

CHAPTER

2

**Restructuring Medicare Part D
for the era of specialty drugs**

Restructuring Medicare Part D for the era of specialty drugs

Chapter summary

The distribution of drug spending under Part D has changed dramatically since the start of the program in 2006. Early on, the vast majority of spending was attributable to prescriptions for widely prevalent conditions such as high cholesterol, diabetes, hypertension, asthma, depression, and gastroesophageal reflux. After the 2012 “patent cliff”—one of the biggest waves of patent expirations for small-molecule brand-name drugs—manufacturers turned to producing orphan drugs, biologics, and other self-administered specialty drugs that treat smaller patient populations for conditions such as rheumatoid arthritis, hepatitis C, and cancer. These newer therapies are often launched at very high prices, with annual costs per person sometimes reaching tens of thousands of dollars or more, and spending for specialty drugs and biologics has risen rapidly.

In Part D, sponsors of private plans encourage enrollees to use lower cost generics and preferred brand-name drugs by placing them on formulary tiers that have lower cost sharing. In addition, CMS permits plan sponsors to use a specialty tier with coinsurance of 25 percent to 33 percent for expensive therapies. Above Part D’s out-of-pocket (OOP) threshold, enrollees who do not receive Medicare’s low-income subsidy (LIS) pay 5 percent coinsurance with no OOP maximum. Although many specialty drugs have no rebates, when patients use rebated drugs, they pay effective rates of coinsurance (as a percentage of a drug’s net price) that are even higher than the stated

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coinsurance amount because manufacturers provide rebates to plans long after patients fill their prescriptions, and plans charge coinsurance on the higher “gross” price at the pharmacy. There is some evidence that high patient cost sharing can pose a financial hurdle to treatment, potentially affecting certain beneficiaries’ decisions to fill their prescriptions. Further, paying coinsurance on gross prices tends to move enrollees more quickly toward Part D’s OOP threshold—the point at which Medicare’s reinsurance pays for 80 percent of benefits.

This chapter introduces a new policy approach that the Commission plans to evaluate further. Modifications to Part D’s defined standard benefit and its catastrophic phase could improve plan sponsors’ financial incentives to manage drug spending and potentially restrain manufacturers’ incentives to increase prices. The approach would retain certain features of the Commission’s 2016 recommendation for Part D, such as requiring plans to bear more risk for catastrophic spending, but the new design would also eliminate the need for some previously recommended measures. The new changes would also create a more consistent defined standard basic benefit that would apply both to enrollees without Part D’s LIS as well as those with the LIS—a departure from current policy.

The new approach would restructure the Part D benefit in several ways. First, it would eliminate the coverage-gap discount that currently applies to non-LIS enrollees, making plan sponsors responsible for a consistent 75 percent of benefits between the deductible and OOP threshold. Second, the new design would require manufacturers of brand-name drugs to provide a discount in the catastrophic phase of the benefit rather than in the gap phase, as they do today. The manufacturer discount would be newly applicable to spending of LIS beneficiaries. Third, the new design would lower enrollee cost sharing or include a hard overall OOP cap to improve the affordability of high-priced drugs and provide more complete financial protection for all enrollees. Plan sponsors would be responsible for a larger share of catastrophic benefits, and Medicare’s reinsurance would be smaller. In general, we expect the approach would provide stronger incentives for plan sponsors to manage enrollees’ spending and potentially restrain manufacturers’ incentives to increase drug prices or launch new products at high prices.

Consistent with the Commission’s 2016 recommendations for Part D, we expect that any policy change that requires plan sponsors to take on more insurance risk would be combined with other changes that would provide sponsors with greater flexibility to use formulary tools. Part D’s risk adjustment system would need to be recalibrated to counterbalance plan incentives for risk selection. Finally, the chapter discusses a key parameter of this policy approach: where to set the OOP threshold.

The approach's financial impact on stakeholders, including Part D beneficiaries and taxpayers who finance the Medicare program, would depend on the specific threshold chosen and behavioral responses to the changes. ■

**TABLE
2-1**

Specialty-tier drugs increasingly drove Part D spending, 2007–2017

	2007	2012	2017	Average annual growth rate	
				2007–2012	2012–2017
All Part D–covered drugs					
Total gross spending (in billions)	\$62.1	\$89.8	\$154.9	7.7%	11.5%
Total prescriptions (in millions)	969.1	1,216.9	1,498.8	4.7	4.3
Spending per prescription	\$64	\$74	\$103	2.9	7.0
Drugs on specialty tiers*					
Total gross spending (in billions)	\$3.4	\$10.1	\$37.1	24.1	29.7
Total prescriptions (in millions)	3.0	4.1	8.3	6.6	15.2
Spending per prescription	\$1,151	\$2,462	\$4,455	16.4	12.6
Specialty-tier drugs as a share of total Part D spending and use					
Gross spending	5.5%	11.2%	24.6%	N/A	N/A
Prescriptions	0.3%	0.3%	0.6%	N/A	N/A
Part D enrollment (in millions)	26.1	33.8	45.2	5.3	6.0

Note: N/A (not applicable). “Gross spending” reflects all payments at the pharmacy (including enrollee cost sharing, covered plan benefits, and manufacturer discounts) before deducting postsale discounts and rebates. The number of prescriptions shown in the table is not adjusted to a standard days’ supply. However, in 2017, only about 5 percent of specialty-tier prescriptions were for a 90-day supply—the typical amount provided by mail-order pharmacies. By comparison, in 2017, more than one-quarter of all Part D prescriptions were dispensed with a 90-day supply. Because specialty-tier prescriptions are more likely to have fewer days’ supply, the numbers shown for specialty-tier prescriptions as a share of total Part D prescriptions would be upper bounds for standardized prescriptions.
*From 2006 to 2016, CMS permitted plan sponsors to place drugs that cost an average of \$600 or more per month on a specialty tier. In 2017, CMS raised the threshold to \$670 per month.

Source: MedPAC analysis of the Part D denominator file and data analyzed by Acumen LLC.

The share of Medicare Part D spending made up of specialty drugs and biologics has risen rapidly, and high patient cost sharing for those therapies can pose a financial hurdle to treatment. This chapter introduces new modifications to Part D’s benefit design that could improve plan sponsors’ financial incentives for managing drug spending, potentially address growth in prices of specialty drugs, and provide better financial protection to all Part D enrollees, including beneficiaries who use high-priced drugs.

The growth of specialty drugs and implications for cost sharing

Part D’s distribution of drug spending has changed dramatically since the start of the program in 2006. Early on, the vast majority of spending was attributable to

prescriptions for widely prevalent conditions such as high cholesterol, diabetes, hypertension, asthma, depression, and gastroesophageal reflux (Medicare Payment Advisory Commission 2010). Most prescription spending was for small-molecule brand-name drugs, and many of the drug classes to treat those conditions included therapies that competed on the basis of clinical effectiveness and price.

Toward the end of the decade, blockbuster treatments began to lose patent protection and Part D enrollees switched to generic versions of their medicines. The generic dispensing rate—defined as the share of Part D prescriptions dispensed that are generic drugs—increased from 61 percent in 2007 to 81 percent by 2012 (a year that saw large losses of brand exclusivity) (Medicare Payment Advisory Commission 2017). Over the same period, Part D gross spending (before postsale rebates and discounts) grew by an average of 7.7 percent annually (Table 2-1). However, that rate was attributable more to growth in

the number of prescriptions filled (4.7 percent per year) commensurate with enrollment growth (an average of 5.3 percent per year) than to increases in prices and spending per prescription (2.9 percent annually). Spending would likely have grown much more rapidly without enrollees' move toward generics.

As revenues for small-molecule brand-name drugs fell, manufacturers turned to developing orphan drugs, biologics, and other specialty drugs that treat smaller patient populations for conditions such as rheumatoid arthritis (RA), hepatitis C, and cancer. Those medicines are often self-injectable, but some are oral tablets or inhalable medicines.¹ Dispensing specialty drugs can sometimes raise challenging logistical issues (such as the need to ship them at a consistent low temperature), and patients may require closer clinical management. Specialty drugs are often launched at very high prices, with annual costs per person sometimes reaching tens of thousands of dollars or more.

Under CMS's current guidance, plan sponsors may place drugs that cost \$670 per month or more on a specialty tier.² Most Part D plans have a specialty tier, but not all plans place every high-cost drug on a specialty tier. Since the start of Part D, spending for drugs on specialty tiers has grown more than 10-fold—from \$3.4 billion in 2007 to \$37.1 billion in 2017 (Table 2-1, p. 29). Between 2007 and 2012, specialty-tier spending grew by an annual average of 24.1 percent, but grew even faster (29.7 percent annually, on average) after the 2012 patent cliff (expirations of patents and periods of exclusivity) of small-molecule brand-name drugs. In 2017, only 0.6 percent of Part D prescriptions were for specialty-tier drugs, but the average price per prescription was \$4,455 at the pharmacy (before postsale rebates from manufacturers and discounts). Spending for specialty-tier prescriptions made up nearly a quarter of gross Part D spending by 2017 (Table 2-1) and was likely an even larger share after taking rebates into account.³ Analysts expect that share to grow further. According to IQVIA, between 2019 and 2023, nearly two-thirds of newly launched medicines will be specialty drugs, and oncology drugs will account for 30 percent (IQVIA Institute for Human Data Science 2019).⁴

Cost-sharing requirements for specialty-tier drugs

In 2017, specialty-tier drugs that accounted for large proportions of Part D spending included treatments for multiple myeloma, hepatitis C, rheumatoid arthritis, multiple sclerosis (MS), breast cancer, lymphoma, prostate

cancer, and HIV (Table 2-2). Among the top 20 drugs often found on specialty tiers with the largest aggregate amounts of gross Part D spending, CMS calculates that the average price at the pharmacy per prescription ranged between \$1,458 (Sensipar[®]) and \$31,208 (Harvoni[®]).⁵ However, other specialty drugs have costs per prescription that are higher. For example, in 2017, Part D gross spending averaged over \$77,000 per prescription for Lemtrada[®], a treatment for relapsing MS in patients who have had inadequate response to other drugs (data not shown) (Centers for Medicare & Medicaid Services 2017a). The numbers of drugs with very high prices has grown to such an extent that in 2017, more than 370,000 enrollees filled a prescription for which a single prescription would have been sufficient to reach Part D's out-of-pocket (OOP) threshold, up from 33,000 in 2010 (Medicare Payment Advisory Commission 2019b).

