

Congress of the United States
House of Representatives
Washington, DC 20515

August 24, 2005

The Honorable Michael Leavitt
Secretary of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Leavitt:

We write to ask for your assistance in investigating current supplies and pricing for intravenous immune globulin therapy (IVIG). The IVIG is a life-saving therapy for patients with primary immune deficiency diseases (PIDD) and neuropathies. Recently we have been made aware that Medicare beneficiaries may be having difficulty accessing this important therapy.

As you know, the Centers for Medicare and Medicaid Services (CMS) implemented the new Average Sales Price (ASP) payment methodology (ASP + 6 percent) as a change from the Average Wholesale Price (AWP) system for drugs covered under Part B of Medicare on January 1, 2005. The IVIG products are among those that are now reimbursed under this system in the physician office setting, although IVIG administered in the hospital continues to be reimbursed at 83 percent of the AWP. While we strongly support the movement away from an AWP-based reimbursement system – given strong evidence of over-reimbursements in the past due to this methodology – there appear to be issues with the reimbursement level of IVIG in physician offices.

Several newspaper articles recently have indicated that the cost for physician offices to purchase IVIG products significantly exceeds the reimbursement by CMS. In response to the concerns that were identified in these articles, staff from the Energy & Commerce and Ways & Means Committees recently met with manufacturers, wholesalers and providers who administer IVIG, to assess the validity of these allegations. As part of this review, staff also requested that the participants supply pricing and related data. This material showed sales prices of IVIG that were generally in line with Medicare reimbursement rates and failed to provide an explanation for why providers reportedly cannot acquire IVIG at similar prices.

We continue to be concerned, however, that Medicare beneficiaries might not be able to get access to IVIG. We are also concerned about recent reports that patients are being transferred from physician infusion suites or home care settings to the hospital, where the reimbursement is 83 percent of average wholesale price until January 1, 2006, when hospitals too will be reimbursed

under the ASP system. The current disparity of reimbursement amounts between the two settings under the Medicare program appears to be driving patients from one setting to another. In addition, there are reports that the supply of IVIG products is currently insufficient and that many settings are unable to purchase the product at any price. This supply problem, while apparently unrelated to any impact of the Medicare reimbursement changes, is also of concern to us. We have discussed this situation with IVIG manufacturers, and they have provided data indicating that there is at least one-month's supply of IVIG available today. Thus the reasons for the reported supply shortages are unclear.

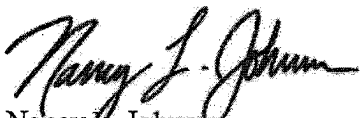
As a result of these reports and concerns raised by IVIG patients, we request that the Office of the Inspector General (OIG) investigate the current state of IVIG supply and pricing. It is our understanding that the OIG is currently conducting an audit, mandated by the Medicare Modernization Act (MMA, P.L. 108-173), to determine the ability of physician practices in the specialties of hematology, hematology/oncology and medical oncology to purchase drugs at 106 percent of ASP. As part of this study, did the OIG specifically examine intravenous immunoglobulin (IVIG) products? If so, could you provide us with the results of this work?

In addition, as part of the OIG-mandated responsibility to compare ASP to widely available market prices, we request that the OIG contact suppliers such as wholesalers and group purchasing organizations to determine the current market prices for IVIG products. In light of recent reports about IVIG product shortages, we also request that the OIG determine whether IVIG products are readily available to physicians.

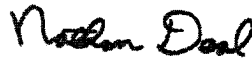
Given the life-saving nature of IVIG for patients who depend on this product, we would request that you provide at least a preliminary response to these questions by no later than September 16th.

We look forward to your prompt response to this important issue.

Best regards,



Nancy L. Johnson
Chairman, Subcommittee on Health
Committee on Ways & Means



Nathan Deal
Chairman, Subcommittee on Health
Committee on Energy & Commerce

cc: Rep. Jim McCrery
Rep. Mark Foley