The National Home Infusion Association (NHIA), a national membership association for clinicians, managers and organizations providing infusion therapy services to patients in home care and outpatient settings, submits to the House Ways and Means Subcommittee on Health this statement for the record related to the June 19, 2012 hearing on the Medicare Payment Advisory Commission's (MedPAC's) June 2012 Report to Congress.

NHIA appreciates that members of Congress,[1] the Government Accountability Office (GAO)[2] and MedPAC have focused recent efforts on exploring comprehensive Medicare fee-for-service coverage of home infusion therapy. We also appreciate the time MedPAC afforded us in presenting how home infusion therapy providers administer high quality, cost effective care. However, we believe that MedPAC report is flawed in several important respects, particularly:

- MedPAC does not fully describe the important role of infusion pharmacists;
- It fails to address the hardships on patients and potential dangers to patients that are due to having to receive infusion services in an institutional setting;
- It erroneously concludes that the savings from a home infusion therapy benefit would be diminished by additional costs associated with the "woodwork effect;"
- It mistakenly assumes that hospital DRG payments preclude any opportunity for savings from a home infusion therapy benefit following patients' discharges from the hospital; and
- It dismisses the decades-long experience of private commercial plans and Medicare Advantage plans that illustrate that a significant number of patients can avoid hospitalization due to the availability of infusion therapy in the home setting.

Most significantly, we believe that the MedPAC report is flawed because it does not recommend a demonstration to evaluate a comprehensive Medicare home infusion therapy benefit. A demonstration conducted by the Centers for Medicare & Medicaid Services (CMS) would provide policymakers with the data needed to fully assess the costs and benefits of a Medicare home infusion benefit. As discussed in more detail below, we believe that a properly designed demonstration would address unanswered questions related to a home infusion benefit and could provide CMS and policymakers with information and guidance that would be helpful to the Medicare program generally.

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[1] The Medicare Home Infusion Therapy Coverage Act of 2011 (H.R. 2195/S. 1203) was introduced on June 15, 2011 in the House of Representatives by Representative Eliot Engel (D-NY) and in the Senate by Senator Olympia Snowe (R-ME).

[2] United States Government Accountability Office, Home Infusion Therapy: Differences between Medicare and Private Insurers' Coverage, June 2010 (GAO-10-426).

The MedPAC Report Does Not Reflect the Professional Services Furnished by Infusion Pharmacists and Does Not Adequately Acknowledge the Variability of the Duration of Nursing Services Required for Home Infusion Therapy.

A multidisciplinary team of healthcare professionals is needed to furnish safe and effective infusion therapies in the home setting. The healthcare professionals involved in providing home infusion therapy services include infusion pharmacists, the prescribing physician, infusion nurses, and when appropriate a nutrition support dietician. Unfortunately, the MedPAC report does not acknowledge the important services furnished by infusion pharmacists.

Infusion Pharmacists Provide Essential Ongoing Services to Patients Who Receive Home Infusion Therapy.

Notably, the MedPAC report fails to recognize that infusion pharmacists provide essential professional services and appropriate clinical interventions throughout the course of a patient's home infusion therapy. Infusion pharmacists coordinate and facilitate safe and appropriate care in the home setting by collaborating with the prescribing physician and infusion nurse, as well as by serving as a resource to these health care professionals as well as the patient and the caregiver. In addition, infusion pharmacists perform specialized routine clinical interventions to maximize a patient's health outcomes and to mitigate potential adverse reactions, such as:

- Developing and implementing the patient care plan;
- Compounding medications in compliance with the US Pharmacopeia 797 regulated sterile compounding procedures;
- Dispensing infusion medications and equipment;
- Conducting ongoing patient assessments, clinical monitoring and treatment plan oversight, including lab and medication profile monitoring;
- Adjusting dosage based on drug levels and pharmacokinetic drug elimination rates;
- Providing on-call services 24 hours/7 days per week; and
- Performing patient discharge services.

It is imperative that any discussion of a comprehensive Medicare benefit for home infusion therapy recognize the broad clinical responsibilities of infusion pharmacists. Their central, active and ongoing role in patient care activities significantly exceeds the activities involved in the retail/mail order pharmacy dispensing of oral and topical medications. The current Part D dispensing fee was explicitly designed as a retail pharmacy dispensing fee. Due to the higher level of care coordination and extensive ongoing clinical oversight involved with infusion therapy, this dispensing fee clearly is insufficient to cover the costs associated with

alternate site infusion therapy drug dispensing. Thus, we believe that it is entirely misleading for MedPAC to state that "[t]raditional fee-for-service (FFS) Medicare general covers some or all components of home infusion depending on the circumstances."

Most Intravenous Medications May Be Safely and Effectively Administered Without the Physical Presence of a Nurse.

Nursing services, while important, are not the only and often are not even the primary professional services provided to infusion patients. Most infusion patients require nursing services. However, the duration of nursing services required to safely and effectively administer home infusion therapy varies depending on the drug being administered and the characteristics of an individual patient and his or her caregiver. For example, as the MedPAC report notes, home infusions of antibiotics may be safely administered independently by a patient or his caregiver. A nurse may be involved in educating the patient and caregiver on how to administer an antibiotic independently. Generally, home nursing visits for a patient on antibiotic therapy occur once or twice weekly depending on the clinical lab monitoring that is required and the ongoing maintenance of the vascular access device.

