

## **Section-by-Section Summary of H.R. 574/ S. 254**

### **Section 1:**

- The short title of the bill is the “Medicare Home Infusion Therapy Coverage Act of 2009.”

### **Section 2:**

- Amends Section 1861(2) of the Social Security Act to establish Medicare Part B coverage of home infusion therapy services, supplies and equipment.
- Home infusion therapy is defined to include items and services furnished by a qualified home infusion therapy provider to an individual, which are provided in an integrated manner in an individual’s home under a plan established and periodically reviewed by a physician. Home infusion therapy includes professional services as well as supplies and equipment needed to administer infusion drug therapies safely and effectively in the home. It would also include nursing services provided in accordance with the physician’s plan, which are furnished directly by a qualified home infusion therapy provider or under arrangement with an accredited homecare organization, except that nursing services are not covered under this benefit if they are covered under the home health benefit.
- The Secretary of the Department of Health and Human Services (the Secretary) would determine a per diem schedule reflecting reasonable costs to pay for the professional services, supplies and equipment included in the definition of home infusion therapy. A separate payment methodology would be developed for the reimbursement of nursing services, which would reflect the reasonable costs associated with the provision of nursing services relating to infusion therapy. Both of these payment schedules would be updated annually by the percentage increase in the consumer price index for all urban consumers (United States city average).
- “Home” is defined as an individual’s home or such other setting as determined by the Secretary.
- “Qualified home infusion therapy provider” is defined as any pharmacy, physician or other provider licensed by a State and which has expertise in preparation of parenteral medications, provides infusion therapy to patients in their homes, and meets other requirements established by the Secretary. A qualified home infusion therapy provider may subcontract with other entities to meet the requirements established by the Secretary.

### **Section 3:**

- Coverage of infusion drugs would be consolidated under Medicare Part D.
- An infusion drug would be defined as “a parenteral drug or biological administered via an intravenous, intraspinal, intra-arterial, intrathecal, epidural, subcutaneous, or intramuscular access device inserted into the body, and includes a drug used for catheter maintenance and

declotting, a drug contained in a device, vitamins, intravenous solutions, diluents and minerals, and other components used in the provision of home infusion therapy.”

- Prescription drugs plans (PDPs) and Medicare Advantage Part D plans (MA-PDPs) would be required to maintain open formularies for infusion drugs for the first two years after the effective date of the Act. The Secretary would request that the United States Pharmacopeia, in consultation with representatives of qualified home infusion therapy providers and other stakeholders develop a model formulary approach for home infusion drugs for PDPs and MA-PDPs to use after the two year period.

#### **Section 4:**

- The Secretary would be required to implement the benefit in a manner that ensures that beneficiaries have safe and timely access to home infusion therapy, with minimal administrative burdens imposed on qualified home infusion providers and beneficiaries.
- The Secretary would be required to ensure that prior authorization or utilization review processes are expeditious; that the medical necessity determinations for home infusion therapy are made by Medicare administrative contractors under Part B and are communicated to the appropriate PDP, except that MA organizations offering MA plans will make the medical necessity determinations for plan enrollees. The Secretary would be required to ensure that the benefit is modeled on current private sector coverage and coding for home infusion therapy. PDPs and MA-PDPs would have to structure their formularies, utilization review protocols, and policies in a manner that guarantees timely and appropriate access to home infusion therapy by Medicare beneficiaries.
- The Secretary would establish an advisory panel to provide advice and recommendations on the development and implementation of the home infusion therapy benefit. The advisory panel would consist primarily of qualified home infusion therapy providers and their representative organizations, and also would include representatives of patient organizations; hospital discharge planners, care coordinators or social workers; and PDP sponsors and MA organizations.
- The Comptroller General would be required to submit a report to Congress on Medicare beneficiaries’ access to home infusion therapy by January 1, 2012 and every two years thereafter.

#### **Section 5:**

- The amendments contained in the Act would apply to home infusion therapy furnished on or after January 1, 2010.