

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 statute or in regulation.
- AWP's 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 AWP's. 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).