1. **What is intravenous immune globulin (IVIG)?**
   Immune globulin is a naturally occurring collection of highly specialized proteins known as antibodies. Antibodies initiate the body’s immune response against foreign antigens. IVIG is derived from human plasma donations and is transfused intravenously.

2. **Who uses IVIG?**
   The FDA has approved IVIG to treat several conditions, including primary immunodeficiency disease. In addition, the medical literature supports using IVIG to treat several autoimmune and neurological conditions, such as Guillain-Barre syndrome, and infection-related diseases.

3. **Why is the current Medicare home infusion benefit for IVIG inadequate?**
   Current Medicare Part B law provides a home infusion benefit specific to patients with a primary immunodeficiency diseases (PIDD) diagnosis. However, coverage for the related “items and services” is excluded. As a result, a 2007 ASPE report found that home infusion providers generally do not take new patients with only Medicare coverage – leaving Medicare patients with prohibitive out-of-pocket costs or no access to home infusion. The Medicare IVIG Access Act seeks to address the absence of coverage for the required items and services for IVIG home infusion for PIDD patients. The bill establishes a 3 year demonstration project to provide coverage of items and nursing services necessary to infuse IVIG in the home. Without such a change, the current law benefit is inadequate.

4. **Why are studies of Medicare IVIG reimbursement necessary?**
   In April 2007, the Assistant Secretary for Planning and Evaluation (ASPE) and the Office of Inspector General (OIG) reported to Congress on the difficulty Medicare patients have accessing IVIG. The OIG report stated that Medicare reimbursement for IVIG many times did not cover the cost providers must pay for the product. The studies in the bill will updated the 2007 ASPE study and analyze 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. These reports are necessary because an astounding 61 percent of responding physicians indicated they had no choice but to send patients to hospitals for IVIG treatment, instead of providing this therapy in a physician’s office, due to their inability to purchase IVIG at prices below Medicare reimbursement. Some physicians reported that they stopped providing IVIG altogether to Medicare patients -- seriously jeopardizing patient care for individuals with compromised health.

5. **How much does the bill cost and is there an offset?**
   An independent analysis by Dobson/DaVanzo of the same language introduced in the 111th Congress estimates that the demonstration project will cost $9.6 million. The bill includes the same offset as the bill introduced last Congress and is estimated to save $216.8 million over ten years. The provision allows Medicare to pay for disposable elastomeric infusion pumps for the treatment of colorectal cancer. Currently, Medicare only reimburses for a durable pump, while private insurance generally covers both. The disposable pump is cheaper, improves patient quality of life and allows patients a choice.

6. **How does this bill differ from legislation introduced in the 111th Congress?**
   During consideration of the health care reform bills, the IVIG bills were filed as amendments and modified to provide greater certainty of the cost of the provisions to the Medicare program and assure that the proposed offset covered any increased Medicare spending. Unfortunately, the amendment did not receive an official estimate by the Congressional Budget Office (CBO). HR 5597 was introduced in 2010 and contains the same language as the floor amendment introduced by Senator Kerry, providing for a demonstration project and study. The Medicare IVIG Access Act introduced in the 112th Congress is identical to HR 5597 and the Kerry Amendment in the 111th Congress.