**ISSUE BACKGROUND**

**Changes in Medicare Part B Payment for Physician Office Drugs and Biologicals**

**Reasonable Charges, Average Wholesale Price (AWP) and Average Sales Price (ASP) Payment Methodologies**

Since the start of the Medicare program in the 1960’s, there has been a limited Part B prescription drug benefit that generally includes drugs and biologicals that are injected by health care professionals. The statute also specifies a few types of products that a beneficiary self-administers that also are covered under Part B (e.g., certain vaccines, cancer drugs and immunosuppressive drugs).

Historically, Medicare has paid for covered Part B drugs furnished in a physician’s office using one of three methodologies: (i) based on the physician’s reasonable charge for the product; (ii) based on average wholesale price; or (iii) based on average sales price.

- **Reasonable Charges**
  - Prior to 1992, Medicare payment rates for Part B drugs were based on reasonable charges by physicians for drugs.
  - Medicare contractors used customary or prevailing charges in a geographic area to determine the payment rates.

- **Average Wholesale Price (AWP)**
  - Beginning in 1992, the Medicare program paid for drugs at their AWP (i.e., 100% of AWP).
  - Effective January 1, 1998, Congress specified that Part B payments to physicians for drugs and biologicals would be at 95% of AWP.
  - For 2004, at the direction of Congress, Medicare payment for most Part B drugs changed to 85% of AWP, although some products continued to be reimbursed at 95% of AWP.
  - AWP is a figure derived from self-reported manufacturer data and does not include volume discounts or rebates. AWP is not a government-regulated figure, i.e. it is not defined in statue or in regulation.
  - AWPs are published by pricing services (e.g., First Data Bank, Red Book) on a National Drug Code (NDC) basis.
    - Wholesale acquisition cost (WAC) is generally the price paid by wholesalers to the manufacturer for a drug, but manufacturers may offer a discount off WAC to their customers.
  - Manufacturers periodically report pricing information to the pricing services and they publish AWPs. Many manufacturers report WAC to the pricing services, which the pricing services mark-up by 20-25% to arrive at the AWP.
The Government Accountability Office (GAO) has described AWP as a “sticker price” or “suggested retail price” and not necessarily a price paid by a purchaser.

Medicare determines Part B drug, AWP-based payment rates by Healthcare Common Procedure Coding System (HCPCS) code.

- For multiple source drugs, AWP is the lesser of the median average wholesale price for all generic forms or the lowest AWP of the brand name products in the code.

**Average Sales Price (ASP)**

- In the Medicare Modernization Act of 2003, Congress revised the Medicare Part B payment rates for physician office drugs to base most payments on average sales price (ASP) effective on January 1, 2005.
- A few products continued to be paid at 95% of AWP.
  - Certain vaccines – permanently.
  - Infusion drugs furnished through an item of durable medical equipment – with the payment set at 95% of the AWP in effect on October 1, 2003.
- Congress set the Part B drug payment rate at ASP + 6%. The important addition of 6% over ASP helps lessen the possibility that a physician’s reimbursement for the therapy is less than the acquisition cost.
- ASP is computed by the Centers for Medicare and Medicaid Services (CMS) on a quarterly basis, and CMS publishes ASP + 6% rates quarterly.
- ASP calculation uses manufacturer sales information submitted to CMS that includes discounts such as rebates, volume discounts, and prompt pay discounts.
- Manufacturers submit ASP information by National Drug Code (NDC) for its Part B covered drugs. CMS associates the NDCs with the pertinent HCPCS code and then computes an ASP + 6% rate for each HCPCS code that CMS posts on its website every calendar quarter. It is a weighted calculation.
  - Manufacturer sales of product that are at nominal charge, or that are exempt from “best price” are exempt from the ASP calculation.
  - Volume discounts, prompt pay discounts, chargebacks and rebates are included in the ASP calculation.
- There is a two quarter lag between when ASP information is reported by manufacturers and when that information is used to set the Medicare payment rates.
  - For example, ASP information for the first calendar quarter of 2013 must be reported to CMS by April 30, 2013, and that information is used to determine the ASP + 6% rates effective for the third calendar quarter of 2013 (i.e., effective July 1, 2013 through September 30, 2013).