

Payment policy for prescription drugs under Medicare Part B and Part D

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Statement of
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Chairwoman Eshoo, Ranking Member Burgess, distinguished Committee members, I am James E. Mathews, Executive Director of the Medicare Payment Advisory Commission (MedPAC). I appreciate the opportunity to be here with you this morning to discuss prescription drug payment policy under Medicare Part B and Part D. In my testimony I will provide:

- a brief overview of how Medicare currently pays for drugs under Part B and Part D and a description of what the Commission has identified as problems with the incentives of those payment systems,
- a look at evidence of rising drug spending and drug prices within Medicare, and
- a brief description of the Commission's standing recommendations for changes to drug payment policies in Part B and Part D.

The Commission's role

MedPAC is a small congressional support agency established by the Balanced Budget Act of 1997 (P.L. 105-33) to provide independent, nonpartisan policy and technical advice to the Congress on issues affecting the Medicare program. The Commission's goal is to achieve a Medicare program that ensures beneficiary access to high-quality, well-coordinated care; pays health care providers and health plans fairly, rewarding efficiency and quality; and spends taxpayer and beneficiary dollars responsibly.

Prescription drugs are an essential component of health care. Because of their role in medical treatment, it is important that Medicare make sure beneficiaries have access to appropriate medications. However, it is becoming increasingly difficult to ensure that access to medicines remains affordable for beneficiaries and financially sustainable for taxpayers. For this reason, the Commission has devoted considerable attention to the issue of drug spending in recent years. In 2016, the Commission recommended major changes in the payment system for outpatient prescription drugs delivered by private plans in Part D. In 2017, we also recommended substantial changes to the payment system for provider-administered drugs under Medicare Part B. As I will describe in a few minutes, both sets of

recommendations would improve payment incentives while using market competition to constrain growth in drug prices. Even after those recommendations, the Commission has continued to examine other potential changes with the goal of better ensuring that appropriate prescription drug treatments are affordable to beneficiaries and sustainable for the Medicare program.

Overview of how Medicare pays for drugs

Medicare accounts for about one-third of U.S. retail pharmaceutical sales. The program also pays for drugs and biologics provided in nonretail settings, including medicines provided in hospitals, physician offices, skilled nursing facilities, and other providers.¹ Across all Medicare sectors, we estimate that spending for drugs and biologics grew from about 20 percent of total Medicare spending in 2007 to 23 percent by 2016.²

Medicare pays for drugs in different ways across its various payment systems. Most institutional providers receive prospective payments, typically for a bundle of services that includes drugs. Physicians and outpatient hospitals are generally paid separately for higher-priced Part B–covered drugs. Under Part D, Medicare pays private drug plans a combination of capitated payments based on plan bids and cost-based reinsurance subsidies.

In each payment system, Medicare’s influence over drug pricing is limited. For example, when CMS administratively sets a bundled payment rate (e.g., as with the hospital inpatient and dialysis facility prospective payment systems), it is providers who negotiate the price of the drugs they administer. Medicare then sets payment rates that take into account the agency’s estimates of providers’ drug costs. Similarly, Medicare payments for high-cost Part B drugs are based on the manufacturer’s average sales price (ASP) to physicians, hospitals,

¹ Biologics are large-molecule medicines derived from living organisms that are used to treat serious diseases such as cancer, rheumatoid arthritis, and multiple sclerosis. The term *biologics* encompasses a wide range of products including vaccines, blood and blood products, allergenics, somatic cells, gene therapy, tissues, and therapeutic proteins. Examples of biologics include monoclonal antibodies, therapeutic proteins, human insulin, recombinant hormones, and growth factors. Biologics can be purified from natural substances, produced through recombinant DNA technology, or manufactured through other methods. Hereafter, we use the term *drugs* to refer to drugs and biologics unless otherwise noted.

² This analysis determined drug and total spending under the inpatient and outpatient hospital, skilled nursing facility, home health, and hospice payment systems; the physician fee schedule, Part B ASP-based system, and other Part B providers (e.g., dialysis facilities); Part A and Part B benefits administered by Medicare Advantage plans; and Part D.

and other purchasers plus a 6 percent add-on (ASP + 6 percent).³ In the case of Part D, private plans negotiate prices for drugs, not the Medicare program.⁴

Part B drugs paid on the basis of ASP

Part B covers drugs that are administered by infusion or injection in physician offices and hospital outpatient departments, as well as certain drugs furnished by suppliers. Medicare Part B drug spending has been growing rapidly, more than doubling between 2009 and 2017. Medicare Part B spending (including beneficiary cost sharing) grew from \$15.4 billion in 2009 to \$32.0 billion in 2017, increasing at an average rate of 9.6 percent per year.