Enrollees who take specialty-tier drugs and receive Part D's low-income subsidy (LIS) do not face large financial hurdles associated with cost sharing. Most LIS enrollees pay nominal copayments (between \$0 and \$8.50 per prescription) rather than their plan's cost-sharing amounts. However, taxpayers bear much of the costs of treatment through Part D's overall premium subsidy and low-income cost-sharing subsidy. Under the latter, Medicare pays plan sponsors the difference between plans' cost-sharing requirements and copayments set for LIS enrollees by law.

For an individual enrollee who does not receive the LIS and uses a specialty-tier drug, Part D's cost-sharing requirements vary during the year depending on the benefit phase she or he has reached. In the initial coverage phase, plans charge coinsurance of 25 percent to 33 percent for drugs on specialty tiers.⁶ Above the initial coverage limit, enrollees pay 25 percent of prescription costs for brand-name drugs in the coverage gap until they reach the OOP threshold.⁷ Above that threshold, enrollees typically pay 5 percent with no maximum OOP limit. Enrollees may not request a tiering exception for specialty-tier drugs.⁸ Under law, Medigap policies may not cover Part D cost sharing, but they do cover cost sharing for Part B drugs. Medicare beneficiaries are not permitted to use manufacturers' copay coupons for either Part B or Part D drugs, but beneficiaries can apply to bona fide independent charity patient assistance programs (PAPs) for help with cost sharing.⁹

As an example, consider a beneficiary who lives in ZIP code 24901 (Greenbrier County, WV), does not receive the LIS, uses a Humira pen[®] to treat RA, and is enrolled

**TABLE
2-2**

Top 20 drugs often found on specialty tiers, ranked by gross Part D spending, 2017

Brand name	Examples of approved indications	Total gross spending (in billions)	Total prescriptions (in thousands)	Average gross spending per prescription	Part D enrollees with prescriptions
Revlimid®	Multiple myeloma	\$3.3	260	\$12,756	37,459
Harvoni®	Hepatitis C virus	2.6	82	31,208	32,397
Humira pen®	Rheumatoid arthritis, Crohn's disease, plaque psoriasis	2.0	371	5,436	51,835
Copaxone®	Multiple sclerosis	1.5	232	6,464	26,171
Sensipar®*	Secondary hyperparathyroidism in patients with chronic kidney disease on dialysis	1.4	985	1,458	154,448
Ibrance®	Breast cancer	1.4	126	11,141	20,441
Imbruvica®	Lymphoma, chronic lymphocytic leukemia	1.4	131	10,432	18,744
Enbrel Sureclick®	Rheumatoid arthritis, plaque psoriasis	1.2	225	5,153	32,005
Tecfidera®	Multiple sclerosis	1.0	128	7,990	17,055
Epclusa®	Hepatitis C virus	0.9	38	25,011	14,073
Zytiga®	Prostate cancer	0.9	94	9,369	17,303
Xtandi®	Prostate cancer	0.9	86	9,971	15,825
Jakafi®	Myelofibrosis	0.7	63	11,474	7,888
Genvoya®	Human immunodeficiency virus	0.7	238	2,900	28,632
Triumeq®	Human immunodeficiency virus	0.7	240	2,710	27,561
Pomalyst®	Multiple myeloma	0.6	44	14,553	7,704
Letairis®	Pulmonary arterial hypertension	0.6	67	9,411	7,741
Imatinib mesylate®	Chronic myeloid leukemia	0.6	79	7,221	10,720
Humira®	Rheumatoid arthritis, Crohn's disease, plaque psoriasis	0.5	99	5,494	14,967
Ofev®	Idiopathic pulmonary fibrosis	0.5	56	8,798	8,645

Note: Total gross spending equals prescription amounts paid at the pharmacy before postsale rebates and discounts.
*Coverage of Sensipar for patients on dialysis was moved to Part B as of 2018.

Source: Identification of drugs on specialty tiers provided by Acumen LLC. Spending, claims, and numbers of beneficiaries from CMS, 2017 (Centers for Medicare & Medicaid Services 2017a).

in the stand-alone prescription drug plan that has the lowest combination of OOP costs and premiums.¹⁰ The total current price at the pharmacy for her Humira pens is \$5,464 per month based on a full year of use (\$65,571 annually).¹¹ In January, the price of her prescription put her past the initial coverage phase and into the coverage gap, with total cost sharing of \$1,672 for that month. Her February prescription took her completely through the coverage gap, into the catastrophic phase, and she paid a total of \$781. In March, she paid \$273 (5 percent coinsurance), and she will continue to do so each of the remaining months of 2019, for annual total cost sharing of

about \$5,183 (averaging about 8 percent of total spending for her Humira treatment). That amount does not include premiums or cost sharing for other medications. About half of this patient's cost sharing for Humira pens will occur in the catastrophic phase of the Part D benefit.

In 2019, enrollees can expect to pay less in cost sharing in the coverage gap than they did a few years earlier. However, because of price increases for specialty drugs, beneficiaries often pay more in the catastrophic phase. Before 2019, cost sharing for brand-name drugs in the coverage-gap phase was higher than 25 percent, and

OOP costs varied more from month to month than they do currently. Between 2016 and 2019, under the coverage-gap phase's scheduled phase-out, cost sharing for brand-name drugs decreased from 45 percent to 25 percent. However, even though the coinsurance rate is lower in the catastrophic phase than in the coverage gap, prices for specialty drugs have increased and beneficiary cost sharing is open ended. One recent study found that, between 2016 and 2019, for non-LIS enrollees who used selected specialty drugs (including Humira, Copaxone[®], Revlimid[®], and others), OOP costs rose even as the coverage gap was closing (Cubanski et al. 2019).¹²

Evidence on cost-related nonadherence for specialty drugs

To get a sense of how cost sharing may affect beneficiary adherence to specialty medications, we surveyed some of the literature on cost-related nonadherence in Part D. Few studies look specifically at adherence to specialty drugs, and even fewer of those focus on the Medicare population. The evidence suggests an association between higher cost sharing and patients not initiating therapy or abandoning prescriptions at the pharmacy. Yet factors beyond cost sharing also affect adherence behavior.

Most research on the effects of cost sharing has evaluated changes in behavior after the introduction of Part D coverage or as beneficiaries reach the coverage gap. Researchers who examined the start of Part D generally found that, as beneficiaries gained coverage, most reported lower OOP spending, modestly higher prescription use, and less cost-related nonadherence (Diebold 2018, Madden et al. 2009, Safran et al. 2010, Schneeweiss et al. 2009). A published literature review found that Part D's implementation was associated with greater use of both underused essential medicines and overused or inappropriate drugs (Polinski et al. 2011).

Subsequent studies examined the effects of the coverage gap on enrollees' medication adherence, focusing on patients with prevalent conditions such as chronic obstructive pulmonary disease, diabetes, heart failure, and hypertension (Fung et al. 2010, Yu et al. 2016, Zhang et al. 2013). That research often compared enrollees who had no cost-sharing subsidies with enrollees who had more generous benefits (e.g., LIS enrollees or enrollees in employer group plans).¹³ Most of the research found that higher cost sharing in the gap decreased rates of medication adherence, primarily for brand-name drugs. Still, researchers also found that some LIS enrollees

remained nonadherent despite low cost sharing and lack of a coverage gap (Wei et al. 2013). This finding suggests that factors in addition to cost affect adherence.

After 2010, changes in law led to a phase-out of the coverage gap by (1) requiring manufacturers of brand-name drugs to provide a 50 percent price discount in the gap (increased to 70 percent as of 2019); (2) gradually lowering cost sharing to 25 percent in the gap (consistent with the initial coverage phase); and (3) restraining annual increases in the OOP threshold. Those changes reduced average OOP costs from \$4,465 in 2010 to \$3,004 in 2011 among non-LIS enrollees with spending high enough to reach the catastrophic phase (Cubanski et al. 2017).

One study focused on the behavioral effects of reductions in gap-phase cost sharing. That research examined elderly enrollees in stand-alone drug plans and used a difference-in-difference approach to compare non-LIS and LIS cancer patients (Jung et al. 2017). Over the 2009 to 2013 period, the authors found that implementation of the manufacturer discount reduced average OOP costs for specialty cancer drugs by 19 percent for non-LIS patients, but did not increase either their likelihood of using the drugs or the number of prescriptions filled. The authors noted that cancer patients may simply not be responsive to cost sharing, or the discount may not have affected their use because the discounts took place after enrollees had already committed to treatment (as evidenced by their reaching the coverage-gap phase of the benefit).

In a 2017 study funded by Pharmaceutical Research and Manufacturers of America, researchers suggested that high and variable OOP costs in Part D put patients who use specialty drugs at risk of poor clinical outcomes due to lower likelihood of initiating treatment and higher risk of gaps in therapy or discontinuation (Doshi et al. 2017).¹⁴ While that hypothesis is plausible, only a limited number of studies have examined how cost sharing affects Medicare beneficiaries' adherence to specialty drugs.

A literature review published in 2016 reviewed 19 studies of cost sharing for patients with cancer, RA, or MS (Doshi et al. 2016c). Most of the studies were from 2009 or earlier, and only two included Part D enrollees. Of those two, one study found that Part D enrollees with cancer paid significantly more OOP than privately insured patients, and individuals with higher cost sharing were more likely to abandon prescriptions that were for oral cancer drugs. Nevertheless, the variable indicating Medicare coverage was not a significant predictor of

abandonment (Streeter et al. 2011). The same study estimated that patients with OOP costs of \$500 or more per prescription had four times the odds of abandoning their prescription at the pharmacy, compared with patients whose cost sharing was \$100 or less. The second study looked at elderly non-LIS Part D enrollees in 2008. Among patients taking higher priced oncology agents, researchers found higher odds of delaying or discontinuing treatment associated with higher OOP costs. However, a puzzling result was that among patients taking lower priced oral cancer drugs, the odds of discontinuation or delay decreased as OOP costs increased (Kaisaeng et al. 2014).

Among all the studies surveyed, Doshi and colleagues' 2016 literature review found wide variation in the estimated effects of cost sharing for specialty drugs and treatment initiation (Doshi et al. 2016c). Initiation of cancer treatment was reported to be largely insensitive to cost sharing. Evidence on the relationship between adherence and cost sharing was mixed and was sensitive to condition, type of adherence measure, and cost-sharing amount. Six of seven studies found a statistically significant relationship between cost sharing and discontinuation of treatment, but only studies of RA patients had consistent results, and the magnitude of effects was small. Authors of the literature review concluded that there was a stronger association between higher cost sharing and not initiating specialty drugs or abandoning a prescription at the pharmacy but less association with or no relationship to patients' adherence.

