M EDICARE IVIG DEMONSTRATION PROJECT
The current Medicare Part B IVIG home benefit for beneficiaries with Primary Immunodeficiency Diseases (PIDD) fails to cover the items and services necessary to administer IVIG in the home. H.R. 1845 establishes a three-year Medicare demonstration project to address this inequity by providing reimbursement for the items and services necessary to administer IVIG in the home. The demonstration project would begin 6 months after enactment and enrollment would be capped at no more than 4,000 beneficiaries. An interim report of the demonstration project would be due within 2 years of enactment and a final report would be due in 2015.

M EDICARE IVIG STUDIES
Requires the Secretary to report to Congress within 2 years regarding IVIG access and reimbursement issues, including an update of the February 2007 ASPE report entitled “Analysis of Supply, Distribution, Demand and Access Issues Associated with Immune Globulin Intravenous (IGIV)”; and an analysis of the appropriateness of implementing a new Medicare payment methodology for IVIG and the feasibility of reducing the lag time with respect to data used to determine the Medicare Part B Average Sales Price.

COST/OFFSET
An independent estimate done in the 111th Congress of the demonstration project estimated a cost of $9.58 million (Dobson/DaVanzo). The bill includes a spending offset which allows Medicare patients undergoing chemotherapy for colorectal cancer the choice of using a disposable elastomeric infusion pump. Currently, Medicare only reimburses for a durable pump, while private insurance generally covers both. The disposable pump is cheaper and improves patient quality of life. Last Congress, Dobson/DaVanzo estimated this provision will save Medicare $216.8 million over ten years.

B ACKGROUND
Intravenous immune globulin (IVIG) therapy is vital in treating patients with frequent life-threatening infections and debilitating illnesses, including those with primary immunodeficiency diseases, autoimmune and neurological conditions such as Guillain-Barré syndrome, certain types of cancer and other chronic illnesses. 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 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). Home treatment is an appropriate setting for many Medicare beneficiaries with PIDD because of the risk of infection in other health care settings. Many private insurers recognize this fact and provide home coverage for IVIG.

Unfortunately, current law specifically excludes from Medicare coverage the items and services necessary to administer IVIG in the home, including the services of a nurse to perform the infusion. The average length of infusion for Medicare patients with primary immunodeficiency diseases (PIDD) is 3 hours and patients are typically infused once each month.
**MEDICARE IVIG ACCESS ACT**

**H.R. 1845**

**Sponsor:** Rep. Brady, Kevin [TX-8] (introduced 5/11/2011)

**COSPONSORS (55), ALPHABETICAL:*


**S. 960**

**Sponsor:** Sen. Kerry, John [MA] (introduced 5/12/2011)

**COSPONSORS (11), ALPHABETICAL:**

- Sen. Crapo, Mike [ID] - 10/31/2011

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