Medicare pays physicians and outpatient hospitals for most separately payable Part B–covered drugs they furnish to beneficiaries at a rate of 106 percent of the manufacturer-reported ASP. A product’s ASP reflects the average price realized by the manufacturer for sales to all purchasers net of rebates, discounts, and price concessions with certain exceptions.⁵ Medicare pays providers 106 percent of ASP for the drug regardless of the actual price a given provider pays for it. CMS updates the Medicare Part B drug payment rates for each product with available ASP data on a quarterly basis; these payment rates are publicly available on CMS’s website. There is a two-quarter lag in the data used to set ASP + 6 percent payment rates. This lag is

³ Under the hospital outpatient prospective payment system, certain Part B–covered drugs (e.g., those that are low cost) are bundled into the payment for other services rather than separately paid. In addition, by statute, certain vaccines and blood products are paid based on 95 percent of average wholesale price (AWP) instead of ASP + 6 percent.

⁴ Details about each of Medicare’s payment systems can be found in the Commission’s *Payment Basics* series of publications available at <http://medpac.gov/-documents/-payment-basics>.

⁵ Manufacturers calculate ASP based on sales to all purchasers, excluding nominal sales to certain entities and prices that are exempt from the determination of Medicaid best price (e.g., sales or discounts to other federal programs, 340B-covered entities, state pharmaceutical assistance programs, and Medicare Part D plans, as well as manufacturer coupons to consumers meeting certain criteria). Bona fide service fees are not considered price concessions for the purposes of ASP. Bona fide service fees are fees paid by the manufacturer to entities such as wholesalers or group purchasing organizations that are fair market value, not passed on in whole or part to customers of the entity, and are for services the manufacturer would otherwise perform in the absence of the service arrangement.

necessary to permit time for manufacturers to submit ASP data and for CMS to calculate and implement the new payment rates.⁶

The ASP system enacted by the Medicare Modernization Act of 2003 represents a significant improvement over the prior payment method that set a drug's payment rate at 95 percent of the average wholesale price (AWP). Under the ASP-based system that Medicare has used since 2005, the program's payment rates for Part B drugs are closer to the prices that providers pay than under the prior AWP-based payment method. Despite its name, AWP does not represent the average wholesale price. Rather, it can be thought of as a manufacturer's suggested list price, which does not have to correspond to any market-based transaction price and does not reflect discounts. Under AWP-based payment, expenditures for Part B drugs increased rapidly, more than 25 percent per year from 1998 to 2003. One of the most significant factors driving spending growth was the AWP payment method. A series of reports by the Department of Health and Human Services Office of Inspector General (OIG) and the Government Accountability Office (GAO) showed that Medicare payment rates under the AWP-based payment system were well above providers' acquisition costs.

In addition to paying ASP + 6 percent for the drug, Medicare makes a separate payment to providers for administering the drug to the patient (e.g., for infusing or injecting the product) under the physician fee schedule or the hospital outpatient prospective payment system. Medicare pays a dispensing or supplying fee to pharmacies that dispense inhalation drugs and oral anticancer, oral antiemetic, and immunosuppressive drugs to beneficiaries; Medicare also pays a fee to providers when they furnish clotting factors.

If a drug lacks ASP data, Medicare has alternative methods for paying for the product. For new single-source drugs that initially lack ASP data, Medicare pays a rate of wholesale acquisition cost (WAC) plus 3 percent for the first two to three quarters the product is on the

⁶ Manufacturers are required to report ASP data for a calendar quarter within 30 days after the close of that quarter. CMS then takes the data submitted by manufacturers and uses it to calculate the ASP + 6 percent payment rates for the next calendar quarter. For example, ASP data for 4th quarter of 2018 were used to set the ASP + 6 percent payment rates for 2nd quarter of 2019. Manufacturers were required to report ASP data for 4th quarter of 2018 by January 30, 2019. CMS then had two months to calculate, publish, and operationalize the new payment rates so they would go into effect at the start of the next calendar quarter, which began April 1, 2019.

market. For drugs that lack ASP data for reasons other than being new, such as the manufacturer not reporting ASP data or the manufacturer having no sales in a particular reporting quarter, the payment method varies and may be 106 percent of WAC, 95 percent of AWP, or invoice priced. WAC- or AWP-based payment methods generally result in Medicare paying more for drugs than it otherwise would under the ASP-based formula. These alternative payment methods do not incorporate rebates, discounts, and other price concessions. Most, but not all, Part B drug manufacturers are required to report ASP data to CMS. A recent Commission recommendation to require all manufacturers to report ASP data would be an important step to ensure that it is not possible for overpayments to occur as a result of manufacturers not reporting ASP data.

Payments for single-source drugs and originator biologics, multiple-source drugs, and biosimilars are set differently. Each single-source drug and originator biologic is paid under its own billing code at 106 percent of its own ASP; brand and generic versions of a drug are assigned to the same billing code and paid the same rate equal to 106 percent of the volume-weighted average ASPs; and each biosimilar is paid under its own billing code at a rate of 100 percent of its own ASP plus 6 percent of the originator biologic's ASP.

An individual provider may purchase a drug for more or less than ASP for a number of reasons. ASP is the average price from the manufacturer's perspective. Generally, some purchasers pay more than ASP and some pay less. For example, prices can vary across purchasers of different sizes (e.g., due to volume discounts) or across types of purchasers (e.g., physicians, hospitals, and pharmacies). In addition, the two-quarter lag in ASP data can result in the average provider acquisition cost for a drug being different from the ASP used to set the Medicare payment amount for a quarter. When prices increase or decrease, it takes two quarters before that price change is reflected in the ASP data used to pay providers.