In subsequent years, three other observational studies found associations between high cost sharing and lower use of specialty drugs. One compared RA patients with and without the LIS who had used a Part D biologic treatment in the year before the study year (Doshi et al. 2016a). Non-LIS enrollees paid an average of nearly \$500 for a 30-day supply, compared with \$5 for LIS enrollees. The authors found that non-LIS enrollees were less likely to use a biologic in the study year, were more likely to fill a prescription for a Part B biologic for RA, and, when they used a Part D agent, had higher odds of a gap in treatment. In a study of Part D enrollees newly diagnosed with chronic myeloid leukemia in the 2011 to 2013 period, authors found that non-LIS enrollees faced average cost sharing of \$2,600 for an initial prescription of a tyrosine kinase inhibitor (TKI) (Doshi et al. 2016b). Compared with LIS enrollees, non-LIS patients were significantly less likely to initiate TKI therapy and, when they did so, took twice as long to fill their first

prescription.¹⁵ A third study using data from 2014 and 2015 included both Medicare and commercially insured cancer patients (Doshi et al. 2018a). It found higher rates of abandonment or delay of an initial oral cancer drug associated with higher OOP costs, but those rates were higher for commercially insured patients than for Medicare beneficiaries.

Cost sharing and the “gross-to-net bubble”

Since the start of Part D, prices at the pharmacy for brand-name drugs have grown rapidly, but postsale rebates and fees paid to plan sponsors and their pharmacy benefit managers (PBMs) by drug manufacturers have grown even faster. Between 2007 and 2017, gross spending for brand-name drugs grew by an annual average of 10 percent, while postsale rebates and fees grew by 19 percent annually. Consequently, the gap between brand prices charged at the point of sale (POS) and prices net of rebates and fees has widened. This expansion has been called the “gross-to-net bubble” (Fein 2019).

With such high prices for specialty drugs, paying 25 percent to 33 percent coinsurance can pose a financial hurdle for treatment. In addition, because patients pay coinsurance on pre-rebate prices, enrollees who fill prescriptions for rebated drugs pay more (and potentially far more) than 25 percent of their Part D plan's net price for certain classes of specialty drugs.

Plan sponsors do not receive manufacturer rebates for all brand-name drugs. Their ability to negotiate for rebates depends on whether a drug has competing therapies, as well as how well the sponsor can deliver a market-share goal to the manufacturer through its formulary and number of enrollees. One recent Milliman analysis of 2016 data provided by a group of Part D plan sponsors found that only 36 percent of brand-name drugs had more than nominal manufacturer rebates (i.e., greater than 1 percent of POS prices) (Johnson et al. 2018). As a share of POS prices, average rebates were largest in drug classes in which brand-name drugs competed directly with one another (39 percent) or when the brand faced competition from three or more manufacturers of a generic substitute (34 percent).

Because there is variation in the degree of competition that specialty drugs face, there is also variation in the proportionate size of their rebates. According to the Milliman study, the group of plan sponsors that provided data negotiated rebates that averaged about 27 percent for

specialty drugs. However, in 2016, hepatitis C drugs—which began to face significant price competition after the entry of new agents—may have significantly influenced that average. The Congressional Budget Office estimates that in 2015, manufacturers’ rebates for specialty drugs averaged 10.5 percent across all plan sponsors compared with 28.4 percent for nonspecialty brand-name drugs (Anderson-Cook et al. 2019). Rebates are less easily obtained and smaller, on average, for brand-name drugs in protected classes such as oncology and antiretroviral agents.¹⁶ In the Milliman study, out of 124 brand-name drugs in protected classes, only 16 received rebates, and among those drugs, rebates averaged 14 percent of POS prices (Johnson et al. 2018).

Addressing the financial burden of high prices through a narrow focus on beneficiary cost sharing

Part D plan sponsors use formularies with tiered cost sharing to give enrollees incentive to use lower cost generics and preferred brand-name drugs. This tiered cost sharing has been key to plans’ success at reaching high rates of generic dispensing. However, Part D enrollees who use specialty-tier drugs sometimes do not have lower cost alternatives that are as effective.

Certain approaches to benefit design for high-priced drugs focus narrowly on beneficiary cost sharing. For example, federal policymakers are considering options that would require Part D plan sponsors to pass manufacturer rebates through to the price of enrollees’ prescriptions at the pharmacy. Similarly, some employers place a dollar limit on what their employees must pay for each prescription. Both of those approaches reduce financial hurdles that cost sharing can pose to certain patients, but neither would necessarily address growth in drug prices. Also, in the context of Medicare Part D, the two approaches may have additional effects that run counter to other policy goals for the program.

Applying manufacturer rebates at the point of sale

Most Part D plan sponsors use manufacturer rebates to lower plan premiums, in part because beneficiaries evaluate premiums closely when comparing plan options, and premiums are the basis on which plans qualify as LIS

benchmark plans. There may also be practical reasons for doing so. For example, most manufacturer rebates and discounts are determined retroactively, and the exact amounts are not known at the time of sale.

Using rebates to reduce plan premiums lowers Medicare program spending because Medicare subsidies pay for a large portion of plan premiums for all enrollees. However, because POS prices are not discounted, coinsurance amounts paid by beneficiaries who use drugs with rebates are effectively higher. As a result, a larger proportion of enrollees reaches Part D’s OOP threshold—the point at which Medicare’s reinsurance pays for 80 percent of benefits. The approach also increases costs for Medicare through higher low-income cost-sharing subsidies. Medicare pays for most of the cost sharing on behalf of LIS enrollees. When plans set cost sharing as a percentage of POS prices, Medicare’s low-income cost-sharing subsidy is higher than it would be on a net-of-rebate basis.

In recent years, plan sponsors have negotiated additional “price-protection” provisions. Under these agreements, if a drug’s list price increases above a specified threshold, the manufacturer rebates any incremental increase above the threshold to the plan sponsor. Sponsors negotiate ceiling prices because manufacturers’ midyear price increases may result in benefit costs that are higher than they expected. While price-protection rebates give more predictability to plan sponsors, enrollees who pay coinsurance are not protected from price increases. Similarly, to the extent that Medicare pays coinsurance on behalf of LIS enrollees, Part D’s low-income cost-sharing subsidy does not benefit from price-protection rebates.

A policy that requires plan sponsors to share at least a portion of manufacturer rebates with enrollees who use drugs with rebates could help lower costs for those beneficiaries. However, a sizable proportion of specialty drugs have few or no direct competitors in their therapeutic class, and thus their manufacturers do not provide rebates (Johnson et al. 2018). While the Food and Drug Administration (FDA) has recently approved larger numbers of biosimilar products, a number of competitive tactics have postponed their market entry. Those tactics include patent litigation, extensions of exclusivity periods through approvals of new orphan indications for originator biologics, PBM agreements with manufacturers of originator biologics in which rebates are conditional on excluding biosimilars from the formulary, and pay-for-delay agreements (Mattina 2019). Patients who fill prescriptions for drugs whose

manufacturers do not offer rebates would not find cost-sharing relief from POS rebates.

Plan sponsors and their PBMs would need to resolve logistical issues before operationalizing POS rebates. For example, the amount of rebate payment may be determined retroactively based on market shares achieved or the magnitude of price increases. However, plan sponsors are already required to use estimated rebates and discounts in the Part D bids they submit to CMS. Plan sponsors would likely need to rely on chargebacks or similar arrangements to ensure the rebate amount is reflected in the beneficiary's cost sharing amount at the pharmacy.¹⁷ Plan sponsors (and their PBMs) and manufacturers may be concerned about the risk of revealing rebate amounts to competitors. Nevertheless, it may be possible to share postsale rebates and discounts with beneficiaries at the POS without disclosing the exact amounts negotiated for individual products by using, for example, average amounts across rebated drugs or by therapeutic class.

Logistical issues are not likely to be the primary obstacle for Part D sponsors; some commercial insurers (that also sponsor Part D plans) today offer plans that use manufacturer rebates to lower members' cost sharing at the POS (Business Wire 2018, Japsen 2018, Tracer 2018). However, Part D is structured differently from most commercial plans. Unlike employer-sponsored coverage provided by a single plan sponsor, Part D enrollees have the opportunity to switch plans annually. As a result, beneficiaries who use high-cost, high-rebate drugs could seek out plans that negotiate the best discounts. Thus, applying discounts to POS prices and having those prices visible on Medicare's Plan Finder may result in adverse selection for the plan, and plan sponsors may not have strong incentives to drive a hard bargain with manufacturers for individualized discounts.

In the past, the Commission has described how Part D's benefit structure, including its coverage gap and cost-based reinsurance subsidies, combined with its focus on premium competition can affect plan sponsors' formulary incentives (Medicare Payment Advisory Commission 2017). A policy of requiring rebates to be passed through at the POS could give plan sponsors better incentives to put products with lower net prices on their formularies. Additionally, POS rebates could limit plan sponsors' ability to financially benefit from rebates on prescriptions filled by LIS enrollees in the coverage gap. Currently,

plans may use those rebates to offset the benefit spending of all plan enrollees. Under a POS rebate approach, Medicare's low-income cost-sharing subsidies would instead be lower.

Nevertheless, requiring POS rebates raises several concerns. A policy that applies rebates to lower prices at the POS would decrease cost-sharing liability for some enrollees (i.e., those who use medications with rebates or discounts). However, the policy would not help beneficiaries who take expensive drugs with no postsale rebates or discounts.

By requiring rebates to be used to lower POS prices, the policy would increase overall Medicare program spending. Because plans' benefit costs and premiums would be higher, Medicare's payments to plans that subsidize all Part D enrollees (the direct subsidy) and LIS enrollees (the low-income premium subsidy) would increase. It is likely that only a minority of beneficiaries would have reductions in cost sharing that exceed their premium increase.

At the same time, however, fewer enrollees would reach the catastrophic phase, thereby reducing Part D's reinsurance payments. Lower POS prices would also reduce Medicare's low-income cost-sharing subsidy payments. On net, however, in the absence of restructuring of the Part D benefit, Medicare program spending would likely increase even if plan sponsors and their PBMs were able to obtain the same level of rebates as under current law. Another concern may be that participants in the drug supply chain would move away from negotiating rebates to negotiating fees or other price concessions that would be exempt from a POS rebate policy.

