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PRESCRIPTION DRUG PRICING

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MEDICARE PART B

The Medicare Part B "buy and bill" payment structure for physician-administered drugs also influences private-sector prices.

Medicare pays for prescription drugs administered in physicians' offices and hospital outpatient clinics as part of Part B coverage of physician services. Total Part B spending on drugs is small ($24.6 billion in 2015), relative to Part B spending overall ($279 billion in 2015). However, it is an important segment of the market for cancer, ophthalmic, and rheumatology drugs, and the unique Part B payment system—in which physicians purchase the drugs and are reimbursed by Medicare—helps determine pricing strategies for those products in private markets as well. Part B is also the only segment of Medicare in which federal payment is tied directly to individual drug product prices. It is, therefore, a likely area for potential reforms to enhance competition or negotiate lower prices for specific drugs.

Background

Part B, the medical component of Medicare, provides payments to physicians and hospital clinics for outpatient services. That reimbursement includes payments for physician-administered drugs (typically intravenous infusions). Part B drug expenditures were $24.6 billion in 2015—less than 10 percent of total Part B expenditures of $279 billion and significantly lower than Part D "retail" prescription drug spending under Medicare Part D ($137.4 billion in 2015).

However, Part B is an important segment for several specific classes of medicines, most notably cancer, ophthalmic, and rheumatology therapies. In those markets, Part B program dynamics often influence the manufacturers' overall pricing strategy; prices set for the government program extend to the commercial market pricing patterns, as described below. That, in turn, means that there are formidable constituencies engaged in any potential changes to the Part B program, including the medical specialty groups that use those classes of drugs.

The Part B program stands out in drug pricing discussions for several reasons. First, Part B drug expenditures have grown faster than the rest of Medicare for much of the past two decades. From 2010 to 2014 Part B grew at an annual rate over 8 percent, while total Medicare expenditures grew at just over 4 percent.

Second, a relatively small number of high-price drugs generate most of the program costs. In 2013 the program spent $9.4 billion (47 percent of total Part B

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spending) on the top ten drugs. The nearly 600 additional covered drugs contribute minimally to total cost because of low prices or limited use.

Third, patients are responsible for a 20 percent coinsurance for Part B drugs, giving them a significant out-of-pocket stake in the program.

> "There are formidable constituencies engaged in any potential changes to the Part B program."

Finally, the congressionally mandated reimbursement formula (average sales price plus a 6 percent handling fee, as described below) favors higher-price products. Because the handling fee is a percentage, it increases with the price of the drug, which encourages physicians to use more costly therapies and manufacturers to set higher prices to attract providers to their products.

Part B is also a rare case in which Medicare policy makers can address individual drug costs directly, since payment is tied to each specific prescription. In contrast, in the Medicare hospital benefit (Part A), drug payments are included in broader reimbursements for inpatient stays. Under the Part D retail benefit, Medicare pays insurance companies a fixed amount for all necessary drugs for covered beneficiaries; there is no direct payment for specific drugs. These factors make Part B fertile ground for testing approaches to control prescription drug spending.

Part B: What You Need To Know

The Medicare Part B payment system includes several unique features that distinguish the program from many public and private models of prescription drug coverage.

"BUY-AND-BILL" MODEL

Part B uses a reimbursement or buy-and-bill model, meaning that providers purchase the drug first, then bill for it after it is administered. Given that some Part B drugs are quite expensive, the certainty of the reimbursement and the attractive add-on handling fee (described below) are important considerations for providers.

THE "SPREAD"

When the program began, the government payment for Part B drugs was tied to a published "list" price, but most providers actually paid much less than that amount when they bought the drugs. Providers came to depend on the "spread" between the purchase price and the Part B payment rate as a source of revenue.

Over the past two decades, four congressional and administrative changes to the reimbursement formula have focused on setting the product cost component of the reimbursement closer to actual market prices (Exhibit 1). Those changes have reduced, but not eliminated, the spread.

ASP + 6 PERCENT

The current payment formula was set in 2003 as part of the Medicare Modernization Act. It ties payment to the average sales price (ASP), a manufacturer-reported average of actual market prices for a given product, after rebates, discounts, and other price concessions. The reimbursement is set at 106 percent of ASP to account for variability in actual prices available to providers and to include payment for providers' handling costs.

While the statutory payment rate remains ASP + 6 percent, the sequestration provisions of the Budget Control Act of 2011 mandate a 2 percent reduction across Medicare expenditures. Because the sequester does not affect the patient copay component of reimbursement, the 2 percent cut means that the effective payment rate for Part B is now ASP + 4.3 percent.

INCENTIVES AT CROSS PURPOSES

Policy makers intended the switch to ASP-based reimbursement to encourage cost-conscious purchasing and therefore price reductions. Providers have an incentive to seek discounts as far below the Part B payment rate as possible. If manufacturers give better prices, the ASP will decline over time, and Medicare reimbursement will decline as well. However, the 6 percent add-on operates in the opposite direction,

encouraging providers to prescribe products with a higher ASP to capture a larger "spread."

The Future Of Medicare Part B

Several important issues will play into the future trajectory of drug spending under Part B

REVISITING A PROPOSED DEMONSTRATION

In 2016 the Centers for Medicare and Medicaid Services (CMS) proposed a Part B demonstration program based on a June 2015 report from the Medicare Payment Advisory Commission (MedPAC). The proposal drew widespread objections from providers and members of Congress and was not implemented. However, it included several elements that policy makers might revisit. These include:

- **Using a flat fee rather than a percentage add-on to ASP:** The demonstration would have changed the reimbursement formula from ASP + 6 percent to ASP + 2.5 percent, plus a flat fee of $16.80 per prescription. The fee was intended to ensure that average reimbursements across Part B would stay the same, while reducing incentives for providers to choose a drug with a higher ASP versus a lower one. In fact, the flat fee would make very-low-price drugs attractive, since the add-on fee might be more than double the cost of the drug.