The Secretary does not routinely collect providers' acquisition costs for Part B drugs.⁷ To get a sense of how physicians' drug acquisition costs compared to Medicare's payment rate, in our June 2016 report to the Congress, we analyzed proprietary invoice price data for 34 high-expenditure Part B drugs from IMS Health Incorporated for the clinic channel of purchasers (e.g., physicians and outpatient hospitals). That analysis found that for two-thirds of the 34 drugs, at least 75 percent of the volume was sold to clinics at an invoice price below 102 percent of ASP.⁸ In addition, the analysis found evidence suggesting that some manufacturers responded to the federal budget sequester that began in 2013 by changing their pricing patterns in a way that mitigated the effect of the sequester for some providers. The sequester effectively reduced Medicare's payment rate for Part B drugs from 106 percent of ASP to 104.3 percent of ASP. Analysis of the IMS data found that across the 34 drugs, the median 75th percentile invoice price as a percent of ASP fell when the sequester was implemented (from around 103 percent of ASP before the sequester to 101.5 percent of ASP in 2nd quarter 2013). This suggests that providers' ability to purchase Part B drugs was generally maintained following the implementation of the sequester because manufacturers appear to have adjusted their prices to take into account the lower Medicare payment amount.

Although the ASP-based method is an improvement over the prior AWP-based method, the ASP-based payment method has raised several concerns. There is concern about the overall price Medicare Part B pays for drugs and the lack of price competition among drugs with similar health effects. There is concern that the ASP-based payment method does not consider evidence about a drug's comparative clinical effectiveness, which means that a drug's payment rate is not related to whether it is clinically comparable to, better than, or

⁷ On a few occasions, the OIG compared the acquisition costs of selected drugs among a sample of providers to Medicare's payments rates under ASP. In the first quarter of 2010, OIG estimated that physician acquisition costs for Lucentis was on average 5 percent below the Medicare payment rate. In the first quarter of 2009, acquisition costs for end-stage renal disease drugs among independent dialysis facilities averaged 10 percent below Medicare payment rates.

⁸ The IMS Health Incorporated data were available by channel of purchaser. We examined the clinic channel, which included physician offices, hospital outpatient departments, dialysis clinics, nonhospital surgical centers, and public health service clinics. The IMS data for the clinic channel included discounted sales to 340B entities. To avoid reflecting 340B prices in our estimates, we did not use data on the average invoice price. Instead, we focused on invoice prices at the 75th percentile (i.e., the 75th percentile reflects the price at which 75 percent of the volume of a drug is sold at or below that price). The prices in the IMS data reflect all on-invoice discounts and rebates but not off-invoice rebates. As a result, in some cases the IMS data overstate the actual end-price paid by the purchaser.

worse than its relevant alternatives. There is also concern about the financial incentives providers face under the ASP payment system. In particular, the 6 percent add-on to ASP may create incentives for some providers to choose higher-priced drugs over lower-priced drugs. Since 6 percent of a higher-priced drug generates more revenue for the provider than 6 percent of a lower-priced drug, selection of the higher-priced drug may generate more profit, depending on the provider's acquisition costs for the two drugs. For example, the 6 percent add-on of a drug with an ASP of \$1,000 is \$60; by comparison, the add-on of a drug with an ASP of \$100 is \$6. It is difficult to know whether the percentage add-on to ASP is influencing drug prescribing patterns because few studies have looked at this issue.

Part D

Part D is a voluntary prescription drug benefit in which Medicare beneficiaries obtain outpatient prescription drug coverage through competing private plans. Between 2007 and 2017, Part D program spending increased from about \$46 billion to about \$80 billion (average annual growth of 5.6 percent). In addition to those taxpayer-financed amounts, in 2017 Part D enrollees paid \$14 billion in premiums and nearly \$17 billion in cost sharing.

Part D was designed to rely on competition among plans that bear insurance risk to manage drug use and keep spending in check, while offering a benefit package that is attractive to enrollees. Rather than Medicare setting prices administratively, Medicare pays Part D plan sponsors that, through their pharmacy benefit managers (PBMs), contract with pharmacies over payment rates for each prescription filled by an enrollee and negotiate with drug manufacturers for prices and post-sale rebates. The Part D statute includes a "noninterference" provision that says the Secretary "may not interfere with the negotiations between drug manufacturers and pharmacies and PDP [prescription drug plan] sponsors." The law also says that the Secretary "may not require a particular formulary or institute a price structure for the reimbursement of covered Part D drugs."

Part D plan sponsors submit bids annually to CMS by the first Monday in June. Those bids reflect plan sponsors' expected benefit costs for an enrollee of average health. CMS adjusts payments to plan sponsors based on the actual health status of the plans' enrollees.