Applying an OOP limit to each specialty-tier prescription

A second approach to addressing high-cost drugs would require that cost sharing for specialty-tier drugs not exceed a per prescription maximum amount. In a recent survey of employers who offer prescription drug benefits, 18 percent charged their employees coinsurance up to a capped dollar amount, with an average of \$164 as the maximum per prescription (Pharmacy Benefit Management Institute 2019). States such as Delaware, Louisiana, and Maryland also enacted laws that cap specialty-drug cost sharing at \$150 for a 30-day supply (McCarty and Cusano 2014).

Policymakers could establish a maximum dollar limit per prescription within Medicare Part D. For example, the

amount of cost sharing for a drug placed on a specialty tier that requires 33 percent coinsurance would be the lower of the maximum dollar limit or 33 percent of the drug's price at the pharmacy. The maximum dollar amount could be indexed in the same way that other Part D benefit parameters are indexed (i.e., to the annual change in average drug expenses under Part D) or use a different index (e.g., the consumer price index), and it could be adjusted for the prescription's days supplied (e.g., 3 times the limit for a 90-day supply through mail order or specialty pharmacy).

In 2017, 0.4 million non-LIS enrollees (1.4 percent of all non-LIS enrollees) filled one or more prescriptions for drugs on their plans' specialty tiers, and the cost of those prescriptions (at POS prices) was \$23.6 billion.¹⁸ The amount of associated cost sharing totaled about \$1.6 billion, an average coinsurance rate of 7 percent. Because specialty drugs have very high prices, over two-thirds of non-LIS enrollees' specialty-tier drug spending occurred after they had already reached the catastrophic phase of the benefit. In a simplified example based on 2017 Part D claims, capping non-LIS enrollees' cost sharing at \$200 per specialty-tier prescription would have reduced their average effective coinsurance rate from 7 percent to about 2 percent. Under current law, Part D benefit costs are paid with a combination of Medicare subsidies and enrollee premiums. Because a cap on cost sharing would have increased benefit costs, Medicare would have subsidized nearly three-quarters of the higher amount, with the remainder paid by all Part D enrollees through higher premiums. As an alternative to increasing premiums, CMS could require plan sponsors to adjust their cost sharing—for example, through higher deductibles, copayments, and coinsurance rates on nonspecialty tiers—in ways that achieve actuarial equivalence to the defined standard benefit value. Both approaches would result in enrollees who do not use specialty-tier drugs paying for more of their Part D benefit than they do today.

Capping the amount of cost sharing per prescription would smooth beneficiary cost sharing during the year, provide more generous coverage, and improve the affordability of specialty-tier drugs for patients whose conditions require specialty products. For conditions for which the only lower cost alternative therapies are less effective, coinsurance of 25 percent to 33 percent may pose financial hurdles to appropriate treatment. A per prescription cap might encourage more initiation of therapy or fewer instances of abandoning a prescription. The policy would also protect

specialty-drug users from the cost-sharing implications of price increases.

While lower cost sharing may encourage use of appropriate treatments, it may also encourage greater use of drugs that may not be clinically appropriate or effective. The Commission has noted that polypharmacy (the use of multiple drugs simultaneously) is already a concern for the Medicare population (Medicare Payment Advisory Commission 2015). Manufacturers increasingly emphasize specialty drugs in their development pipelines, and as those medicines enter the market, we can expect greater use of them. Higher demand for specialty medications would increase premiums for all enrollees and Medicare program costs.

A limit on per prescription cost sharing may also have implications for manufacturers' pricing behavior. With the patients' cost sharing capped, manufacturers might have greater ability to increase list prices because patients would be insulated from such increases and price increases would be less visible. Unlike employers and other payers of commercial health plans, Part D plan sponsors do not bear insurance risk for large portions of the benefit, particularly in the coverage gap and catastrophic phase. These gaps in benefit liability may reduce plans' incentives to negotiate for rebates as hard as they might otherwise. Moreover, when two or more competing specialty drugs are available within a drug class, a per prescription cap could limit plans' ability to encourage one preferred therapy over another, which would reduce their leverage in negotiating rebates. In turn, drug manufacturers might be able to raise prices of specialty drugs further or to launch new specialty drugs at even higher prices.

The need for a broader approach

The Commission has previously examined the potential use of POS rebates in Part D. We noted that while we share concern for enrollees who pay coinsurance on high-priced specialty drugs, shifting rebates to the POS would increase enrollee premiums and Medicare program spending. Further, the policy would not help beneficiaries who take expensive drugs that have no rebates (Medicare Payment Advisory Commission 2018). Under proposed revisions to the federal anti-kickback statute, we noted that limiting how Part D plan sponsors may use rebates could lead to uncertain and potentially undesirable outcomes, and thus the Commission has substantial concerns about those proposed changes (Medicare Payment Advisory Commission 2019a). Likewise, at our public meetings

in April 2019, the Commission examined using a dollar limit on cost sharing for each specialty-tier prescription in Medicare Part D, but decided not to pursue that approach. Instead, the Commission’s position is that the Medicare program and Part D enrollees would be better served by broad structural change to the Part D benefit.

Eliminating the coverage-gap discount and restructuring the catastrophic benefit

Rather than focus narrowly on specialty-tier cost sharing, the Commission plans to further evaluate a broader structural reform that would, as was the case in our 2016 recommendations, improve financial protection for all Part D enrollees. It would also address inflationary incentives in Part D’s benefit structure by eliminating the coverage-gap discount and restructuring the catastrophic benefit.¹⁹ In general, we expect the policy would provide stronger incentives for plan sponsors to manage enrollees’ spending and potentially restrain manufacturers’ incentives to increase drug prices or launch new products at high prices. However, the ultimate financial impact on beneficiaries and the Medicare program would depend on the specific policy parameters chosen as well as behavioral responses to the changes.

Past changes to Part D’s coverage gap

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. The defined standard basic benefit initially covers 75 percent of drug spending above the deductible and all but 5 percent coinsurance once an enrollee reaches the OOP threshold. That threshold is known as “true OOP” because it excludes cost sharing paid on behalf of a beneficiary by most sources of supplemental coverage, such as employer-sponsored policies and enhanced alternative plans. Before 2011, enrollees with spending that exceeded the initial coverage limit were responsible for paying a prescription’s full price (i.e., 100 percent cost sharing) at the pharmacy up to the OOP threshold.

The Patient Protection and Affordable Care Act of 2010 (PPACA) called for gradually lowering cost sharing in the coverage gap from 100 percent to 25 percent by 2020 and for constraining annual increases in the OOP threshold.

To finance much of this expansion of benefits without directly raising enrollee premiums and program spending, PPACA required manufacturers of brand-name drugs, as a condition of the drug’s Part D coverage, to provide non-LIS enrollees with a 50 percent discount on prescriptions filled during the coverage gap. As a result, in 2011, cost sharing in the coverage gap for brand prescriptions fell from 100 percent to 50 percent.

The law also required that the manufacturers’ discount be counted as though it were the enrollee’s own OOP spending for calculating the “true OOP” amount. That change lowered OOP costs for some beneficiaries but also increased the number of non-LIS enrollees who reached the OOP threshold above which Medicare pays 80 percent of spending through reinsurance.

The Bipartisan Budget Act of 2018 changed Part D to phase out the coverage gap more quickly by increasing the manufacturers’ discount from 50 percent to 70 percent. In 2019, enrollees who reach the coverage gap pay 25 percent cost sharing for brand-name drugs until they reach the OOP threshold (Figure 2-1, p. 39). (Cost sharing for generic drugs in the coverage gap is 37 percent.) Counting the 70 percent discount as though it were the enrollee’s own spending lowers the OOP costs non-LIS enrollees must incur to reach Part D’s catastrophic phase, which in turn means that more enrollees are likely to reach the catastrophic phase.

Over time, plans’ liability for benefit spending on brand-name drugs in the coverage gap rose from 0 percent in 2011 to 15 percent in 2018. In 2019 and thereafter, plan sponsors cover just 5 percent of spending for brand prescriptions filled in the gap phase, while they continue to obtain postsale rebates and discounts. CMS’s Office of the Actuary projects that, in 2019, plan sponsors will obtain postsale rebates and discounts worth about 26 percent of the plans’ total drug costs (Boards of Trustees 2018). In its 2019 call letter to plan sponsors, CMS raised significant concerns about the effects of the higher coverage-gap discount and low plan liability on Part D drug costs in 2019 and in future years (Centers for Medicare & Medicaid Services 2018).

Part D’s benefit design contributes to the inflationary trend

In the Commission’s March 2017 report, we highlighted how Part D’s unique benefit design, Medicare’s cost-based reinsurance payments, and plan sponsors’ focus on premium competition can affect incentives regarding

which drugs a plan covers on its formulary (Medicare Payment Advisory Commission 2017). Because plan sponsors are not liable for much benefit spending in the coverage gap, Part D's benefit design can create incentives for plan sponsors to include certain high-cost, high-rebate drugs on their formulary over others, which can increase beneficiary cost sharing and Medicare spending for reinsurance.

Manufacturers of brand-name drugs and biologics are not required to pay any discount for LIS enrollees who have spending high enough to reach the coverage gap. In the gap phase, plan sponsors face weaker financial incentives to manage spending for LIS enrollees than for non-LIS enrollees because they have no benefit liability; Medicare's low-income cost-sharing subsidy pays for all of the drug costs other than the nominal LIS copayments. Nevertheless, plan sponsors obtain rebates on brand-name prescriptions filled by LIS enrollees in the gap. Because rebates are often calculated as a percentage of a drug's list price and they increase with market share (i.e., volume), plan sponsors and their PBMs may be less resistant when manufacturers raise prices and LIS enrollees fill prescriptions for drugs with high list prices.

LIS beneficiaries continue to account for the majority of beneficiaries who reach the catastrophic phase of the benefit. In the catastrophic phase, plan sponsors' incentives to manage the benefits of LIS enrollees are similar to those for non-LIS enrollees: Plans are responsible only for 15 percent of catastrophic benefit spending. In addition, because nearly all of LIS enrollees' cost sharing is paid by Medicare's low-income cost-sharing subsidy, some sponsors may not bargain hard with manufacturers over the price of medications more likely to be used by LIS enrollees, particularly when there are rebates to offset some or all of the plan's benefit liability.

At the same time, manufacturers may find that, for some products, higher prices allow them to offer larger rebates than their competitors and gain more market share through favorable formulary placement. In this sense, Part D's benefit design may contribute to the inflationary trend in pharmaceutical pricing.