MedPAC cited a single example in its report of an infusion provider that sends a nurse to provide each administration of the infusion drug. This does happen from time to time, due to limited drug stability or administration issues particular to the medications, but it occurs very infrequently and should not be the basis for policies pertaining to home infusion.

The MedPAC Report Fails to Address the Hardships on Patients and Potential Dangers to Patients Resulting From Having to Receive Infusion Services in an Institutional Setting.

The MedPAC report does not reflect adequate consideration of the increased danger and added expense of complications associated with extended hospital stays for Medicare-aged patients. It is well-established that extending the length of a hospitalization significantly increases the risk of hospital-acquired infections and other complications and adverse outcomes associated with institutionalized care. In addition, there is considerable literature that indicates that vascular devices with direct access to the bloodstream increase the risk of acquiring MRSA or other difficult and costly infections. Also, transitioning patients' care to other institutions, such as skilled nursing facilities (SNFs), extends the risk of morbidity and mortality.

We believe that absent evidence to the contrary, the general principles related to hospital-acquired infections are applicable to infusion therapy. MedPAC suggests that "the literature has not compared infection rates among patients receiving infusions in the home versus other settings." While we believe there is substantial evidence that infections are far more frequent in institutional settings than in the home, a demonstration project could provide data that specifically compares the health outcomes and complications experienced by patients that receive infusion therapy in different health care settings.

Despite the section of the report entitled "Medicare beneficiary experience," we do not believe that MedPAC staff actually spoke with infusion patients, regardless of their payer type. Similarly, we do not believe that MedPAC staff spoke with disease advocacy organizations, such as the American Diabetes Association, the AARP, and disability organizations such as the American Association of People with Disabilities. Rather, the MedPAC report indicates that "Interviews of discharge planners, providers, and physicians provide insight into Medicare beneficiaries' experience accessing home infusion services."

However, we believe that the patient experience with home infusion therapy is one of the most important motivations for Congress to act to improve coverage for home infusion. Consultations with patients and their families would make clear, we believe, how the availability of home infusion can keep families together during stressful episodes of illness and how home care can be the most appropriate, economical and convenient option for patients with serious mobility issues. Soliciting patients' perspectives would be consistent with the current focus on "patient-centered care." We have attached a Wall Street Journal article from 2008 as well as a compilation of patient experiences to illustrate this point.

MedPAC's Concern that Savings Would Be Reduced by the "Woodwork Effect" is Unwarranted and Can Be Mitigated by Utilization Controls, Such As Prior Authorization.

We disagree with MedPAC's concern that the savings to the Medicare program would be diminished by additional costs associated with the woodwork effect (i.e., providing Medicare coverage of home infusion therapy would cause more beneficiaries to use intravenous drugs who otherwise would have been treated with other therapies). The MedPAC report references the potential costs of the woodwork effect several times despite recognizing that (1) patient demand would not increase utilization because patients do not generally seek out IV drugs, and (2) physicians would not increase utilization since there are inherent risks with IV medication, and therefore, they will not take prescribing decisions lightly. The report cites one study that suggested that there may be over-prescribing of infusion drugs when oral medications may be sufficient, but it did not explore why the physicians ordered infusion drugs. In addition, MedPAC's concern regarding the woodwork effect is contrary to evidence in the GAO's 2010 report on home infusion therapy, which suggests that the home infusion therapy benefit "is largely free from inappropriate utilization and problems in quality of care."[3]

We believe that patients will benefit from an alternative "woodwork effect" that may result from Medicare coverage of a comprehensive home infusion therapy benefit. Physicians often limit the medications that they prescribe to beneficiaries based on what is covered by Medicare. Thus, a Medicare fee-for-service beneficiary is often prescribed an oral medication that is covered by Medicare as incident to a physician's service, even if an infusion drug would be more appropriate for the particular patient. We believe that patients will benefit if physicians have the opportunity to prescribe the most clinically appropriate drug, regardless of whether it is

[3] United States Government Accountability Office, Home Infusion Therapy: Differences between Medicare and Private Insurers' Coverage, June 2010 (GAO-10-426), page 26.

in oral or infusion form. This scenario would increase patients' access to clinically appropriate drugs and would improve the quality of care furnished to Medicare beneficiaries.

We believe the threat of the woodwork effect would be minimized if Medicare adopts proper guidelines that reflect the private sector's payer guidelines for home infusion therapy, and if physicians engage in appropriate prescribing patterns supported by home infusion therapy provider verification of each prescription. The MedPAC report acknowledges that prior authorization has worked well in the private sector and with Medicare Advantage (MA) plans, and indicates that the plans, physicians and providers did not generally perceive it as overly burdensome. It is worth noting that the legislation pending in Congress to establish comprehensive coverage of home infusion therapy (H.R. 2195, S. 1203) would authorize prior authorization and other mechanisms to ensure the proper use of infusion therapy in the home. As discussed below, we believe that implementing a targeted prior authorization program for home infusion therapy would address MedPAC's concern regarding increased utilization and could very well benefit the entire Medicare program.