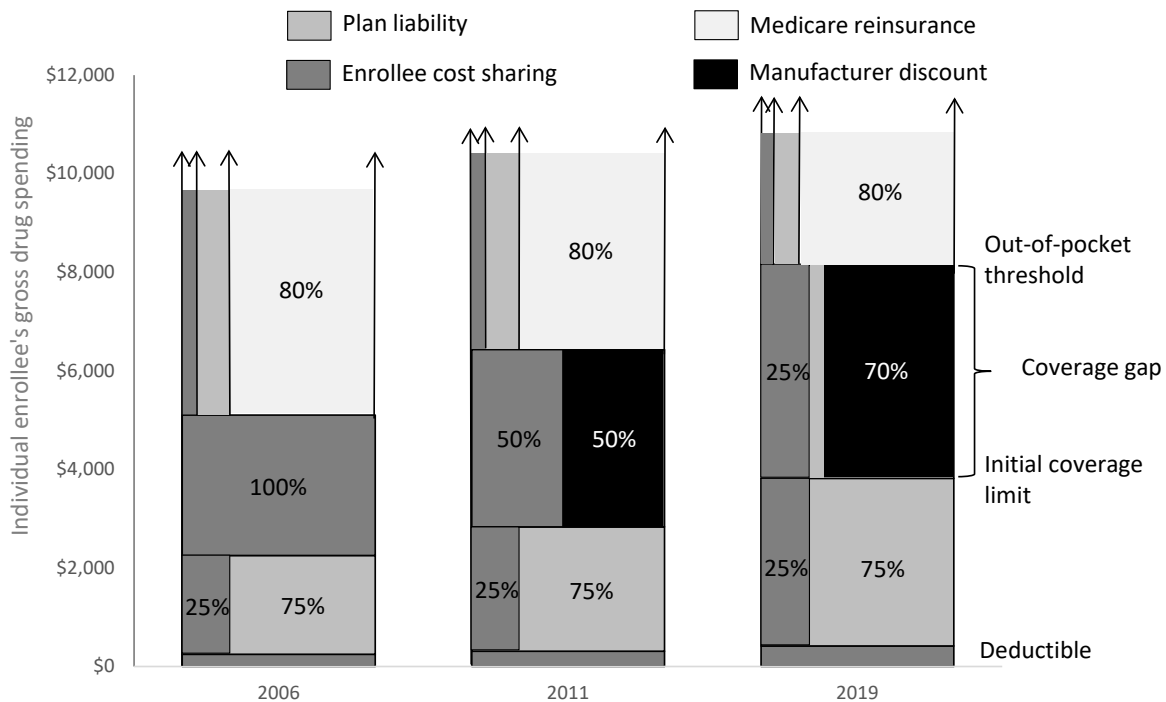
Medicare's payments to Part D plan sponsors consists of two components: 1) the direct

subsidy, which is a per enrollee capitated payment based on plans' bids and 2) individual reinsurance in which Medicare pays for 80 percent of an enrollee's drug spending above Part D's out-of-pocket (OOP) threshold (cost-based payment). Together, the two forms of Medicare payments are intended to cover 74.5 percent of the expected costs of standard benefits, with enrollee premiums making up the remaining 25.5 percent. Part D also includes a low-income subsidy (LIS) that pays plans certain premium and cost-sharing amounts on behalf of about 12.5 million individuals who have low incomes and assets.

Medicare shares risk with Part D plan sponsors in three ways to counteract incentives for sponsors to avoid enrollees who have high spending. First, CMS risk adjusts direct subsidy payments to reflect each enrollee's predicted spending. Second, Medicare pays individual reinsurance for enrollees who reach the OOP threshold. Third, Medicare establishes symmetric risk corridors unique to each plan. Under risk corridors, Medicare limits a plan's overall losses (or profits) by financing some of the higher-than-expected costs (or recouping excessive profits).

The original design of the Part D benefit was intended to provide both basic coverage for most enrollees who have relatively low drug spending as well as some catastrophic protection for enrollees with high drug costs. In 2006, the defined standard basic benefit covered 75 percent of drug spending above the deductible and all but 5 percent coinsurance once an enrollee reached the OOP threshold (Figure 1). The benefit also included a coverage gap in which enrollees paid 100 percent of the cost of prescriptions. The standard benefit was later modified by the Patient Protection and Affordable Care Act to phase out the coverage gap by 2020—in part, by requiring manufacturers of brand-name drugs to provide a discount on prescriptions filled by non-LIS enrollees in the coverage gap.

Figure 1. Part D’s defined standard benefit structure has changed over time



Note: “Gross drug spending” refers to amounts paid at the pharmacy before post-sale rebates and discounts. The amount of drug spending at which a beneficiary reaches the out-of-pocket (OOP) threshold in 2011 and 2019 depends on the mix of brand-name and generic prescriptions he or she fills in the coverage gap. The coverage-gap phase (between the initial coverage limit and OOP threshold) is depicted as it would apply to brand-name drugs for an enrollee who does not receive Part D’s low-income subsidy (LIS). Non-LIS enrollees’ cost sharing for generic drugs in the coverage gap was 100 percent in 2006, 93 percent in 2011, and 37 percent in 2019.

Source: MedPAC depiction of Part D benefit structure as set by law.