The Commission's 2016 recommendations would affect drug pricing incentives indirectly

In 2016, the Commission recommended an integrated set of changes to Part D that would phase in a reduction

of Medicare's reinsurance from 80 percent to 20 percent while simultaneously increasing capitated payments to plans, among other changes (Medicare Payment Advisory Commission 2016). Those recommendations could better align plan sponsors' financial incentives to include lower priced drugs on their formularies. Beneficiaries would also benefit from lower cost sharing if they selected those lower priced drugs.

However, the Commission's 2016 recommendations only indirectly address pharmaceutical manufacturers' pricing incentives. Because plan sponsors would be responsible for a greater share of insurance risk in the catastrophic phase, the recommendations would reduce the financial benefits of including high-price, high-rebate products on their formularies (Barnhart and Gomberg 2016). To the extent that plan sponsors move away from preferring those products, there may be an indirect effect on manufacturers' pricing strategies. Those indirect effects may be limited and would likely vary depending on the availability of therapeutic competition and the size of the Part D market relative to total U.S. sales of the relevant products.

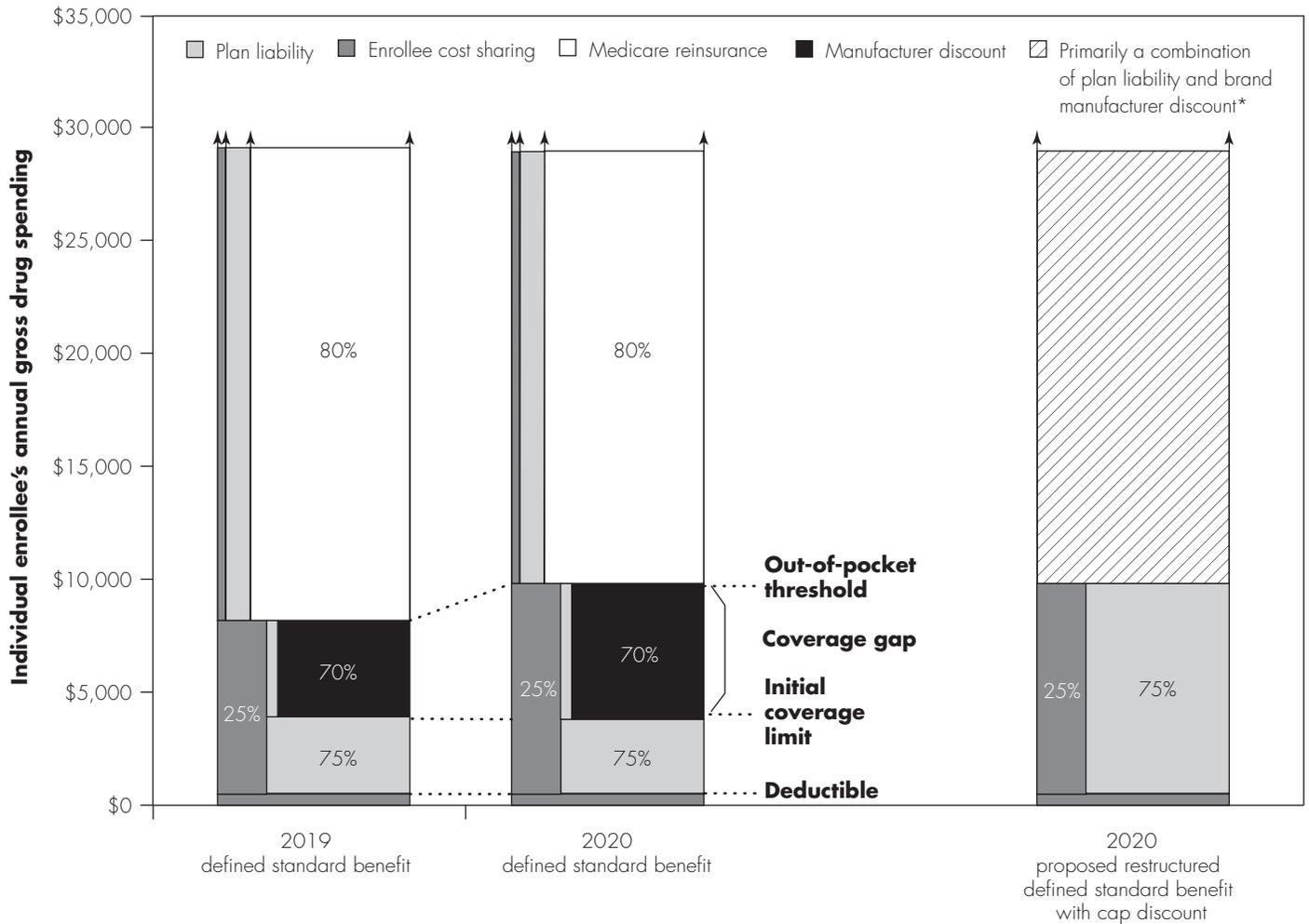
While Medicare's influence on drug pricing is indirect, the program accounts for a large share (about one-third) of U.S. retail pharmaceutical sales (Martin et al. 2019). As a result, Medicare's payment policies can have a significant financial effect on drug manufacturers. For example, policymakers' decisions about the amount manufacturers must pay in coverage-gap discounts may factor into manufacturers' decisions about price increases or launch prices, especially for drugs that have relatively lower POS prices because gap discounts make up a higher proportion of the manufacturers' revenues.

Converting the coverage-gap discount to a cap discount

A potential policy approach that would offer better pricing incentives would be to require manufacturers to provide discounts in Part D's catastrophic phase ("cap discount") rather than in the coverage gap (see right side of Figure 2-1). This change may deter manufacturers of high-priced drugs from increasing prices as rapidly as they have in recent years. The policy would provide better formulary incentives and simplify the benefit structure with a 25 percent cost sharing (or actuarially equivalent cost-sharing amounts) and 75 percent plan liability across all drug and biologic products between the deductible and the OOP threshold. Manufacturers of brand-name drugs and biologics (including biosimilar products) would be

FIGURE 2-1

A proposed restructured defined standard benefit that would apply a brand manufacturers' discount to the catastrophic phase instead of the coverage gap



Note: The cross-hatched area would be paid primarily through a combination of brand manufacturers' discounts and plan liability, but could also include Medicare reinsurance and/or enrollee cost sharing. "Gross drug spending" refers to amounts paid at the pharmacy before rebates and discounts. "Cap discount" refers to applying a manufacturers' discount to brand-name drugs above Part D's out-of-pocket threshold (i.e., in the catastrophic phase of the benefit) instead of during the coverage gap. The coverage gap (between the initial coverage limit and the out-of-pocket 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). Although not shown in the figure, non-LIS enrollees' cost sharing for generic drugs in the coverage gap is 37 percent in 2019 and will be 25 percent in 2020. Under current law, Part D's out-of-pocket threshold is expected to increase by nearly 25 percent in 2020. *The Commission is continuing to evaluate the percentages that would be paid by each stakeholder (Part D plans, brand manufacturers, the Medicare program, and enrollees) under a restructured benefit.

Source: MedPAC depiction of current and proposed Part D benefit structure.

required to pay a cap discount on prescriptions filled in the catastrophic phase of the benefit.

This cap-discount program would be combined with other changes to the catastrophic phase: a lower rate of Medicare reinsurance, an increase in plan liability, and better insurance protection for beneficiaries. Medicare's capitated payments would increase so that the overall

subsidy rate would remain unchanged at 74.5 percent of basic benefits.

Policymakers would need to decide the shares of benefits to be paid by the four current sources of financing Part D benefits: enrollees, Medicare (through reinsurance payments to plans), plan sponsors, and pharmaceutical manufacturers (depicted as the cross-hatched region in

Figure 2-1 (p. 39). (Note that for generic drugs, because there would be no manufacturer discount, plan sponsors would cover a larger share of spending so that Medicare and enrollee shares would be the same for both brand and generic drugs.)

- **Enrollees:** Currently, enrollees pay 5 percent cost sharing (based on POS prices) in the catastrophic phase of the benefit with no maximum OOP limit. The Commission's standing recommendation from 2016 would eliminate all enrollee cost sharing above Part D's OOP threshold. Under a new option with a redesigned benefit, policymakers could eliminate cost sharing as the Commission recommended, use a coinsurance rate lower than 5 percent, or select a dollar copay amount.
- **Medicare:** Currently, Medicare provides 80 percent reinsurance for spending (net of postsale rebates and discounts) in the catastrophic phase of the benefit. The Commission's 2016 recommendation would reduce Medicare's reinsurance from 80 percent to 20 percent of catastrophic spending while simultaneously increasing capitated payments to plans so that Medicare's overall subsidy would remain at 74.5 percent. Under a new option to restructure the defined standard benefit, Medicare's reinsurance would be lowered to 20 percent or less or would be eliminated altogether. Medicare's risk corridors would remain in place and would limit plan sponsors' risk of unforeseen losses.²⁰
- **Plan sponsors:** Currently, plan sponsors are liable for 15 percent of spending (net of rebates and discounts) in the catastrophic phase of the benefit. The Commission's 2016 recommendation would increase plan sponsors' liability from 15 percent to 80 percent of catastrophic spending, while simultaneously increasing capitated payments to plans so that the overall subsidy remained at 74.5 percent. Under the new option to restructure Part D, plan liability in the catastrophic phase would be higher than the current 15 percent to ensure that plan sponsors have a stronger incentive to manage spending.
- **Manufacturers:** Currently, Medicare requires manufacturers of brand-name drugs and biologics to provide a 70 percent discount on prescriptions filled by non-LIS beneficiaries in the coverage-gap phase. The law also counts the manufacturer discount as though it were the enrollees' own spending for purposes of determining the OOP

threshold. The Commission's 2016 recommendation would discontinue counting the brand discount in this manner. (This recommendation would lead some beneficiaries to incur higher OOP costs than under current law. However, the recommendation also introduced a hard cap on beneficiaries' OOP spending.) Under a new option to restructure the defined standard benefit, Part D's gap discount would be replaced with a cap discount. This cap discount would help finance benefit spending and might deter price growth. (Also, by eliminating the gap discount, only the beneficiaries' own spending would be relevant for determining whether she or he reached the OOP threshold.) To ensure that both Medicare program spending for Part D and enrollee premiums remain affordable, policymakers would need to decide on a manufacturer discount rate that most effectively counterbalances the inflationary incentives in pharmaceutical pricing.

We expect that by requiring plan sponsors to bear insurance risk on a larger share of spending, they would have greater incentives to negotiate rebates with manufacturers and design formularies in ways that encourage the use of lower cost therapies. As a result, pharmaceutical manufacturers may face stronger resistance to price increases and higher launch prices.