EXHIBIT 1

Part B Reimbursement Formula: A Short History

Date	Reimbursement Formula	Comments
1992 (Physician Fee Schedule for 1992)	**100% Average Wholesale Price (AWP)—**a published suggested wholesale price or "list" price. Estimated Acquisition Cost (EAC) used for high-volume, low-cost items.	CMS initially proposed that reimbursement be set at 85% of a national AWP but backed off when the agency "received many comments, primarily from oncologists, indicating that an 85 percent standard was inappropriate."
1997 (Balanced Budget Act of 1997)	**95% AWP** for single-source products; lower of 95% of median AWP for generics in multisource category or 95% of AWP for lowest brand-name product.	Several reports from the HHS Office of Inspector General in 1996 and 1997 found that 100% of AWP bore "little or no resemblance to actual wholesale prices."
2005 (Medicare Modernization Act of 2003)	**106% Average Sales Price (ASP)**, calculated by CMS from quarterly sales data provide by manufacturers from their sales to all purchasers in the US. ASP is net of any price concessions such as volume, prompt-pay, and cash discounts; free goods contingent on purchase requirements; chargebacks; and rebates other than those obtained by the Medicaid drug rebate program.	Six percent add-on payment created to help cover the overhead costs associated with the drug and differences in acquisition costs. A 2010 analysis of the new rate for reimbursement of chemotherapy drugs versus a transition rate in 2004 found that "the new payment system set chemotherapy reimbursements at 1.06 times the average costs of the drugs. This rate represented a notable decline from the 2004 weighted average payment-to-cost ratio of 1.22."
2013 (Budget Control Act of 2011; Sequester, March 2013)	**104.3% ASP—**net effect of the 2% sequester reduction for Medicare payments is reduced to 1.6% because patient copays are not reduced.	"For example, for a $100 charge where the patient co-pay is 20 percent or $20, sequestration reduces the $80 Medicare payment to $78.40. Assuming the provider receives the full co-pay, total reimbursement drops to $98.40, not $98.00. The net effect in this example is a 1.6 percent reduction." Explanation by Alex Brill (American Enterprise Institute) and Brett Leitner (Hooper Lundy & Bookman), June 11, 2013.
2016 (CMS proposed demonstration project—not implemented)	**102.5% ASP plus $16.80 per day of drug use.**	CMS calculated the two-piece reimbursement formula to create the same aggregate spending as the current 1.06% ASP formula across the full line of Part B drugs. CMS describes the new formula as being more generous for lower-price items than higher-priced ones.

SOURCE Prevision Policy LLC.

- **Outcome-based payments:** A second phase of the demonstration would have tied payment to outcomes associated with use of a drug, or to a third-party assessment of a given therapy's value. The proposal never got far enough beyond objections to the first step of the demonstration (the rate change) to generate substantial discussion.
- **Reference pricing:** The demonstration would also have applied reference pricing in classes where there are two or more similar options available. The formula would tie reimbursement to the lowest-cost option, the average price of all the options, or the price of a specific therapy deemed most cost-effective.

MERGING PARTS B AND D

The federal government's multiple modifications to the reimbursement formula indicate its intent to bring Medicare payment rates closer to what the broader market pays for physician-administered drugs. These refinements have been necessary because the private sector adjusts quickly to new reimbursement formulas, continuing to make the buy-and-bill system attractive for manufacturers and physicians.

These dynamics suggest a different solution: folding Part B drugs into Part D, Medicare's program for outpatient drugs. Doing so would shift payment controls onto private insurers with cost-control mechanisms such as formularies, which are not used in Part B. At a minimum, that change would eliminate any artificial incentives at play in the selection of therapies in categories where oral medicines covered by Part D are available as alternatives to injectable/infusion therapies covered by Part B.

Such a proposal, however, would need to take into account the potential impact on provider payments (such as the loss of the spread) and on beneficiary cost sharing. Part D plans can impose relatively high copayment levels; in some cases, that might mean exposing beneficiaries to more than the 20 percent coinsurance required under Part B.

COMPETITIVE BIDDING

One of the abandoned pieces of the 2003 Medicare Modernization Act was the establishment of a competitive bidding system to inject market competition into Part B. MedPAC has suggested restructuring the previously proposed Competitive Acquisition Program (CAP) as follows: (1) Empowering contracted private-sector vendors to use selective formularies to negotiate discounts from manufacturers—and share associated savings among beneficiaries, physicians, and the vendor; and (2) encouraging physicians' enrollment in CAP by removing the 6 percent handling charge from the existing buy-and-bill program. While less ambitious than abandoning buy-and-bill completely or folding Part B into Part D, this approach faces many challenges, including strong support from physicians and manufacturers for the 6 percent handling charge.

BUNDLED PAYMENT

Over the years some Part B drugs have moved from the standard reimbursement model to being included as part of bundled price-for-therapy approaches. Bundling—the model used with kidney dialysis as well as CMS's Bundled Payments for Care Improvement initiative—injects competition among all the components of care related to a procedure or episode: drugs, physician services, and any related treatments.

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