The law also required that the manufacturers’ discount be counted as though it were the enrollee’s own OOP spending for determining when he or she reached the OOP threshold. That change lowered OOP costs for some beneficiaries, but it also increased the number of non-LIS enrollees who reached the OOP threshold—the point at which Medicare begins to pay individual reinsurance.

A 2018 change in law quickened the timeframe for closing the coverage gap from 2020 to 2019 by increasing the manufacturers’ discount on brand-name drugs from 50 percent to 70 percent. This change also reduced the portion of benefits that plans must cover for brand-name drugs in the coverage gap from 25 percent to 5 percent. Because the discount is counted as though it were the enrollee’s own spending, the increase in that discount lowered

the OOP costs non-LIS enrollees must incur to reach Part D's catastrophic phase. This means that more enrollees are likely to reach the OOP threshold.

Medicare's reinsurance (which covers 80 percent of enrollees' spending in the catastrophic phase of the benefit after rebates) has been the fastest growing component of Part D program spending, with average increases of nearly 17 percent annually between 2007 and 2017. Over time, a growing share of Medicare's payments to plans have taken the form of cost-based reinsurance subsidies rather than capitated payments. Between 2007 and 2017, the portion of the basic benefit payments paid to plans through capitated direct subsidies fell from 55 percent to 21 percent, while the portion paid through Medicare's reinsurance grew from 25 percent to 54 percent. Despite significant growth in catastrophic benefits, average premiums for basic Part D benefits have remained low, in part reflecting the effects of Medicare's reinsurance subsidy. As a result, taxpayers—not plans—bear an increasing share of the insurance risk for Part D spending.

The Commission has highlighted how Part D's unique benefit design, Medicare's cost-based reinsurance payments, and plan sponsors' focus on premium competition can affect which drugs a plan covers on its formulary. Because plan sponsors are not liable for much benefit spending in the coverage gap, Part D's structure may provide a financial advantage to sponsors when they select certain drugs with high prices and large postsale rebates over lower-cost alternatives. The dollar amount of rebates for certain drugs can be larger than a plan sponsor's liability for the associated benefit spending. For example, during the coverage-gap phase, a plan could increase its net revenue by encouraging use of a brand-name drug that received a rebate of 20 percent because the plan would only be liable for 5 percent of the prescription's cost. In this sense, Part D's benefit design may contribute to growth in drug spending. The recent changes to the coverage gap, which further reduced plan sponsors' liability, heighten those concerns.

Rising spending for prescription drugs in Part B and Part D

In recent years, growth in Medicare's spending for prescription drugs under both Part B and Part D has been driven by increases in average price per claim, particularly for high-cost

brand-name therapies. Those increases reflect both higher prices for existing products and high launch prices for new drugs.

Part B drugs

Price growth is the largest driver of Medicare Part B spending growth. Almost two-thirds of the growth in Part B drug spending between 2009 and 2016 was accounted for by price growth. Growth in Medicare's ASP-based payment rates for individual drugs is driven by manufacturer pricing policies. There is no statutory or regulatory constraint on how much Medicare's ASP-based payment rate for an individual drug can increase over time.

For separately payable drugs (excluding vaccines), Medicare Part B drug spending grew at an average annual rate of 10.7 percent between 2009 and 2016, with 6.9 percentage points of the growth due to an increase in price (as measured by the average annual payment per drug per user) (Table 1). This 6.9 percent increase reflects a combination of factors—increased prices for existing products, the launch of new high-priced products, and other changes in the mix of drugs used.

Table 1. Payments and utilization for separately payable Part B drugs, 2009–2016

| | 2009 | 2016 | Annual average change, 2009-2016 |
|--|-----------|-----------|----------------------------------|
| Total payments: Separately payable Part B drugs excluding vaccines (in billions of dollars) | \$12.8 | \$26.1 | 10.7% |
| Number of beneficiaries receiving Part B drug | 2,840,166 | 3,750,634 | 4.1 |
| Average payment per beneficiary | \$4,524 | \$6,962 | 6.4 |
| Average number of drugs per beneficiary | 1.41 | 1.36 | -0.5 |
| Average annual payment per drug (price increase) | \$3,206 | \$5,119 | 6.9 |

Note: This analysis includes all Part B drugs paid the average sales price plus 6 percent (ASP + 6 percent) as well as the small group of Part B drugs that are paid based on the average wholesale price or reasonable cost or that are contractor priced. “Vaccines” refers to the three Part B–covered preventive vaccines: influenza, pneumococcal, and hepatitis B. Total payments include Medicare payments and beneficiary cost sharing. Data include Part B drugs furnished by physicians, hospitals paid under the outpatient prospective payment system, and suppliers. Excluded from the analysis were any Part B drugs that were bundled or packaged in 2009 and/or 2016 (i.e., drugs that were packaged under the outpatient prospective payment system, regardless of the setting where they were furnished, and drugs furnished by dialysis facilities), drugs billed under not-otherwise-classified billing codes, blood and blood products (other than clotting factor), and data for critical access hospitals and Maryland hospitals. The average annual growth rates displayed in the table may differ slightly from the average annual growth rates calculated using the 2009 and 2016 values displayed in the table due to rounding.