Rationale for eliminating the coverage-gap discount

Currently, the coverage-gap discount both lowers the price of brand-name drugs relative to generic drugs and quickens the pace at which an enrollee reaches the OOP threshold. As of 2019, plan sponsors are responsible for just 5 percent of benefit liability for brand-name drugs in the coverage gap. By comparison, plans are responsible for 63 percent of the cost of generics in 2019, and will be responsible for 75 percent of generic prescription costs in 2020, when the coverage gap is fully phased out. Among beneficiaries with similar dollar amounts of drug spending, those who use more generics are penalized under the current gap-discount policy because they incur higher OOP costs than beneficiaries who use more brand-name drugs and, as a result, reach the OOP threshold more quickly. From the perspectives of both plan sponsors and beneficiaries, eliminating the coverage-gap discount would equalize treatment of brand-name and generic drugs in the coverage gap. Beneficiaries and plan sponsors would face stronger incentives to use lower cost products and improve plans' formulary incentives.

Rationale for restructuring the catastrophic benefit and adding a cap discount

Insurance risk provides plan sponsors with incentives to offer attractive benefits while managing their enrollees' drug spending through formularies and other tools. Medicare's reinsurance subsidy reduces sponsors' insurance risk and, instead, provides cost-based reimbursement. In turn, reinsurance diminishes financial incentives for plan sponsors to manage spending of enrollees who incur spending high enough to reach the catastrophic phase of the benefit.

Between 2007 and 2017, Medicare's payments for reinsurance increased at an average annual rate of nearly 17 percent, compared with a decrease of about 2 percent per year for the capitated direct subsidy payments (Medicare Payment Advisory Commission 2019b). As a result, the portion of basic benefit costs for which plans are at risk (direct subsidy payments plus enrollee premiums) accounted for only 46 percent in 2017, down from 75 percent in 2007. This trend is contrary to the original intent of Part D, in which private plans would be at risk for their enrollees' benefit spending; to attract enrollees, plan sponsors would need to provide access to beneficiaries' medications while managing spending so that premiums remain competitive.

Part D's individual reinsurance is part of a system of subsidies and regulations that was designed to encourage broad participation of private plan sponsors in a new program. Given plans' more than 13 years of experience delivering Part D benefits, it is appropriate to consider whether plan sponsors still need the reinsurance subsidy and, if so, what the right level of reinsurance protection is.²¹

A restructured design would move Part D closer to a benefit structure more typical of the commercial sector. Under a restructured Part D benefit, plan sponsors would ultimately be at risk for a much larger share of spending above the OOP threshold than the 15 percent they face today. Because more of Medicare's overall subsidy would be paid through capitated payments, plan sponsors would bear more insurance risk for their enrollees' spending and would have stronger incentives to manage benefit spending while retaining the protection afforded them through risk corridors. As a result, the restructured benefit would also address misaligned incentives that provide a financial advantage to plan sponsors that bid in certain ways while increasing taxpayer costs (Medicare Payment Advisory Commission 2016, Walker and Weaver 2019)

(see text box, p. 43, on patterns of Medicare payments and bidding incentives).

In addition, replacing the gap discount with a cap discount would improve the affordability of high-priced specialty drugs and biologics by addressing high prices directly. Many therapies recently approved by the FDA have few or no lower cost alternatives. For those therapies, plan sponsors and their PBMs have limited ability to negotiate price concessions.

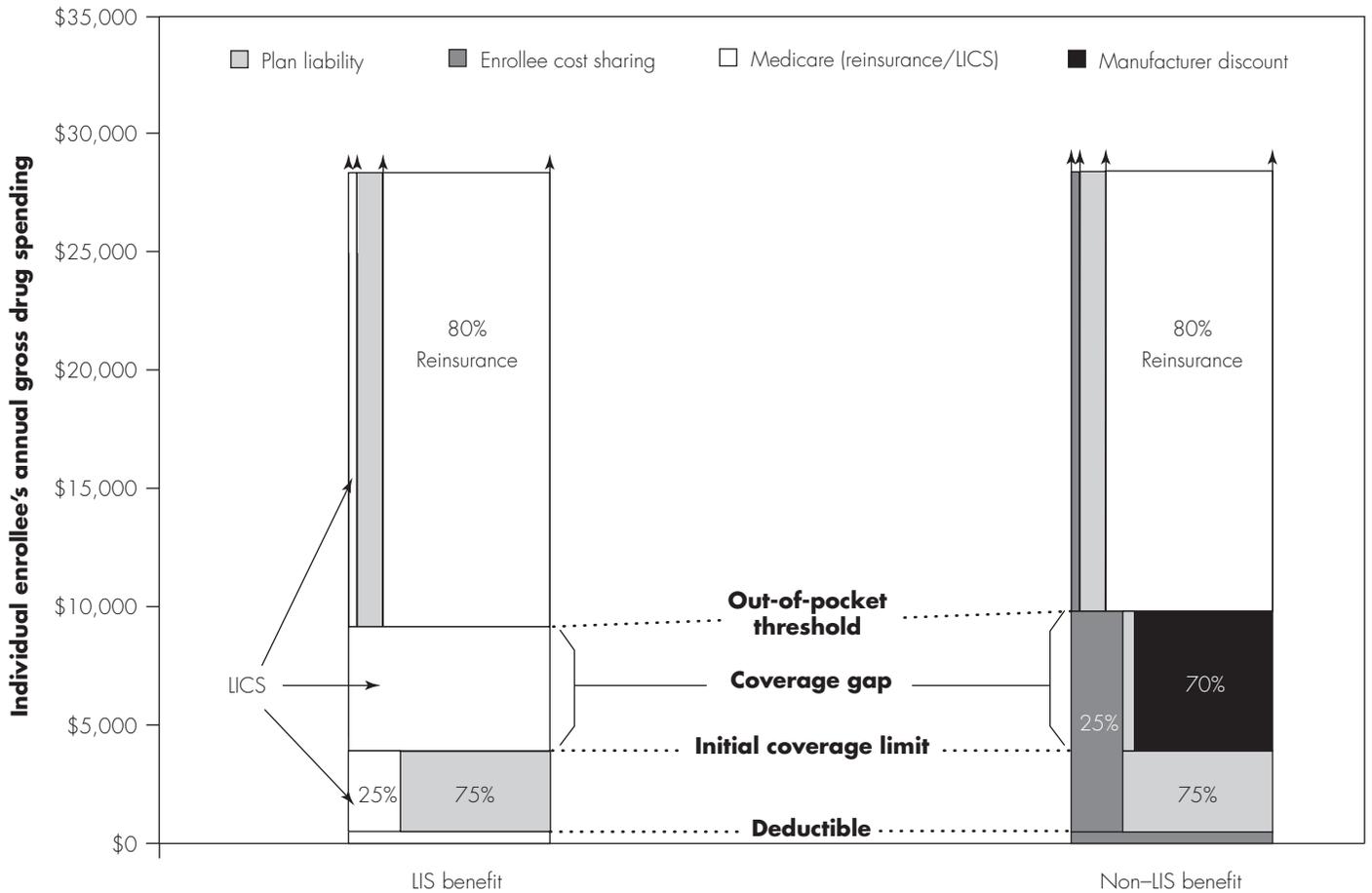
In 2017, drugs and biologics placed on specialty tiers accounted for more than half of all Part D gross spending above the OOP threshold, while they accounted for less than 10 percent of spending below the OOP threshold. As currently structured, the coverage-gap discount affects only a small share of spending for specialty-tier drugs and biologics. A cap discount, on the other hand, would be more likely to apply to drugs and biologics that command high prices. Because the size of the discount would increase in proportion to the price, manufacturers of drugs and biologics with high prices would be subject to a greater financial liability than those with lower priced products. As a result, such an approach may make high prices or price increases less attractive to manufacturers than they are under the current coverage-gap policy. At the same time, because manufacturers would be able to estimate the effects of cap discounts on their net prices under Part D, they might increase their prices to compensate for the cap-discount liability. However, their ability to do so may be held in check by the size of the cap discount and the effect of such price increases on other payers (both public and private).

A consistent benefit for LIS and non-LIS beneficiaries

Past changes that phased out the coverage gap applied only to non-LIS beneficiaries (p. 37). As a result, today, LIS enrollees have a different benefit structure from non-LIS enrollees. LIS beneficiaries reach the catastrophic phase of the benefit at a lower level of spending because 100 percent of costs in the coverage gap (mostly paid by Medicare's low-income cost-sharing subsidy) are counted toward the OOP threshold (Figure 2-2, p. 42). In 2020, an LIS beneficiary would reach the OOP threshold at about \$9,039 in gross drug spending, nearly \$700 lower than the amount for a non-LIS beneficiary (Centers for Medicare & Medicaid Services 2019). This discrepancy is one reason LIS enrollees account for a higher share of individuals who reach the catastrophic phase.²²

FIGURE 2-2

Part D's basic benefit is different for LIS and non-LIS beneficiaries, 2020



Note: LIS (low-income subsidy), LICS (low-income cost-sharing subsidy). LICS pays for most or all cost-sharing liabilities for LIS enrollees. LIS enrollees pay nominal copayments (set in law) until they reach the out-of-pocket (OOP) threshold. The coverage-gap phase (between the initial coverage limit and the OOP threshold for the non-LIS benefit) is depicted as it would apply to brand-name drugs for an enrollee who does not receive Part D's LIS. Although not shown in the figure, non-LIS enrollees' cost sharing for generic drugs in the coverage gap is 37 percent in 2019 and will be 25 percent in 2020. "Gross drug spending" refers to amounts paid at the pharmacy before rebates and discounts.

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

Part D's LIS was designed to ensure that beneficiaries with low incomes and assets have access to appropriate medications. At the same time, the structure of the LIS subsidy may encourage plan and beneficiary behaviors that increase program costs. Plan sponsors do not bear liability for LIS enrollees' spending in the coverage gap. As a result, certain plan sponsors may give preferred formulary placement to brand-name drugs with high rebates rather than generic alternatives, while Medicare's low-income cost-sharing subsidy pays the higher cost of brand-name drugs. This subsidy structure may be one

of several reasons that explains why LIS enrollees use more brand-name drugs even when generic alternatives are available (Medicare Payment Advisory Commission 2016). In addition, our examination of 2015 claims showed that plans with a higher proportion of LIS enrollees tended to cover a lower share of their enrollees' spending and charged a higher percentage in average cost sharing (Medicare Payment Advisory Commission 2019b).

