

## **Medicare Patient IVIG Access Act of 2009**

### **Problem**

Access problems have been reported for Medicare beneficiaries needing intravenous immune globulin (IVIG) treatments – a plasma-derived product critical to maintain health for a variety of serious conditions. The HHS Office of Inspector General (OIG) and the HHS Assistant Secretary for Planning and Evaluation (ASPE) reported to Congress in April 2007 regarding IVIG issues and concluded that problems with payment exist. Many physicians and hospital outpatient departments cannot purchase the product at Medicare reimbursed rates. As a result, patients have experienced delays in treatment, have been shifted to more expensive care settings, and have had greater trouble locating a provider willing to treat them.

Current Medicare law provides a home infusion benefit under Part B specific to beneficiaries with primary immunodeficiency diseases (Section 1842(o)(1)(E)). The current benefit is hollow because related professional services like nursing and supplies were excluded from coverage making the benefit unavailable. The ASPE report found that home infusion providers generally do not take new patients with only Medicare coverage. These patients have a genetic disorder causing the immune system to malfunction and thus should avoid unnecessary exposure to infection in other care settings. Home infusion is a more appropriate option for many.

### **Solution**

The Medicare Patient IVIG Access Act --

- (1) Grants the Secretary of HHS authority to update the payment for IVIG, if appropriate, based on new or existing data.
- (2) Makes whole the current Part B home infusion benefit for patients with a primary immunodeficiency diagnosis – allowing coverage for related items and services.
- (3) Reviews current physician infusion complexity codes for IVIG.
- (4) Requires MedPAC to review IVIG payment and provide recommendations.

### **Background**

Intravenous immune globulin (IVIG) therapy is vital in treating patients with frequent life-threatening infections and debilitating illnesses, including those with primary immunodeficiency diseases, chronic lymphocytic leukemia, Kawasaki disease, neurological conditions such as Guillain-Barre syndrome, myositis, multiple sclerosis, neuropathies, and autoimmune conditions. Without regular access to IVIG therapy, these patients experience a poor quality of life, disability and potentially death. In January 2005, the basis for Medicare Part B drug reimbursement was changed to average sales price (ASP) and soon after reports of access problems were reported to patient groups. The OIG and ASPE studied IVIG issues and reported to Congress in 2007. The OIG reported that even after the 6 month time lag allowed Medicare payment to adjust to changes in product cost, 44% of hospital outpatient departments and 41% of physicians were unable to purchase IVIG at the Medicare reimbursed rate. In addition, the ASPE report concluded that home infusion providers generally do not accept new PIDD patients with only Medicare coverage noting that limitations in service are caused because health care providers: (1) are not able to acquire IVIG at prices at or below the Medicare Part B reimbursement level, and (2) are not reimbursed for the infusion services (*i.e.*, nursing time).