Source: MedPAC analysis of Medicare claims data for physicians, hospital outpatient departments, and suppliers.

Part B drug spending is concentrated in a small number of expensive products. In 2017, Medicare spending (including beneficiary cost sharing) for the top 10 drugs paid under the ASP system totaled about \$13.6 billion, about 43 percent of all Part B drug spending that year. Notably, all 10 of these products are biologics. Many of these products are used to treat cancer or its side effects, while some treat macular degeneration, rheumatoid arthritis, and other immunologic diseases.

The patterns of spending growth within the top 10 highest-expenditure products illustrate two pricing factors driving spending growth: new products with high launch prices, and existing products with price inflation. For example, two products—Opdivo and Keytruda—are recent market entrants (approved in late 2014) and belong to a new class of immuno-oncology biologics. Spending on these products in 2017 reached \$1.5 billion and \$1 billion,

respectively, reflecting the products' substantial launch prices. Average 2017 Medicare spending per user for these products was about \$51,000 and \$48,000, respectively.⁹

Price growth among biologics that have been on the market longer has also driven spending growth. For example, over the eight years between 2009 and 2017, the ASPs increased 44 percent for Remicade (which treats certain immunologic diseases such as rheumatoid arthritis), 53 percent for Rituxan and Herceptin (which treat certain cancer types), and 89 percent for Neulasta (which stimulates the growth of white blood cells after chemotherapy). Although we lack data on Medicare expenditures beyond 2017, we do have ASP-based payment rates through first quarter 2019. In the two years between January 2017 and January 2019, the ASPs for 5 of the top 10 products increased by more than 10 percent. Although price declines have occurred among a few of the top 10 products, these declines have been modest given the existence of competing products and the magnitude of spending on these products. For example, Eylea and Lucentis are competing products used to treat macular degeneration and related eye conditions, and they accounted for \$3.5 billion of 2017 Part B drug spending. Eylea's ASP declined 2 percent since its launch and Lucentis' ASP declined 11 percent between 2009 and 2019.

With biologics accounting for more than two-thirds of Part B drug spending and all 10 of the highest-expenditure products, biosimilar approval and entry may offer savings potential, but to date the effects have been modest. Two originator biologics paid under Part B—Remicade and Neupogen—have faced biosimilar entry in recent years.¹⁰ We have observed little decline in the ASPs of Remicade and Neupogen, but we have seen lower and declining ASPs for their biosimilars.¹¹ As of the first quarter of 2018 (the most recent calendar quarter for which complete utilization data are available), the use of biosimilars under Part B has been mixed. Use of the more costly originator product Remicade accounted for 94 percent of

⁹ Because some beneficiaries begin treatment mid-year and treatment carries into the following year, average spending per user in any given year understates the cost of a full year of treatment with the product.

¹⁰ Neupogen is used to stimulate the growth of white blood cells after chemotherapy.

¹¹ The ASP for the originator product Neupogen has remained roughly the same between the first quarters of 2016 and 2019 while the ASP for its biosimilar Zarxio has declined by 34 percent. The ASP for the originator biologic Remicade declined 7 percent between 2017 and 2019; however, that decrease followed a 55 percent increase in Remicade's ASP between 2005 and 2017. The ASP for Remicade's biosimilar Inflectra has declined by 43 percent between the first quarters of 2017 and 2019.

utilization while use of its biosimilars accounted for only 6 percent of utilization. By contrast, utilization has shifted away from the more costly originator biologic Neupogen, with its biosimilars accounting for 63 percent of the market in the first quarter of 2018.

In recent years, drugs furnished in physician offices account for the majority of Part B drug spending, but spending on drugs furnished in hospital outpatient departments (HOPDs) has grown more rapidly than drug spending in physician offices. Of total Part B spending in 2017 (including beneficiary coinsurance), about \$18.4 billion was for drugs administered in physician offices, about \$12.3 billion was for drugs administered in HOPDs, and \$1.8 billion was for drugs furnished by suppliers. Between 2009 and 2017, Part B drug spending increased at an average annual rate of 15 percent in HOPDs and 7 percent in physician offices. The greater spending growth in HOPDs partly reflects a shift in site of service from physician offices to HOPDs, particularly for oncology drugs.

Part D drugs

Overall growth in Part D spending is increasingly driven by the relatively few enrollees who reach the catastrophic phase. In 2017, 3.6 million Part D enrollees (about 8 percent) had spending high enough to reach the catastrophic phase of the benefit (high-cost enrollees). High-cost enrollees accounted for nearly 60 percent of all Part D spending in 2017, up from about 40 percent before 2011.

Among high-cost enrollees, nearly all growth in spending was due to increases in the average price per prescription filled (Table 2). That growth reflects inflation of the existing products' prices, greater availability of higher-priced drugs and biologics, and other changes in the mix of medications prescribed. Between 2010 and 2017, the average price per standardized, 30-day prescription for high-cost enrollees grew at an annual rate of 9.4 percent, while the number of prescriptions filled per enrollee per month remained flat. This pattern is in stark contrast to enrollees who did not reach the OOP threshold. The average price of their prescriptions fell 2.9 percent annually, while the number of prescriptions they used grew by 1.3 percent annually.