Restructuring the catastrophic benefit would provide stronger incentives for plan sponsors to manage LIS

Patterns of Medicare payments and bidding incentives

In the Commission's June 2015 report to the Congress, we noted regular patterns in spending that may suggest a bidding strategy that provides a financial advantage to plan sponsors (Medicare Payment Advisory Commission 2015). First, many plan sponsors bid too low on the amount of benefit spending they expect above Part D's out-of-pocket threshold relative to their enrollees' actual catastrophic spending. Second, plan sponsors bid too high on benefit spending other than catastrophic benefits.

When plans underestimate catastrophic spending in their bids, they are able to charge lower premiums to enrollees and then later get reimbursed by Medicare for 80 percent of actual catastrophic claims (net of postsale rebates and discounts) through additional reinsurance at

reconciliation. Because premiums are lower than they would have been had they reflected actual catastrophic prescription costs, in nearly every year since 2007, Medicare's overall Part D subsidy has been higher than the 74.5 percent specified in law.

At the same time, when plan sponsors bid too high on benefit spending, other than catastrophic benefits, the structure of Part D's risk corridors allows plan sponsors to keep most of the difference as profits (Centers for Medicare & Medicaid Services 2017b). Between 2009 and 2017, the majority of plan sponsors returned a portion of their prospective payments to Medicare through risk corridors, meaning that they had profits above and beyond those assumed in their bids. ■

enrollees' spending. However, in many cases, patterns of prescription therapy are established long before beneficiaries reach the OOP threshold. In 2017, nearly 60 percent of LIS enrollees who reached the coverage gap also reached the catastrophic phase of the benefit. That figure is about one in four for non-LIS beneficiaries.

If benefits in the coverage gap were changed so that plan sponsors were at risk for LIS enrollees' spending, that would likely affect how plan sponsors manage benefits. Under an equalized benefit, plans would be liable for 75 percent of LIS enrollees' spending for all drugs and biologics in what is now the coverage gap, just as plans would be for non-LIS beneficiaries. Medicare's low-income cost-sharing subsidy would pay 25 percent cost sharing minus LIS enrollees' nominal copayments.

With a consistent benefit structure, LIS and non-LIS beneficiaries would reach the OOP threshold at the same level of spending. A consistent benefit structure may also simplify bid calculations for plan sponsors. The change would, however, result in higher benefit costs and enrollee premiums because much of what is currently covered by Medicare's low-income cost-sharing subsidy would become part of Part D's basic benefit. For example, in 2017, low-income cost-sharing subsidies for LIS enrollees'

prescriptions filled during the coverage gap totaled more than \$12 billion. If the basic benefit covered 75 percent of LIS enrollees' spending in the coverage gap, the average premium for all Part D enrollees would have been at least 10 percent higher, assuming no behavioral change by plan sponsors or LIS enrollees. From Medicare's perspective, that would result in higher direct subsidy payments and low-income premium subsidies, offset by lower spending on low-income cost-sharing subsidies.

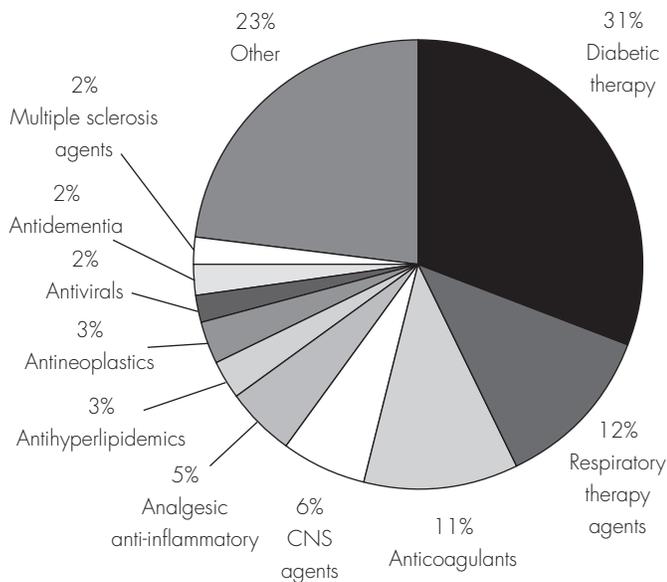
A cap discount would change the incidence of discounts across manufacturers

In 2017, coverage-gap discounts paid by manufacturers totaled \$5.8 billion. Four drug classes—diabetic therapies, respiratory therapy agents, anticoagulants, and central nervous system (CNS) agents—accounted for 60 percent of that amount (Figure 2-3, p. 44). Examples of medications in these classes include Januvia[®] (diabetic therapy), Lantus Solostar[®] (insulin), Eliquis[®] (anticoagulant), Advair Diskus[®] (respiratory therapy agent), and Lyrica[®] (CNS agent), with average prices ranging from about \$485 to \$576 per prescription.

Some of the therapeutic classes that tend to have higher priced products and account for large shares of Part D

**FIGURE
2-3**

Most coverage-gap discounts apply to non-specialty tier drugs, 2017



Note: CNS (central nervous system). Therapeutic classification is based on the First DataBank Enhanced Therapeutic Classification System 1.0.

Source: MedPAC analysis of Medicare Part D prescription drug event data from CMS.

spending had relatively small shares of manufacturer discounts. For example, antineoplastics and antivirals accounted for nearly 10 percent and 7 percent, respectively, of total gross Part D spending in 2017. Because of their high prices, even a single prescription for many of the drugs in those classes would be sufficient to meet the OOP threshold. For example, in 2017, the price for one of the most frequently used hepatitis C treatments (an antiviral) averaged about \$31,000 per prescription, and many cancer therapies had prices that ranged from around \$10,000 to over \$14,000 per prescription (see Table 2-2, p. 31). As a result, most of the costs of these therapies fell in the catastrophic phase of the benefit, and coverage-gap discounts made up a relatively small share of their costs. In 2017, antineoplastics and antivirals accounted for 3 percent and 2 percent, respectively, of total coverage-gap discounts paid by manufacturers (Figure 2-3).

A cap discount rate would need to be set at 11 percent or greater, applied to prescriptions filled by all (LIS and non-LIS) beneficiaries to ensure that the aggregate amount paid by manufacturers was at least as large as the amount currently paid through the gap-discount policy. If the cap discount applied only to prescriptions filled by non-LIS beneficiaries—the approach used today for the gap-discount policy—the minimum rate of cap discount required to maintain parity with current gap-discount amounts would be higher than 11 percent.²³

Under a cap-discount policy that applied to all beneficiaries, the incidence of manufacturer discounts would shift toward drugs and biologics that are more frequently placed on plans' specialty tiers. For example, antineoplastics and antivirals would account for 20 percent and 15 percent, respectively, of the manufacturer discounts compared with 3 percent or less in 2017 under the gap-discount policy (Figure 2-3 and Figure 2-4). Manufacturers of anti-inflammatory drugs (e.g., the Humira[®] pen used for RA and other inflammatory conditions) and MS agents would also pay more under a cap discount than under the gap discount. These four classes combined would account for 52 percent of manufacturer discounts, an increase from 12 percent under current policy. Diabetic therapies, on the other hand, would account for a much smaller share under the cap discount than under the gap discount (11 percent compared with 31 percent).

The design of a cap-discount policy would affect the incidence of discounts paid across manufacturers, reflecting differences in the drug classes used by affected beneficiaries. Because non-LIS beneficiaries who reach the catastrophic phase are often patients using drugs to treat cancer, MS, and RA, a cap discount that applied only to non-LIS enrollees would be more concentrated among those therapeutic classes than under a policy that applied the cap discount to all beneficiaries (Medicare Payment Advisory Commission 2019b).

Issues to consider in restructuring Part D's catastrophic benefit

Requiring plan sponsors to shoulder more insurance risk may provide plan sponsors with stronger incentives to manage benefit spending, but it also raises the question of whether plans could or would be more effective at managing their enrollees' spending than they are today. The Commission expects that any policy change that requires plan sponsors to bear more insurance risk would be combined with other changes that would provide sponsors with greater flexibility to use formulary tools.²⁴

Because Part D’s nominal cost-sharing amounts provide little financial incentives for LIS enrollees to use lower cost products, we also recommended changes in law to allow the Secretary of Health and Human Services to modify some LIS copayments. Finally, CMS would need to recalibrate Part D’s risk adjustment system to counterbalance plan incentives for selection.

The effects of the restructured Part D benefit on various stakeholders—including beneficiaries and taxpayers who finance the Medicare program—would depend on the specific parameters chosen. In this section, we discuss a key parameter: the OOP threshold amount.

Tradeoffs between a lower OOP threshold and Part D’s benefit and premium costs would depend on policy parameters

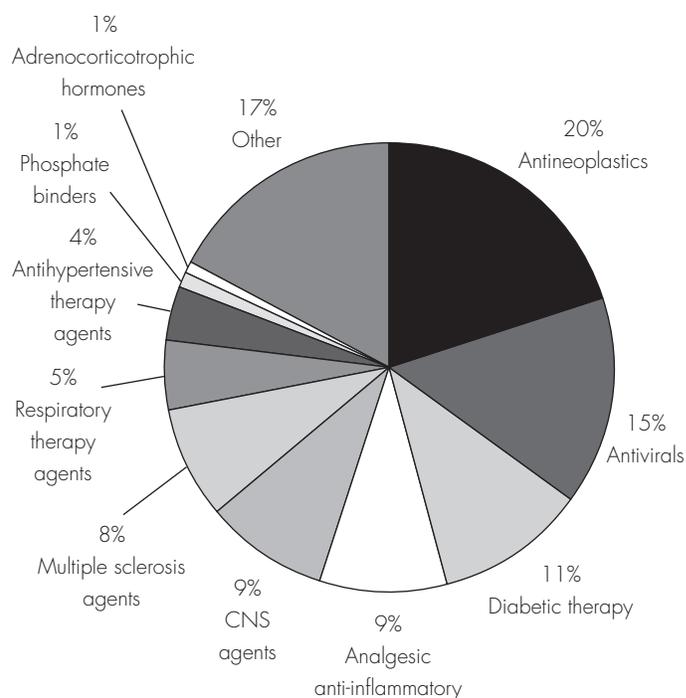
As part of PPACA, one mechanism for closing Part D’s coverage gap was to restrain annual increases in the OOP threshold. However, under law, the OOP threshold will revert back to a level that it would have reached otherwise, increasing from \$5,100 in 2019 to approximately \$6,350 in 2020.²⁵ Under the current coverage-gap discount, in 2020 we would expect enrollees who use brand-name drugs or biologics to pay about \$2,750 in cost sharing to reach that threshold. (Brand manufacturer discounts would pay the remainder. Beneficiaries who use generic drugs would need to spend a larger amount to reach the OOP threshold.) If the coverage-gap discount were eliminated, all non-LIS beneficiaries, regardless of their mix of brand-name and generic drugs, would pay the full amount of the OOP threshold (\$6,350 in 2020) in cost sharing to reach the OOP cap.

