding assessment on the overall clinical care provided to the patient appears to us to be extremely reckless.

In this study, the OIG also does not address the reason why Congress exempted infusion drugs provided under the DME benefit from the ASP payment methodology in 2003. If the OIG's recommendations find their way into a new payment policy for these drugs, then the very situation that Congress was trying to avoid in 2003 could become a reality, to the serious detriment of Medicare beneficiaries. The exclusion of all factors other than drug pricing in the OIG study becomes a serious problem if it leads to a reduction in overall payment for this therapy to a level that excludes even indirect recognition of professional services.

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For example, the OIG study is 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 $207 million from 2005 to 2011. 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 they are not candidates for transplant, and 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, and any interruption in the therapy can have devastating and tragic results. 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.

Thus, it is apparent that a drastic reduction in the payments for the drug likely will result in most of these milrinone patients being forced to remain in the hospital or a long-term care setting to receive these complex infusions. This is a serious adverse consequence for these patients. In addition, the report does not address the significant costs that will be incurred as a result of lengthy periods of institutional care these patients would require in the absence of a viable home infusion treatment option.

By its own admission, 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, the recommendations included in this report should not be acted upon. However, we believe there is a clear path towards sensible, cost-effective coverage of home infusion drugs—and that is for Congress to enact comprehensive coverage of home infusion therapy that includes explicit coverage all of the components of these therapies.

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 a holistic approach to policy

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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.

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 HHS, CMS, OIG and Congress to find a realistic solution to ensure home infusion is a viable care option for seniors.

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—I will await your feedback on this important matter.

Sincerely,

Russell T. Bodoff
NHIA President & Chief Executive Officer

cc: Marilyn Tavenner, RN, Centers for Medicare and Medicaid Services, Acting Administrator
Daniel R. Levinson, J.D., LL.M., Inspector General, U.S. Department of Health and Human Services