Table 2. Spending for high-cost enrollees drove overall Part D spending, 2010-2017

| | 2010 | 2017 | Average annual growth rate, 2010-2017 |
|--|------------|------------|---------------------------------------|
| High-cost enrollees | | | |
| Average price per 30-day prescription | \$118 | \$221 | 9.4% |
| Prescriptions per enrollee per month | <u>9.5</u> | <u>9.7</u> | 0.3% |
| Gross drug spending per enrollee per month | \$1,117 | \$2,140 | 9.7% |
| Lower-cost enrollees | | | |
| Average price per 30-day prescription | \$41 | \$33 | -2.9% |
| Prescriptions per enrollee per month | <u>3.7</u> | <u>4.1</u> | 1.3% |
| Gross drug spending per enrollee per month | \$151 | \$135 | -1.6% |
| All Part D enrollees | | | |
| Average price per 30-day prescription | \$55 | \$67 | 2.7% |
| Prescriptions per enrollee per month | <u>4.2</u> | <u>4.5</u> | 1.1% |
| Gross drug spending per enrollee per month | \$231 | \$302 | 3.9% |

Note: Spending includes all payments to pharmacies, including payments by drug plans, Medicare’s low-income subsidy, and beneficiary out of pocket. Changes in the average price per prescription reflects both price inflation and changes in the mix of drugs used.

Source: MedPAC analysis of Part D prescription drug event data and denominator file from CMS.

Early on, the vast majority of spending was attributable to prescriptions for widely prevalent conditions such as high cholesterol, diabetes, hypertension (high blood pressure), asthma, depression, and gastroesophageal reflux. After the 2012 “patent cliff” of small-molecule, brand-name drugs, manufacturers turned to producing orphan drugs, biologics, and other specialty drugs that treat smaller patient populations for conditions such as rheumatoid arthritis, hepatitis C, and cancer.¹² These newer therapies are often launched at very high prices, with annual costs per person sometimes reaching tens of thousands of dollars or more.

¹² The “patent cliff” refers to a year in which manufacturers of widely-used brand-name drugs lost market power over pricing because of expirations of patents and periods of exclusivity.

Most Part D plans have a specialty tier for drugs with high prices.¹³ Since the start of Part D, spending for drugs on specialty tiers has grown more than tenfold—from \$3.4 billion in 2007 to \$37.1 billion in 2017. Antineoplastics and antivirals accounted for nearly 10 percent and 7 percent, respectively, of total gross Part D spending in 2017. The price for one of the most frequently used hepatitis C treatments (an antiviral) averaged about \$31,000 per claim, and many cancer therapies had prices that ranged from about \$10,000 to over \$14,000 per claim. Because of their high prices, even a single claim for drugs in those classes would be sufficient to meet the OOP threshold. In 2017, more than 370,000 enrollees filled such a claim, up from just 33,000 in 2010.

Over the past decade, prices of drugs typically placed on specialty tiers have grown rapidly. Between 2007 and 2017, prices of drugs placed on specialty tiers grew by a cumulative 145 percent. The price growth was even greater for some drug classes. For example, between 2007 and 2017, prices of antineoplastics grew by a cumulative 168 percent. While the prices measured do not reflect postsale rebates or discounts, the 168 percent growth likely provides a reasonable approximation of the growth in net prices. This is because, given the protected class status and the general lack of close substitutes, Part D plan sponsors have limited ability to negotiate rebates for antineoplastics.

Changes to Part D's coverage gap and manufacturer discounts combined with the expanding role of high-cost medicines may be eroding plans' incentives for and ability to achieve cost control. The increase in brand-manufacturer discounts to 70 percent beginning this year correspondingly decreases what plan sponsors must cover in benefits and likely weakens sponsors' incentives to manage spending. Going forward, increasing emphasis on specialty drugs in the drug development pipeline will lead to greater use of high-cost medicines. Higher demand for such medications would increase premiums for all enrollees and increase Medicare program costs.

¹³ Under CMS's current guidance, plan sponsors may place drugs that cost \$670 per month or more on a specialty tier. Before 2017, Medicare's specialty-tier threshold was \$600 per month.

Recent Commission recommendations related to drugs

The Commission recommended to the Congress in 2017 changes to payment policy for Part B drugs, and it recommended changes in 2016 and 2018 to improve Medicare Part D.

Part B drugs (June 2017 chapter¹⁴)

In 2017, the Commission recommended a set of policies that seeks to improve the current ASP payment system in the short term while developing, for the longer term, a voluntary, market-based alternative to the ASP payment system. Specifically, the recommended short-term actions would:

- *Improve ASP data reporting.* Currently most, but not all, Part B drug manufacturers are required to report ASP data to CMS. The Commission recommended requiring all manufacturers to report ASP data, with civil monetary penalties for failure to report.
- *Reduce payment rates for drugs paid at 106 percent of wholesale acquisition cost (WAC).* The Commission recommended reducing the payment rate from 106 percent to 103 percent of wholesale acquisition cost for new single-source Part B drugs that initially lack ASP data and for existing drugs that lack ASP data. (CMS has adopted this policy for new drugs but has not adopted it for other drugs that lack ASP data).
- *Establish an ASP inflation rebate.* This policy would require manufacturers to pay the Medicare program a rebate when the ASP for a drug grows at a rate in excess of an inflation benchmark.
- *Establish consolidated billing codes.* This policy would group an originator biologic and its biosimilars into the same billing code to maximize price competition.