Without manufacturer discounts counting toward the OOP threshold, most individuals likely would not reach Part D’s catastrophic phase as quickly, and some would not reach it at all. In 2017, slightly over 1 million non-LIS enrollees reached the OOP threshold by paying an average of about \$2,200 in cost sharing. That amount is less than the \$4,950 threshold amount for 2017 because manufacturer discounts averaging nearly \$2,500 were counted as though they were the enrollees’ own spending. Without the coverage-gap discount, potentially more than half of the 1 million enrollees would not have reached the catastrophic threshold in 2017.

In typical commercial insurance, the tradeoff for a lower OOP cap is higher premiums. However, under a restructured Part D benefit, the tradeoff would depend on the benefit parameters chosen. With a manufacturer’s

FIGURE 2-4

Under a cap-discount policy that applied to all beneficiaries, specialty-tier drugs would have been responsible for larger shares of a cap discount, 2017



Note: CNS (central nervous system). Therapeutic classification is based on the First DataBank Enhanced Therapeutic Classification System 1.0.

Source: MedPAC analysis of Medicare Part D prescription drug event data from CMS.

discount applied to catastrophic spending rather than coverage-gap spending, plan sponsors would be responsible for 75 percent of spending in what is now the coverage-gap phase, but potentially less than 75 percent of covered catastrophic benefits. As a result, lowering the OOP threshold could actually reduce benefit costs and premiums. However, a lower OOP threshold would expand the catastrophic phase. Because plan sponsors would be liable for less benefit spending, they would also have weaker incentives to manage those benefits. These behavioral responses would tend to put upward pressure on benefit costs and enrollee premiums and offset, at least partially, the reductions in benefit costs resulting from lower overall benefit liability.

A lower OOP threshold would enhance financial protection for all enrollees, and more beneficiaries would reach the catastrophic phase of the benefit. Because a

restructured Part D benefit would lower or eliminate cost sharing in the catastrophic phase, such a change would likely increase both necessary and unnecessary use of high-priced and other therapies.

The effects of a lower OOP threshold would be different for LIS beneficiaries. Because plan sponsors currently have no benefit liability for LIS enrollees in the coverage gap, lowering the OOP threshold would result in higher benefit liability (for plan sponsors and for Medicare in reinsurance spending) regardless of whether the cap discount applied to LIS beneficiaries. Medicare would pay less in low-income cost-sharing subsidies.

Summary

The Commission has a long-standing interest in improving the financial sustainability of the Part D program. Previously we have raised concerns about misaligned

incentives that increase financial burdens on beneficiaries and the taxpayers who pay for the program. Meanwhile, prices and spending for specialty drugs have grown, and the Commission recognizes that, for patients, paying coinsurance on high-priced specialty drugs could affect their decisions to fill their prescriptions. Nevertheless, policy approaches that attempt to address high prices by focusing narrowly on cost sharing would only shift costs from patients who use specialty-tier drugs to other Part D enrollees and taxpayers without fundamentally changing the misaligned incentives.

We believe, consistent with positions the Commission took in our 2016 and 2018 recommendations, that the Medicare program and Part D enrollees would be better served by broad structural change to the Part D benefit. For this reason, we plan to continue our examination of ways to restructure Part D beyond those included in our previous recommendations. ■

Endnotes

- 1 Specialty drugs that are administered by health care providers in offices, clinics, and hospital outpatient departments are covered under Medicare Part B. In this chapter, we refer to self-administered specialty drugs that are dispensed by community, mail-order, and specialty pharmacies and covered under Medicare Part D.
- 2 CMS's specialty-tier threshold was \$600 per month until 2017, when the agency increased it to \$670 per month.
- 3 A recent report by the Congressional Budget Office (CBO) examined Part D spending for specialty drugs net of manufacturers' rebates and discounts. Using a somewhat different definition from what is described in this chapter (i.e., specialty drugs versus specialty-tier drugs), CBO found that in 2015, specialty drugs accounted for 30 percent of Part D spending on a net-of-rebate basis (Congressional Budget Office 2019).
- 4 This prediction reflects the combination of drugs that fall under both outpatient pharmacy and medical benefits.
- 5 In 2018, coverage of Sensipar for patients on dialysis was moved to Medicare Part B.
- 6 CMS set the lower bound of coinsurance for specialty-tier drugs at 25 percent because it is the same percentage as in the initial coverage phase of Part D's defined standard benefit. Plan sponsors may charge up to 33 percent coinsurance for specialty-tier drugs if the plan has no deductible or a decreased deductible under an actuarially equivalent alternative benefit design.
- 7 In 2019, enrollees pay 37 percent of the cost of generic prescriptions in the coverage gap. In 2020, cost sharing for both generic and brand-name drugs will be 25 percent in the coverage gap.
- 8 A tiering exception is a request to obtain a drug at the lower cost-sharing amount charged for a preferred drug that is prescribed for the same condition.
- 9 Pharmaceutical manufacturers can provide cash donations to independent charity PAPs without invoking anti-kickback concerns if the charity is structured in accord with Department of Health and Human Services Office of Inspector General (OIG) guidelines. Guidance from OIG states that independent charity PAPs must provide assistance to broad rather than narrow disease groups, manufacturers must not exert direct or indirect control over the charity, and the PAP must not limit assistance to a subset of available products (Office of Inspector General 2014). The Internal Revenue Service is investigating the relationship between certain patient assistance charities and several major pharmaceutical manufacturers (Sagonowsky 2017). OIG has rescinded its advisory opinion for at least one major PAP on the grounds that the PAP did not fully disclose all relevant facts in OIG's investigation (Office of Inspector General 2018).
- 10 This example is based on information from the Medicare Plan Finder as of March 12, 2019.
- 11 Note, however, that according to CMS's Part D drug data dashboard, in 2017, average spending per beneficiary for the Humira pen was \$38,888, suggesting that, on average, beneficiaries filled about 7 prescriptions per year rather than 12 prescriptions. Humira is used to treat other conditions in addition to RA.
- 12 OOP cost sharing fell for 2 of the 10 drugs analyzed in the Cubanski study: Harvoni and Sovaldi[®], treatments for hepatitis C that have been subject to price competition from other therapies.
- 13 Many of the studies used claims data to measure the proportion of days covered or medication possession ratios, while others used survey data to examine self-reported behavior such as skipping doses, pill cutting, or not filling a prescription because of cost. A medication possession ratio is the sum of the days' supply for all prescription fills of a given drug during a particular period of time, divided by the number of days in the time period.
- 14 The same study and a subsequent blog post (Doshi et al. 2018b) criticized part of the Commission's 2016 package of Part D recommendations: specifically, our recommendation that Medicare should no longer count brand manufacturers' discounts as enrollees' own spending for purposes of reaching Part D's OOP threshold. In our 2016 report, the Commission acknowledged that under the recommendation, some beneficiaries would remain in the coverage gap longer and pay more out of pocket before reaching the OOP threshold. However, the package of recommendations also provided a hard OOP cap for beneficiaries with the highest spending. The Commission also noted that the brand discount and the policy of counting that discount toward the OOP threshold artificially lowers the price of brand-name drugs relative to generics much in the same way as manufacturers' copay coupons.
- 15 Those results are consistent with a separate study, using commercial claims data, of TKI use among nonelderly chronic myeloid leukemia patients (Dusetzina et al. 2014).

- 16 There are six protected classes: anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants for the treatment of transplant rejection. In Part D price indexes developed for the Commission by Acumen LLC, POS prices for antineoplastics and antiretrovirals have increased by a factor of nearly two between 2007 and 2017, while indexes for the other four classes have fallen because of generic substitution.
- 17 Pharmacies purchase their stock of drugs from wholesalers and pay the wholesaler a single negotiated purchase price for each drug (identified by its national drug code). However, when a pharmacy dispenses the exact same drug to different patients, the negotiated prices that PBMs (representing the patients' plans) pay the pharmacy differ from one another. Sometime after the drug is dispensed, the PBMs receive rebates from the drug's manufacturer which, under Part D, the PBM must pass through to the plan. Under an alternative system of POS rebates, the pharmacy would still buy the drug from the wholesaler at a single price. However, the pharmacy would need to reflect any discounts at the POS that the plan's PBM negotiated with the manufacturer, which would lower the dollar amount of a patient's coinsurance. A "chargeback" system would ensure that the pharmacy would be credited for the difference between its purchase price and the PBM's negotiated price.
- 18 In addition, nearly 0.6 million LIS enrollees filled specialty-tier prescriptions. However, because LIS enrollees pay only nominal copayments, we focus here on non-LIS enrollees.
- 19 One version of this approach was first proposed by American Action Forum (Hayes 2018). Aetna commissioned Milliman to estimate the same proposal's effects (Sheldon 2018).
- 20 Risk corridors limit each plan's overall losses or profits if actual spending is much higher or lower than anticipated. Corridors provide a cushion for plans in the event of large, unforeseen aggregate drug spending.
- 21 Medicare's individual reinsurance captures about 8 percent of enrollees and 50 percent or more of Part D's basic benefit costs. In comparison, a typical private reinsurance policy for a commercial health plan would be expected to capture less than 1 percent of beneficiaries and about 10 percent of benefit costs (Johnson 2015).
- 22 Multiple factors likely contribute to higher average drug spending among LIS enrollees. One contributing factor is that plan sponsors have more limited tools to manage their drug benefits because LIS enrollees pay nominal copays set in law rather than the cost-sharing amounts set by plan sponsors.
- 23 To estimate the equivalent cap-discount rate, defined as the discount rate needed to keep manufacturer payments for discounts unchanged from the amounts they pay under the current gap-discount program, we used 2017 claims data and applied the current coverage-gap discount rate of 70 percent instead of the 50 percent rate that was in place in 2017.
- 24 The Commission's June 2016 recommendations included removing protected status from two of the six drug classes for 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 costs while maintaining access to needed medications. In 2018, CMS finalized a number of regulatory changes in Part D and proposed other steps to allow plan sponsors to use tools already available for managing pharmacy benefit in commercial populations. Some of those policies are consistent with the Commission's 2016 recommendations.
- 25 PPACA requires that in 2020, the OOP threshold revert to what it would have been had it grown at the same rate as other Part D benefit parameters.

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