MedPAC Mistakenly Assumed that Hospital DRG Payments Prevent Any Opportunity for Savings from a Home Infusion Benefit Following Patients' Discharges from the Hospital.

The MedPAC report incorrectly assumes that hospital DRG payments preclude any opportunity for savings on home infusion following patients' discharges from the hospital. The report emphasizes that since Medicare makes DRG payments for hospital stays, Medicare payments are unaffected by shorter hospitalizations except in a few instances. However, the report fails to acknowledge that Medicare currently makes more than one payment for infusion therapy services for most beneficiaries.

Most hospitalized Medicare beneficiaries receiving infusion services are discharged from the hospital to a SNF, hospital outpatient department or a physician's office where they continue to receive needed infusion services. As a result, in addition to DRG payments to hospitals, Medicare currently is paying SNFs, hospital outpatient departments and physician's offices for infusion services. In many cases, Medicare coverage of home infusion therapy would be a cost effective alternative to these settings, and is certainly a more convenient one for the patients.

The MedPAC Report Improperly Dismisses the Experiences of Private Commercial Plans and MA Plans which Illustrate that (1) Patients Have Avoided Hospitalizations By Receiving Home Infusion Therapy Services; and (2) Fraud and Abuse Has Not Been an Issue.

Most private commercial plans and most or all MA plans cover home infusion therapy. The actual experiences of these plans indicate that there are infusion patients who avoid hospitalizations altogether due to the availability and receipt of home infusion therapy services. In contrast to the first-hand experiences of the private commercial plans and MA plans, the MedPAC report notes that several commentators, including hospital discharge planners and physicians, believe that there would be very few instances where the availability of home infusion therapy could result in avoided hospitalizations for Medicare beneficiaries.

We believe that MedPAC should defer to the actual experiences of the private commercial plans and the MA plans when evaluating the potential for avoiding hospital stays since home care has not been an option for Medicare beneficiaries due to a lack of coverage of home infusion therapy. In addition, our members' experiences indicate that a significant number of their non-Medicare home care patients never need or receive inpatient hospital care (ranging from 5% to 30%, depending on the particular infusion drug). We believe that the prospect of savings due to avoided hospitalizations should be an issue addressed through a demonstration.

The MedPAC report also acknowledges that the private commercial plans and MA plans did not report that fraud and abuse was more prevalent in the area of home infusion therapy than in any other type of service. Nonetheless, MedPAC concludes that an unmanaged expansion of a Medicare fee-for-service benefit could lead to fraudulent actors entering the field. We are unclear why a new home infusion therapy benefit would be unmanaged. We believe that any benefit that is poorly managed has the potential for fraud and all Medicare benefits should be well managed. Proper utilization controls, such as prior authorization, could help mitigate this concern. These controls are specifically provided for in the infusion coverage legislation cited above and which is currently pending before Congress. Thus, we do not believe that a new home infusion therapy benefit would have a higher risk for fraud and abuse than any other Medicare benefit.

The MedPAC Report Fails to Recommend that CMS Conduct a Demonstration on a Home Infusion Therapy Benefit to Enable Policymakers to Thoroughly Assess the Costs and Benefits of the Therapy.

We agree with the MedPAC report that more information is needed to thoroughly evaluate the costs and benefits of a comprehensive home infusion therapy benefit. As noted by MedPAC, more information is needed related to several key areas, such as the selection of patients, possible savings and appropriate payment levels for a Medicare benefit. We believe that the absence of these data as well as some of the issues highlighted above strongly supports the need for CMS to conduct a demonstration.

As mentioned throughout this statement, we believe that several of the concerns raised in the MedPAC report can be addressed by proper utilization controls that have worked well in the private sector and for MA plans, including prior authorization. Section 1834(a)(15) of the Social Security Act authorizes the Secretary to use prior authorization practices for certain items of durable medical equipment, and thus the concept is not entirely new to Medicare Part B. The MedPAC report acknowledges that if it developed a targeted prior authorization program for a home infusion therapy demonstration, it could be a useful tool for home infusion as well as other areas and could benefit the Medicare program as a whole.

We believe that CMS should invest in developing a targeted prior authorization program for a demonstration regarding home infusion therapy coverage. The narrow focus of the program will enable CMS to gain experience with implementing prior authorization for a limited number of beneficiaries. CMS can refine the prior authorization program based on the demonstration, and can begin applying it to other areas. While it may be a challenge for CMS to implement management controls within the Medicare fee-for-service program, we believe that

the investment in a prior authorization program will benefit providers, beneficiaries and the Medicare program.

A request that CMS conduct a demonstration on a home infusion therapy benefit is not akin to when the Medicare program is asked to evaluate a new type of therapy. Rather, home infusion therapy is covered widely by virtually all payers other than Medicare fee-for-service. Thus, the issue is how to translate this widespread coverage into a form that can work within the Medicare program. We believe that a properly designed demonstration project would improve the Medicare program and would significantly benefit Medicare beneficiaries.

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