Over the longer term, the Commission recommended that Medicare develop the drug value program (DVP) as a voluntary, market-based alternative to the ASP payment system for physicians and outpatient hospitals, replacing the current buy-and-bill payment method. The DVP's intent would be to obtain lower prices for Part B drugs by permitting private vendors

¹⁴ Medicare Payment Advisory Commission. 2017. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

to use tools (such as a formulary and, in certain circumstances, binding arbitration) to negotiate prices with manufacturers and by improving incentives for provider efficiency through shared savings opportunities. Under the program, a small number of DVP vendors would negotiate prices for Part B drugs, but vendors would not ship products to providers. Providers that chose to enroll in the DVP would continue to buy drugs in the marketplace but at the DVP-negotiated price, and Medicare would reimburse those providers at the same negotiated price. To encourage enrollment in the DVP, providers would have shared savings opportunities through the DVP while the ASP add-on would be reduced gradually in the ASP system. Savings achieved through the DVP would also be shared with beneficiaries (through lower cost sharing) and with DVP vendors and Medicare.

Taken together, this recommendation takes a balanced, multipronged approach to improving payment for Part B drugs and would achieve savings for beneficiaries and taxpayers. The recommendation includes policies that would improve Medicare payment for Part B drugs, through both a regulatory approach (by reforming the ASP-based system) and a market-based approach (by developing a voluntary alternative DVP) and through policies that would achieve savings not just by modifying provider payment incentives but also by creating pressure for drug manufacturers to reduce or slow the growth of drug prices.

Part D drugs (June 2016 and March 2018 chapters¹⁵)

The Commission recommended a combination of changes designed to improve the efficiency and financial sustainability of Part D while maintaining the program's market-based approach.

One set of changes would give plan sponsors greater financial incentives to manage the benefits of high-cost enrollees by shifting more of the plan payments from open-ended reinsurance to capitated payments. Over a transition period, Medicare would significantly lower the amount of reinsurance it pays plans from 80 percent of spending above the OOP threshold to 20 percent, and the insurance risk that plan sponsors shoulder for catastrophic

¹⁵ Medicare Payment Advisory Commission. 2016. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC. Medicare Payment Advisory Commission. 2018. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

spending would rise commensurately from 15 percent to 80 percent. The reduction in the reinsurance would be accompanied by larger capitated payments to plan sponsors, so that Medicare's subsidy of basic Part D benefits would remain unchanged at 74.5 percent.

At the same time, sponsors would be given greater flexibility to use formulary tools. The Commission recommended removing protected status from two of the six drug classes in which plan sponsors must now cover all drugs on their formularies (antidepressants and immunosuppressants for transplant rejection), streamlining the process for formulary changes, requiring prescribers to provide supporting justifications with more clinical rigor when applying for exceptions, and permitting plan sponsors to use selected tools to manage specialty drug use.

Other parts of the Commission's recommendations would exclude manufacturer discounts on brand-name drugs from counting as enrollees' true OOP spending, but would also provide greater insurance protection by eliminating cost sharing above the OOP threshold. Because enrollees who receive the LIS pay nominal cost-sharing amounts that provide little incentive to use lower-cost drugs and biosimilars, the recommended improvements would also moderately increase financial incentives by directing the Secretary of Health and Human Services to modify some LIS copayments.¹⁶

On net, the Commission's recommendations would restrain Medicare's drug costs and make the benefit more affordable for beneficiaries and taxpayers. The recommendations enhance the Part D benefit so that the program would provide real insurance protection against catastrophic OOP spending. However, the recommendation would also expose some beneficiaries to higher cost sharing in the coverage gap. Because of this, the Commission noted that, to the extent that the adoption of this combined set of recommendations results in

¹⁶ In the 2019 Part C & D final rule published on April 2, 2018 (Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program), CMS lowered the maximum copay applicable to biosimilars (and interchangeable biological products) for LIS beneficiaries who are subject to copays and for non-LIS beneficiaries in the catastrophic phase of the benefit.

net program savings, the Congress could consider enhancing protections for beneficiaries facing high cost-sharing burdens.

Conclusion

Prescription drugs play a critical role in treating many medical conditions. As such, it is important to ensure that beneficiaries have access to appropriate medication therapies. At the same time, the Commission is concerned that high prices for certain drugs make it increasingly difficult to ensure beneficiaries' access to medications while protecting taxpayers and beneficiaries whose dollars finance the program. The Commission looks forward to continuing to be a resource for the Committee as it deliberates on policies aimed at ensuring access to and the affordability of clinically appropriate medications for beneficiaries and taxpayers.